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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

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CIRCULAR

Subject: Guidance document for Risk Based Inspection of drug manufacturing sites- reg

In order to streamline and achieve uniformity in execution and action to be taken based on Risk Based Inspections of drug manufacturing sites, a copy of draft regulatory guidelines for Risk Based Inspections of drug manufacturing sites was circulated to all State Licensing Authorities for their comments and suggestions.

In this regard, the inputs/suggestions were received from some of the States were incorporated appropriately in the guidance document.

Therefore, In order to have uniform methodology for conducting risk based inspections and taking action thereof, the guidance for Risk Based Inspection of drug manufacturing sites has been finalized and is annexed herewith for necessary overall compliance.

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Drugs Controller General (I)

To,

1. All State Licensing Authorities
2. All Zonal/Sub Zonal offices of CDSCO

GUIDANCE DOCUMENT
FOR
RISK BASED INSPECTION OF
DRUG MANUFACTURING SITES

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE

GOVT. OF INDIA

Contents

1. Introduction

- Ensuring the quality, safety, and efficacy of medicines is a critical aspect which contributes significantly to strengthening the assurance in public health systems including healthcare professionals and other stakeholders.
- Enforcement is one of the key components in the regulatory system to ensure that the safe, quality and efficacious drugs reach the patients.
- Schedule M to the Drugs Rules,1945 provides requirements for Good Manufacturing Practices (GMP) and requirements of plant and equipment for manufacture of drugs.
- It specifies in detail the requirements of premises, surroundings, personnel, sanitation, storage of raw materials, documentation and records, self-inspections and quality control systems and site master files etc.
- The manufacturer is required to comply with the requirements of Good Manufacturing Practices prescribed in Schedule M under the conditions of the licence so as to ensure that the drugs manufacturers in the country conform to the standards prescribed for them.
- In the Indian context, the enforcement in drug regulation is designed as a control system in which the quality of the drugs manufactured are mainly monitored through random sampling, testing of the products and in case of quality failure, regulatory actions are taken through administrative measures by way of suspension, cancellation or launching prosecution depending on the nature and criticality of the product quality failure.
- While, the Indian drug industry is spread out in the various States and Union Territories, the enforcement has been found to be of varying level among the states. Non-uniformity in the interpretation of the provisions of the law and their implementation, lack of adequate infrastructure and varying level of the competence of the regulatory officials have resulted in less than satisfactory performance in many States.
- Compliance to the Good Manufacturing Practices (GMP) is checked through inspections that are undertaken predominantly in a routine manner. In contrast to this other well regulated country like the USA and the EU which follow a risk-based approach to inspections. They identify the facilities that need to be

inspected based on history of inspection, risk associated with the product and findings of past inspections. Such risk-based inspections result in optimization of allocation of resources ensuring better quality products.

2. Background

- Risk Based Inspection is a methodology that is based upon the concept of rating manufacturing sites on the basis of an estimated risk that they may pose to patients, consumers, animals and users of medicines. The methodology also takes into account the risk to product quality.
- A risk based approach to inspection planning will improve the depth of GMP inspections and will allow effective implementation of the provisions of Schedule M of Drugs Rules 1945 for maintaining a high level of patient safety.
- Risk-based approach makes the best use of surveillance and enforcement resources.
- The principles of Quality Risk Management are employed while planning the risk-based inspection of the pharmaceutical manufacturing sites.

3. Objective

- The Central Drugs Standard Control Organization is responsible for laying down the standards of drugs, cosmetics, diagnostics and devices and enforcing the rules of Good Manufacturing Practice (GMP) in India for manufacturers of Finished Pharmaceuticals Products (FPP) and Active Pharmaceutical Ingredients (API).
- The objective of the drug regulation is to ensure safety, efficacy and quality of the drugs available in the country.
- The objective of this document is to provide uniform enforcement procedures for onsite inspections to evaluate compliance of the quality system and infrastructure with nationally & internationally accepted GMP Standards (based on the reference document as prescribed in the D & C Act & Rules and WHO-GMP/TRS guidelines)

- The Competent Authority may also carry out unannounced inspections at the premises of manufacturers of active substances used as starting materials or at the premises of manufacturing License Holders whenever it considers that there are grounds for suspecting non-compliance with the principles and guidelines of good manufacturing practice.
- A risk based approach to inspection planning will enable the frequency, depth and breadth of inspections to be determined accordingly. This will allow flexible and effective administration and supervision whilst maintaining a high level of patient safety.

This document sets out a simple and flexible **Quality Risk Management tool** that may be used by GMP Pharmaceutical Inspectorates when planning the frequency and scope of GMP inspections. It is a methodology that is based upon the concept of rating manufacturing sites on the basis of an estimated risk that they may pose to patients, consumers, animals and users of medicines. The methodology also takes into account the risk to product quality.

4. Purpose:

- This document outlines recommendations for a risk based planning system according to which sites that fall under regulatory supervision are subject to inspection.
- It is intended that each GMP Pharmaceutical Inspectorate uses the document as the basis for developing and implementing its own annual Inspection programme.
- The purpose of this document is to provide a simple and qualitative Quality Risk Management tool that may be of use to GMP Pharmaceutical Inspectorates to priorities sites for inspections when planning the frequency and scope of GMP inspections.

5. Scope:

- The planning of routine GMP inspections of active substance and drug product manufacturers by the Competent Authorities;
- The planning of routine GMP inspections of Vaccines, New Drugs, Subsequent New drug etc. manufacturers by the Competent Authorities.
- Follow-up activities, such as assigning a new risk rating to the site following the receipt of new information about the site or its products. (Note: the types of new information might include information on quality defects, product recalls, market surveillance test results, etc.
- The scope of this document does not extend to the planning of inspections at new manufacturers before any inspection has taken place.
- A useful rule of thumb to use is that the tool should not be applied to a site until the site has been granted a Manufacturing Authorisation and/or a GMP Certificate, as these actions indicate that the site will have been assessed from a compliance perspective.

6. Typesof Inspection

A. Routine Inspection

i. Inspections for grant/renewal of licenses under CLAA Scheme.
ii. Inspections for issuance / revalidation of COPPs as per WHO Certification Scheme for use in international commerce only.
iii. Inspections for approval of Testing Laboratories.
iv. Risk based inspections

B. Follow up inspection

i. Compliance verification inspection for verification of corrective & preventive actions.

7. Conduct During Inspection

- The inspectors are public servant within the meaning of Sec. 21 of IPC. Inspector shall act according to the procedures for handling of confidential information. All information observed or passed to the inspector is confidential and shall not be disclosed to anybody other than his controlling authority.

- Inspector shall neither carry with him any written or printed materials relating to other units nor disclose any information relating to another company.
- The inspector's task is not only to point out deficiencies but also to provide guidance based on scientific evidence.

8. Steps in conduct of inspection

Identification of risk

There are two different kinds of risk –risk factor

A. An intrinsic risk: The intrinsic risk estimated for a site reflects the complexity of the site, its processes and products, the criticality of the products or services provided by the site including from a supply perspective as well as status of sample drawn and tested.

B. Compliance-related risk: The compliance-related risk reflects the GMP compliance status of the site immediately following the most recent routine inspection at the site.

The details of Quality Risk Management Tool for Risk Rating based on the intrinsic risk and compliance risk and Guidance on How to Score the Intrinsic Risk Factors is annexed as **Annexure I and II** respectively

9. Selection of Site for Risk Based Inspection:

a) ***Complexity*** refers to the complexity of the site, its manufacturing processes, and its products.
b) ***Criticality*** relates to how critical the availability of the products manufactured at the site is from a supply perspective, or how critical the services provided by the site.
c) ***Compliance*** reflects the compliance status of the site following the most recent routine inspection at the site. When this risk is being estimated, the classification and number of deficiencies identified at the last inspection are taken into account.

Following criteria should be applied for site selection for risk based inspection:

- The compliance history of the establishment;
- Complaints
- History of “Not of Standard Quality” drugs
- The record, history, and nature of recalls linked to the establishment;
- The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment;
- The inspection frequency and history of the establishment;
- Whether the establishment has been inspected by a foreign government or an agency of a foreign government
- The level of competence demonstrated by staff at the site
- The major changes at the site since the last inspection
- The criticality of the products manufactured/wholesaled by the site, and the criticality of the analytical tests used by the site
- Any other criteria deemed necessary and appropriate

10. Planning of Inspection:

- The planning of the RBI will be done as per the risk criteria.
- The risk based inspection will be conducted in accordance with Risk Based Inspection checklist as per **Annexure III** and **IV**
- The Risk Based Inspection checklist encompasses of the GMP provisions of the Schedule M of the Drugs Rules, 1945 and WHO TRS.

A general schedule of Inspection is to be followed by the Inspection team.

- Receipt of File of the firm to the deputed inspection team member(s).
- A review should be made relating to the firm to be visited from the documents available in the office file. This may include: -
    - Drug Manufacturing License.
    - Product permission for the applied products.
    - Site Master File
    - Evaluation of: -
        - i. Product records (process validation and stability studies),
        - ii. Reports of adverse Drugs reaction,

iii. Market complaint,

iv. Product recall record,

v. NSQ reports available in the office file,

vi. Discrepancies pointed out in previous inspection reports.

Preparation of the day wise inspection plan (1-3 days)

Communication with the Local Authority for access to the site of inspection and regarding the Schedule of inspection.

11. Conduct of Inspection:

- There will be a preliminary tour of the site to allow the inspectors to get a general orientation of the site. It is recommended that the inspecting team start the plant tour as soon as possible after arrival. It is advisable to follow the inspection plan as per material flow.
- Over the course of the inspection the inspectors shall review all procedures, production and laboratory records, validations and any other record or documentation relating to production and control of the production process.
- It is advisable to check the items that are specific to certain areas of the facility, such as, Sampling /Dispensing of RM/PM, in process testing and working documents at the point of operation.
- The inspection shall also include detailed tours of all production facilities, laboratories, stores, utilities, the plant's record and documentation centre.

The following specific issues shall be investigated,

a) The suitability of the facility for its purpose, including the orderliness of its Lay-out for man and material movement, equipment and cleanliness;
b) The production equipment – its qualification/validation, calibration and cleanliness, preventive maintenance, daily equipment usage logs. Whether production records are fully maintained and in real time.
c) Critical systems: HVAC, water system, filtered compressed air, drainage. ETP and any other relevant systems.
d) The documents such as master formulae, test specifications, Standard Operating Procedures, batch records (including protocols of analysis and

documents relating to the control of printed material and labelling operations) requires close verification.

- The inspection team may adopt the additional and other plan for areas of inspection based on the need of particular inspection for the required purpose.

12. Areas to be covered during inspection

To cover following areas as per SOP, Checklist benchmarks etc. provided in the Guidance document available on CDSCO website under Public notices vide F. No. DCG(I)/Misc/2016(60) dated 26-05-2016

1.	Building and premises
2.	Ancillary areas
3.	Security system
4.	Water & Compressed air system
5.	Disposal of waste(Ambient protection)
6.	Health, clothing and sanitation of workers
7.	Training
8.	Warehousing Area
9.	Raw Materials
10.	Production Area for Non Sterile preparation
11.	Air Handling Systems (HVAC
12.	Cleaning validation
13.	Manufacturing Operations and Controls:
14.	Precautions against mix-up and cross-contamination
15.	Sanitation in the Manufacturing areas:
16.	Equipment
17.	Production Area for Sterile Preparation

18.	Air Handling System (Central Air Conditioning)
19.	Environmental Monitoring
20.	Garments
21.	Sanitation
22.	Equipment
23.	Manufacturing Process

13. Findings:

How to write a Deficiencies / Non-compliance statements:

a) The non-compliance statement should include the requirement (R), evidence (E) and deficiency (D).
b) Example: (R) The relevant cleaning records and source data should be kept in cleaning validation reports; (E) the source of three samples taken for recovery testing during the process equipment validation was not traceable; (D) cleaning validation reports did not include sufficient data.
c) Deficiencies/noncompliance statements should distinguish whether the defect lies in the system itself or in a failure to comply with the system.
   For instance, when cleaning is found to be suboptimal, it is important to know whether the standard operating procedures (SOPs) are inadequate or lacking, or whether adequate written procedures exist but are not being followed by personnel.
d) Where more than one deficiency relates to the same basic quality system failure, the deficiencies should be grouped and listed as a single observation, under a heading that reflects the basic system failure.
e) Deficiencies should be reported with a focus on risk to patient health and/or need for corrective and preventive action (CAPA). Recommendations should relate to recommended regulatory action as appropriate.
f) Each deficiency should be classified as critical, major or other, according to the following definitions, which may be adapted according to the national or regional legal context.

The report should not include comments that could be construed as proposed specific solutions to issues raised.

14. Classification of Findings of Risk Based Inspection:

Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of the products manufactured, e.g. in some circumstances an example of another deficiency may be categorized as *major.*

A deficiency that was reported at a previous inspection and was not corrected may be reported with a higher classification.

One-off minor lapses or less significant issues are usually not formally reported, but are brought to the attention of the manufacturer during the inspection.

a) Critical deficiency

A critical deficiency may be defined as an observation that has produced, or may result in a significant risk of producing, a product that is harmful to the user.

Item/area/system/knowledge is missing or of such nature to warrant serious quality/compliance concerns.

b) Major deficiency

A major deficiency may be defined as a non-critical observation that:

a) has produced or may produce a product that does not comply with its condition of licence

b) indicates a major deviation from the GMP guidelines;

c) indicates a failure to carry out satisfactory procedures for release of batches;

d) indicates a failure of the person responsible for quality assurance/quality control to fulfil his or her duties;

e) consists of several other deficiencies, none of which on its own may be major, but which together may represent a major deficiency and should be explained and reported as such.

c) Other deficiency

A deficiency may be classified as other if it cannot be classified as either critical or major, but indicates a departure from GMP. A deficiency may be other either because it is judged as minor or because there is insufficient information to classify it as major or critical.

15. Outcome of inspection:

Based on the number of the critical and major observations regulatory action like issuance of show cause notice or cancel a licence or suspend a licence for period as licensing authority thinks fit either wholly or in respect of any of the drugs or other actions as deemed fir under the provisions of D & C Act, 1940.

16. Action to be taken based on inspection findings:

a) When there is one or more critical or several major deficiencies (e.g.≥6):

I. The site is considered to be operating at an unacceptable level of compliance with Good Manufacturing Practices (GMP) guidelines.
II. Administrative (Show cause notice followed by Stop production order, Cancellation of product permission, Cancellation of manufacturing license) and/or legal enforcement actions (prosecution) as necessary.
III. Another inspection will normally be required.
IV. This action will continue till satisfactory resolution of the non compliance after joint verification by CDSCO& State.

b) When there are few major deficiencies (e.g.<6) and other deficiencies:

I. The site shall submit compliance report after rectification of deficiencies and the same shall be verified for determination of compliance to GMP. CAPAs for all deficiencies to include actions implemented and/or planned, timelines and documented evidence of completion, as appropriate.
II. CAPAs are to be evaluated on paper and shall include an on-site inspection for verification of compliance submitted by the site.

c) When there are other deficiencies only:

I. The site is considered to be operating at an acceptable level of GMP compliance.
II. The manufacture is expected to provide CAPAs. CAPAs for all deficiencies to include actions Implemented and/or planned, timelines and documented evidence of completion, as appropriate.

III. CAPAs are to be evaluated on paper and followed up during the next routine inspection.

Annexures:

Annexure I- Quality Risk Management Tool for Risk Rating based on the intrinsic risk and compliance risk

Annexure II- Guidance on How to Score the Intrinsic Risk Factors

Annexure III- Risk Based Inspection checklist

Annexure IV- Risk Based Inspection Benchmark tool

References:

1. PICS document on “A Recommended Model for Risk-Based Inspection Planning in The GMPEnvironment”

2. USFDA documents on “Understanding CDER’s Risk-Based Site Selection Model”

3. WHO TRS 981, Annex 2 “WHO guidelines on quality risk management”

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Annexure-I

Quality Risk Management Tool for Risk Rating based on the intrinsic risk and compliance risk

A. The Intrinsic Risk Associated with the Site

<table>
<tr><th>Risk Factor</th><th>Risk Score</th><th>Matrix for Estimating the Intrinsic Risk</th></tr>
<tr><td>The Complexity of the site, its processes and products, is regarded as:</td><td>1 2 3
Circle one</td><td rowspan="2">
<table>
<tr><th></th><th colspan="3">Criticality</th></tr>
<tr><th>Complexity</th><th>1</th><th>2</th><th>3</th></tr>
<tr><td>1</td><td>1 (Low)</td><td>2 (Low)</td><td>3 (Med)</td></tr>
<tr><td>2</td><td>2 (Low)</td><td>4 (Med)</td><td>6 (High)</td></tr>
<tr><td>3</td><td>3 (Med)</td><td>6 (High)</td><td>9 (High)</td></tr>
</table>
Use the above matrix and record the Intrinsic Risk associated with the site below:

Low ❑ Medium ❑ High ❑
</td></tr>
<tr><td>The Criticality of the products manufactured by the site, or the criticality of the analytical testing or other service offered provided by the site, is regarded as:</td><td>1 2 3
Circle one</td></tr>
</table>

B. The Compliance-related Risk based on the last Inspection

The **compliance risk** indicated by the most recent deficiency profile of the site is:	**Low ❑** **Medium ❑** **High ❑**	- No Major or Critical Deficiencies - 1 to 5 Major Deficiencies: *Number of Majors* = ____ - 1 or more Critical Deficiencies or more than 5 Majors *(Note: Customise as appropriate)*

C. The Risk-Rating assigned to the Site

Complete the matrix below by combining the Intrinsic risk score and the Compliance-related risk score to determine the **Risk Rating** for the site.

	Intrinsic Risk		
Compliance Risk	**Low**	**Medium**	**High**
Low	Risk Rating = A	Risk Rating = A	Risk Rating = B
Medium	Risk Rating = A	Risk Rating = B	Risk Rating = C
High	Risk Rating = B	Risk Rating = C	Risk Rating = C

The Risk Rating associated with this site is: A ❑ B ❑ C ❑

Annexure II

Guidance on How to Score the Intrinsic Risk Factors

No	Intrinsic Risk Factor & Scoring Mechanism
1	**Complexity:** This concerns the complexity of the site, its processes and its products. (Note: The Site Master File (if available) and the last GMP inspection report can be useful sources of information on which to assign the Complexity score.) There are three possible scores here, 1, 2 and 3. Sites with a low risk factor score in this area are known to have a low level of complexity in the design of the site, in its products and processes. When scoring this Risk Factor, it is useful to consider the following: General but useful indicators of **site complexity** are: • The size of the site – large sites are rated more complex than smaller sites • The number of different manufacturing or distribution processes that are in use at the site – larger numbers generally give rise to more complexity • The level of dedication of equipment and facilities (e.g. Air Handling Units) that is in place at the site – sites with a low level of dedication are considered more complex than other sites • The number of staff at the site – larger numbers generally give rise to more complexity • The number of commercial markets/countries supplied by the site - larger numbers generally give rise to more complexity • The number of customers supplied by the site - larger numbers generally give rise to more complexity • If the site is a contract manufacturer or contract laboratory, the site can be regarded as being relatively complex General but useful indicators of **process complexity** are: • Sterile and aseptic manufacturing processes – these are always considered highly complex processes. • Parametric release activities – these are usually considered highly complex processes. • The number of critical steps that must be controlled within a process – generally, processes with a high number of critical steps can be considered to be more complex processes. • The type of products manufactured – some product types such as low concentration/high potency dosage forms and sustained released dosage forms can be more complex to manufacture than

	other types of products (such as immediate release tablets) and the complexity of their manufacturing process should be rated more highly here. • The number of unit operations in a non-sterile manufacturing process – larger numbers generally give rise to more complexity. • Repackaging activities - repackaging an already packaged batch can be considered a moderately to highly complex process. • The extent of reprocessing or reworking taking place at the site: these activities can add complexity to the process • Biological processes • The extent of subcontracting in use by the site - a significant use of contract manufacturers, off-site distribution sites or contract laboratories generally gives rise to complexity. • In case of importers, the complexity of importation, batch release and product distribution processes – sometimes the arrangements in place for importation can be quite complex. General but useful indicators of **product complexity** are: • The number of components that make up any one product pack - larger numbers of components in a pack generally give rise to more product complexity. For example, a pack of an injectable product may have 4 components within it (a lyophilised vial, a diluent vial, a transfer needle and a technical leaflet, whereas a pack of a tablet product may have just a blister strip and a patient information leaflet within it.) • Products requiring special storage and distribution: (e.g. cold chain products and short-shelf-life products such as radiopharmaceuticals can be complex to manage.) Scoring Guideline: Assign a score of 1 to sites with a low overall level of Complexity Assign a score of 2 to sites with a moderate overall level of Complexity Assign a score of 3 to sites with a high overall level of Complexity Note: When assigning the overall complexity rating, the rating (1, 2 or 3) which most reflects the various individual complexity ratings that were assigned to site, process and product complexity should be chosen. This is similar to taking an average of all of the individual complexity ratings that were assigned. In cases where there is insufficient information or knowledge about the complexity associated with the site, its processes and products, a medium score of 2 should be assigned.
2	**Criticality:** This concerns how critical the availability of the products manufactured by the site are from a supply perspective, or how

	critical the services provided by the site are. An example of a critical service provided by a site may be an analytical testing service performed for several other companies. (Note: The Site Master File (if available) and the last GMP inspection report can be useful sources of information on which to assign the Criticality score.) There are three possible scores here, 1, 2 and 3. Scoring Guideline: Assign a high score (of 3) for the sites where “Not of Standard Quality” are more than 5 per year. Assign a high score (of 3) to sites that are known to manufacture essential products or that are known to be sites that provide an essential service that is not readily available elsewhere. • These may be sites that are the major or sole supplier of an essential product (such as an important vaccine, a critical blood product, etc.). Note: it is recognised that being the major or the sole supplier of an essential product does not present any risk to product quality; rather, it presents a risk to product availability. • The test methods (and related equipment) used by these sites cannot easily or readily be performed or used by other laboratories. • These may be sites that provide a contract manufacturing or testing service to a number of other manufacturers and a disruption in such services would have a significant impact on product availability. Assign a low score (of 1) to sites that are known to manufacture only non-essential products or that are known to be sites that do not provide an essential service. Assign a high score (of 1) for the sites where “Not of Standard Quality” are 0-3 per year • These may be sites that are not the sole supplier of any important products (such as an important vaccine, a critical blood product, etc.). • The test methods (and related equipment) used by these sites are not such that they cannot be readily performed or used by other laboratories. • These are not sites that provide a contract manufacturing or testing service to many other manufacturers, where a disruption in such services would have a significant impact on product availability.

	Assign a medium score (of 2) to sites that are in between the above types of sites. Assign a high score (of 2) for the sites where “Not of Standard Quality” are 3-5 per year Note: In cases where there is insufficient information or knowledge about the criticality associated with the site, a medium score of 2 should be assigned.

Risk Based Joint Inspection Report

Name of the manufacturing unit	
Address	
Mfg. Lic. no.	
Validity of License.	
Constitution of the firm	
List of Directors/Partners/Proprietor	
License issuing authority	
Categories of drugs permitted to be manufactured	
Specify whether COPP has been issued to the firm	
Name and Designation of the Inspecting team members	
Site Specific Data	
No. of Products manufactured at site (during last year)	
No. of manufacturing blocks	
No. of Technical Personnel in Manufacturing	
No. of Technical Personnel in QA	
No. of Technical Personnel in QC	
No. of Technical Personnel in Microbiology	
No. of Technical Personnel from other Department	
No. of Technical Personnel in R&D	

No. Of technical personnel in Formulation development	
No. of Samples drawn by QC (during last year)	
No. of Samples declared OOS (during last year)	
No. of samples declared NSQ by Govt. Analyst (during last year). Collect reasons for such failures and annexe with this checklist	

Observations should be descriptive without ambiguity and answer like "Yes" or "No" should be avoided

1 Building and premises: -			**Observations**	**Rating**
1.1	Sch-M	Specify whether the whole facility is separated, dedicated and is not a part of any other non-drug facility.		
1.2	Sch-M	Specify whether the surroundings of manufacturing area is clean and as per the SOP prescribed in this regard. (Mention the SOP nos.)		
1.3	Sch-M	Describe the pest, insects, birds and rodents control system followed in the premises. Specify pest control schedule- area wise, along with materials and methods used.		
1.4	Sch-M	What measures have been taken to make Interior surface (of walls, floors, and ceilings) smooth and free from cracks, and to permit easy cleaning Specify material of construction and finish for walls, ceiling, floor, coving etc. i.e. whether Epoxy or PU coated, kota / granite stone with epoxy sealed joints, solid / GI / gypsum / cal. Silicate board ceiling with epoxy, PU or any other pre-fabricated panel (GRP, powder coated SS or Aluminium etc.) paint.		

1.5	Sch-M,	Specify the lux level maintained in various parts of the premise (Storage area, manufacturing area specially visual inspection, Laboratory areas etc.).		
1.6	Sch-M,	Specify the air handling system used in various areas i.e. stores, production, packing, QC areas.		
1.7	Sch-M,	Specify drainage system which prevents back flow and entry of insects and rodents into the premises. Specify number and location of drains installed.		
2 Ancillary areas: -				
2.1	Sch-M,	Specify the position of rest and refreshment rooms and mention whether they are separated and not leading directly to the manufacturing and warehouse areas.		
2.2	Sch-M,	Are there general change rooms in plant? specify number of washing station & toilets provided for number of users.		
2.3	Sch-M,	Specify whether primary clean garments are provided for each personnel entering the factory premises.		
2.4	Sch-M,	Is there in-house general laundry for garment washing / cleaning? If not how garment washing is carried out and monitored.		
2.5	Sch-M, Para	Whether change room facilities separated for both sexes.		
2.6	Sch-M, Para	Whether maintenance workshop is separated and away from production.		
3 Security system:-				
3.1	WHO TRS	Is the men & material movement inside the factory premises, observed & checked through security system.		
3.2	WHO TRS	Is CCTV available to control the Entry & Exit from Factory premises?		
3.3	WHO TRS	Is there a system for identifying persons visiting the factory ? How?		

3.4	WHO TRS	What is the precautionary activity taken for the movement of carriers i.e. vehicles?		
4 Water & Compressed air system: -				
4.1	Sch-M, Para	Verify whether a current drawing of the water system showing all equipment in the system from inlet to the points of use is available.		
4.1.1	Sch-M, Para	Specify the MOC of the water storage tank (Both PW & WFI) and its pipe line.		
4.1.2	Sch-M, Para	Specify weather storage tank for WFI is steam jacketed.		
4.2	Sch-M, Para	Specify whether water system validation/qualification has been carried out as per protocol and reports have been prepared and maintained.		
4.3	WHO TRS-970	Whether IQ protocol include at least facility review, equipment specification vs. design, welding roughness testing on pipelines, absence of dead points / section in the pipelines, pipe and tank passivation, drawings, SOP for operations, cleaning, sanitation, maintenance and calibration of gadgets. Whether its report includes Conclusion / Summary, Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.		
4.4	WHO TRS-970	Whether OQ protocol includes at least System production capacity (L/min), Flow type and water rate, Valve operation, Alarm system operation and Controls operation? Whether its report includes Conclusion / Summary, operations performed Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.		
4.5	WHO TRS-970	Please specify whether Phase 1, Phase 2 and Phase 3 studies carried as part of PQ stages?		
4.6	WHO TRS-970	Phase 1: Whether the operations parameters, cleaning and sanitation procedures & frequencies defined.		

		Whether daily sampling records for every pre-treatment point and usage point for a period of 2 to 4 weeks maintained and SOP's prepared.		
4.7	WHO TRS-970	PHASE 2: Whether daily sampling records for every pre-treatment point and usage point for a period of 4 to 5 weeks after Phase 1 maintained and reviewed.		
4.8	WHO TRS-970	PHASE 3: Whether weekly sampling records available of every usage point for a one-year period.		
4.9	Sch-M	Specify source of raw water and give details of treatment processes, sampling points, distribution and storage system for raw and purified water. Verify whether the Raw Water holding tank was sanitised as per specified SOP.		
4.10	Sch-M	Verify whether the softener column is regenerated as per the specified SOP.		
4.11	Sch-M	Specify whether the quality of potable water used for the preparation of purified water meets the requirement of Schedule M in respect of microbiological limit.		
4.12	Sch-M	Specify whether the quality of Purified Water used for the preparation of WFI meets the requirement of IP/BP/USP.		
4.13	Sch-M	What is the process for preparation of Water for Injection (WFI)?		
4.14	Sch-M	Specify the process of sanitisation of SS storage tank of WFI.		
4.15	Sch-M	Specify whether the quality of WFI meets the requirement of IP/BP/USP & Schedule M.		
4.16	Sch-M	Specify whether WFI is used for: 1) Bulk preparations of liquid injections 2) Final rinse of product containers for sterile preparations. 3) Final rinse of machine parts (for sterile preparations)		

		4) Preparation of disinfectant solutions for use in critical areas (for sterile preparations.)		
4.17	Sch-M	How bio burden in purified water & WFI are controlled / reduced (Mention the SOP no. followed in this regard).		
4.17.1	Sch-M	Specify whether WFI has been stored and circulated above 70 degree centigrade.		
4.18	WHO TRS-970	Verify whether the circulation rate of purified water & WFI is at least twice the storage capacity of the holding vessels per hour.		
4.19	WHO TRS-970	Verify the Dead leg of non returned valve at the discharge point.		
4.20	WHO TRS-970	Specify how the circulation loop is sanitised. Verify the SOP.		
4.21	WHO TRS-970	Specify whether spray ball is used to wet the surface of head space in the storage vessel.		
4.22	WHO TRS-970	Specify whether pressure release valves are provided in the storage vessel.		
4.23	Sch-M	How water tanks are cleaned periodically and records maintained thereof.		
4.24	WHO TRS-970	Specify whether on line TOC test is available for WFI & PW.		
4.25	PIC/S Guidelines	Specify whether replacement of Air Vent filters on the purified/WFI water tank is carried out as per relevant SOP. Whether the provision to keep dry the vent filter is made.		
4.26	Sch-M	Specify the arrangement for preparation of pure steam & its use.		
4.27	Sch-M	Specify whether pure steam (condensate) used in production meets the microbiological specification of not more than 10 cfu/100ml and IP/BP/USP specifications of WFI.		

4.28	WHO TRS-970	Verify PQ of the PSG.		
4.29	Sch-M	Specify the system in place for the compressed gases / air used in the facility.		
4.30	ISO/PICS	Verify the qualification documents of compressed air system specially where it comes in contact with product or primary container.		
4.31	WHO TRS-970	Specify whether action and alert limits are followed based on qualification of water and compressed Air system.		
5 Disposal of waste(Ambient protection):-				
5.1	Sch-M	Specify the system of disposal of sewage, and effluents (solid, liquid, and gas) from the manufacturing site.(Enclosed the copy of NOC obtained from State Pollution control board in this regard.)		
5.2	Sch-M	Mention the procedure for storage and disposal of rejected drugs and applicable SOP.		
5.3	Sch-M	Whether adequate records are maintained for the disposal of waste.		
5.4	Sch-M	Whether provision for disposal of bio-medical waste made as per the provisions of the Bio Medical Waste (Management and Handling) Rules 1996.		
6 Health, clothing and sanitation of workers: -				
6.1	Sch-M	Whether all personnel prior to employment have undergone medical examination including eye examination and are all free from Tuberculosis, skin and other communicable or contagious diseases & thereafter at regular intervals.		
6.2	Sch-M	Whether investigational reports, e.g. of X rays etc. preserved. Whether records of such medical examination are maintained thereof		

6.3	Sch-M	Specify whether employees report their illness to the supervising authority before entering into the production area.		
6.4	Sch-M	Specify whether person from infectious disease is barred to enter into production area.		
6.5	Sch-M	Specify if any unhygienic practise is observed within the manufacturing areas.		
6.6	Sch-M	Whether all personnel are trained to ensure high level of personal hygiene. Mention the SOP no. followed in this regard.		
6.7	Sch-M	Specify whether cross over bench is in place in the change room and if so whether it rules out the possibility of dust particle entering the clean side.		
6.8	Sch-M	Whether arrangements provided for cleaning of outside dust and dirt from foot.		
7 Training:-				
7.1	Sch-M	Specify whether basic training on GMP is provided to all personnel attached to production and quality control activity at the time of induction.		
7.2	Sch-M	Specify whether specific training related to the job duty are provided to all personnel at the time of induction.		
7.3	WHO TRS-986	Specify whether continuous training is provided.		
7.4	WHO TRS-986	Specify whether concept of QA and its importance is part of training session.		
7.5	WHO TRS-986	Are all the persons associated with various production activities properly trained as per guidelines provided in WHO working document. Verify the assessment records of the training of few selected people who are associated with critical operations and procedure		
8 Warehousing Area:-				
8.1	WHO TRS-986	Is access to the area restricted to authorised personnel only.		

8.2	Sch-M	Whether adequate areas have been allocated for warehousing of Raw Materials, intermediates, Packaging Material, products in quarantine, finish products, rejected or returned products. How are these areas marked or segregated. Please specify the total area provided for warehousing.		
8.3	Sch-M	How the warehousing areas being maintained to have good storage conditions. Are they clean and dry and maintained within specified temperature limits?		
8.4	WHO TRS-986	Is there any SOP defining maximum exposure time at room temperature for thermo labile materials i.e. prior to storage in a refrigerator.		
8.5	Sch-M	Specify the storage arrangement provided for materials which are sensitive to temperature, humidity and light and how the parameters are monitored. Is cold room or deep freezers required for storage of goods?		
8.6	WHO TRS-986	Verify the Thermal mapping of the cold rooms or deep freezers		
8.7	Sch-M	Whether receiving and dispatch bays are maintained to protect in coming and out going materials.		
8.8	Sch-M	How incoming materials are treated and cleaned before entry into the plant. Please specify the cleaning system for the outer surface of the container.		
8.9	Sch-M	How quarantined materials are segregated from other materials. How access to quarantined area is restricted.		
8.10	Sch-M	Specify the system followed for storing passed raw materials.		
8.11	Sch-M	Whether proper racks, bins and platforms have been provided for the storage.		

8.12	WHO TRS-986	What is the control on entry of material and men into the sampling area? Whether reverse LAF have been provided for sampling. Whether log book for sampling booth maintained.		
8.13	Sch-M	Specify the storage arrangement provided for primary packaging materials.		
8.14	Sch-M	Specify the arrangements provided to sample the primary packaging materials foils, bottles, etc. which are used as such.		
8.15	WHO TRS-986	Specify sampling plan used.		
8.16	WHO TRS-986	Which type of sampling tools are used and how they are cleaned, dried and maintained.		
8.17	WHO TRS-986	How containers are cleaned before and after sampling. (Specify whether the sampling is carried out as per the current SOP).		
8.18	Sch-M	What provisions have been made for segregated storage of rejected, recalled or returned materials or products. How is the access to these areas restricted?		
8.19	Sch-M	How printed secondary packaging materials are stored in safe, separate and in secure manner.		
8.20	Sch-M	How printed packaging materials, product leaflets etc. are stored separately to avoid chances of mix-up?		
8.21	Sch-M	How labels, cartons, boxes, circulars, inserts and leaflets are controlled. ?		
8.22	Sch-M	How records of receipt of all labelling and packaging materials are maintained.		
8.23	Sch-M	Whether unused packaging materials return to the store or destroyed.		
8.24	Sch-M	How returned/unused packaging material like foils is controlled so as to prevent contamination and cross-contamination.		

8.25	Sch-M	Specify the arrangement provided for dispensing of starting materials.		
8.26	WHO TRS-986	What is the control on entry of material and men into the dispensing area? Whether reverse LAF have been provided for dispensing with back ground clean air supply.		
8.27	WHO TRS-986	Whether pressure differential is maintained between the dispensing and adjacent areas.		
8.28	WHO TRS-986	Specify the pressure differential maintained.		
8.29	Sch-M	Examine the record of the daily check of balances in the dispensing area.		
8.30	WHO TRS-986	How containers are cleaned before and after dispensing. Who carries out the dispensing?		
8.31	WHO TRS-986	Specify whether appropriate air velocity is maintained in sampling & dispensing areas which rule out any influence in the balance readings placed inside the RLAFs Benches.		
8.32	Sch-M	Specify whether the dispensing is carried out as per the current SOP.		
8.33	Sch-M	Specify whether dispensed material for each batch of final product are kept together and conspicuously labelled.		
8.34	Sch-M	What steps are taken against spillage, breakage and leakage of containers?		
8.35	Sch-M	How highly hazardous, poisonous and explosive materials, narcotics, and psychotropic drugs are handled and stored. How these areas are safe and secure.		
9 Raw Materials: -				
9.1	Sch-M	Please specify the procedures followed for receiving and processing of in-coming materials (Starting materials and packing material). Verify the SOP.		

9.2	Sch-M	Whether first in / first out or first expiry principal has been adopted.		
9.3	Sch-M	How they are labelled and stored as per their status – Under Test, Approved and Rejected		
9.4	Sch-M	Whether incoming materials are purchased from approved vendors.		
9.5	Sch-M	Whether list of approved vendors is available to the user.		
9.6	WHO TRS-986	Specify the norms of vendor qualification.		
9.7	Sch-M	How damaged containers are identified recorded and segregated		
9.8	Sch-M	Whether each batch of a consignment is considered for sampling, testing and release.		
9.9	WHO TRS-986	Whether all the containers of each batch of starting materials sampled for identification test.		
9.10	Sch-M	Whether labels of raw material in the storage area have information like; a) designated name of the product and the internal code reference, where applicable, and analytical reference number; b) manufacturer's name, address and batch number; c) the status of the contents (e.g. quarantine, under test, released, approved, rejected); and d) The manufacturing date, expiry date and re-test date.		
9.11	Sch-M	Whether separate areas are provided for under test, approved and rejected materials.		
9.12	Sch-M	How the containers from which samples have been drawn labelled.		
9.13	Sch-M	Please specify the procedures by which it is ensured that the raw materials which has been released by the		

		Quality Control Department and which are within their shelf life are going to be used in the product.		
10 Production Area for Non Sterile preparation:-				
10.1	WHO TRS-986	Verify whether access to production area is restricted to authorised personnel only.		
10.2	WHO TRS-986	Whether the facility is provided with a well-sealed structure with no air leakage through ceilings, cracks or service penetrations.		
10.3	WHO TRS-986	Whether entry and exit doors, for materials and personnel, have an interlock mechanism or other appropriate system to prevent the opening of more than one door at a time.		
10.4	WHO TRS-986	Specify the procedures for entry of maintenance people into the production area.		
10.5	WHO TRS-986	Whether the change rooms have an arrangement with step-over/cross-over bench.		
10.6	Sch-M	Is there any cris cross flow of materials and men?		
10.7	Sch-M	Whether the premises and equipment are appropriately designed and installed to facilitate cleaning and decontamination.		
10.8	WHO TRS-986	Specify the position of IPQC lab in the manufacturing area.		
10.9	Sch-M	Specify whether non storage areas are used for storage of any material.		
10.10	WHO TRS-986	Specify the provisions for storage of dirty, washed and cleaned equipment in process areas.		
10.1	Sch-M	Specify how service lines are identified for nature of supply and direction of the flow.		
10.12	WHO TRS-986	Whether service lines in production areas are through service pendants. If not, how they are placed so as to avoid accumulation of dust.		
11 Air Handling Systems (HVAC):-				

11.1	WHO TRS-986	Please specify whether following parameters are qualified: — (IQ,OQ,PQ) — Temperature — Relative humidity — supply air quantities for all diffusers — return air or exhaust air quantities — room air change rates — room pressures (pressure differentials) — room airflow patterns — unidirectional flow velocities — filter penetration tests (HEPA) — room particle counts — room clean-up rates — microbiological air and surface counts where appropriate — operation of de-dusting — warning/alarm systems		
11.2	WHO TRS-986	Verify the SOPs for AHUs operation and cleaning.		
11.3	WHO TRS-986	Specify whether the facilities and premises have following basic air-handling characteristics: a) The absence of direct venting of air to the outside. b) Whether the facility is maintained at a negative air pressure to the environment. c) The precaution taken to prevent the infiltration into the core areas. d) Whether appropriate air pressure alarm systems as well as alert and action limit is provided. e) The type of HEPA filters used in the HVAC system f) Whether the change rooms are supplied with same quality of air as supplied to the working area.		

		g) The measures taken to prevent air flow from the primary packing area to the secondary packing area.		
11.4	WHO TRS-986	Whether HVAC system description includes: 1) Schematic drawings detailing the filters and their specifications 2) Number of air changes per hour 3) pressure gradients		
11.5	WHO TRS-986	Specify the emergency power systems in case of power failure.		
11.6	WHO TRS-986	Specify whether recirculated air is used. If yes, specify the proportion of fresh air supplied.		
11.7	WHO TRS-986	Whether risk assessment study has been carried out in case of return air/ recirculated air system. Verify the records thereof.		
11.8	WHO TRS-986	Specify what precaution has been taken during filter change of AHUs.		
11.9	WHO TRS-986	Whether all exhaust systems from the facility, including dust extraction systems, vacuum system exhaust, fluid bed drier exhaust, coating pan exhaust, etc., are passed through safe change filter housings and wet scrubber before being exhausted to the atmosphere.		
11.10	WHO TRS-986	Whether all exhaust points outside the building are located as far as possible from air entry points, exit points and at a high level, to minimize the possibility of re-entrainment of exhaust air.		
11.1	WHO TRS-986	Whether the return air ducts are checked periodically for dust accumulation.		
11.11	Sch-M	Whether the dust collectors are located in a room maintained at a negative pressure.		
11.12	WHO TRS-986	Whether the filters cleaning facility is maintained at negative pressure.		

11.13	WHO TRS-986	Whether records for safe disposal of all contaminated filters and dust are maintained.		
11.15	WHO TRS-986	Specify whether total No. of AHUs used to cover the whole production Area is commensurate with the requirements		
11.16	WHO TRS-986	Specify the Terminal Air Filter of various core areas.		
11.17	WHO TRS-986	Specify the no. of Air Change maintained in various core areas.		
11.18	WHO TRS-986	Specify the pressure balancing to segregate different areas.		
11.19	WHO TRS-986	Are the returns risers cleaned during Product Change Over?		
11.20	WHO TRS-986	Verify if the AHU's / HVAC systems have been shut down. If yes the reasons there of such as cleaning & maintenance & the procedures for re-initiation / re-start of the systems		
12 Cleaning Validation:-				
12.1	Sch-M	Is a validation performed to confirm cleaning effectiveness?		
12.2	WHO TRS-986	Does the protocol define the selection criteria for products or groups of products subject to cleaning validation?		
12.3	WHO TRS-986	Is data produced supporting the conclusion that residues were removed to an acceptable level?		
12.4	WHO TRS-986	Specify whether the validation is implemented to verify cleaning of: 1) Surfaces in contact with the product 2) After a change in product 3) Between shift batches.		
12.5	WHO TRS-986	Specify whether the Validation Strategy include contamination risks & equipment storage time.		

12.6	WHO TRS-986	Whether Quality Control responsible of the sampling for cleaning verification?		
12.7	WHO TRS-986	Whether personnel engaged in cleaning, sampling etc. trained.		
12.8	WHO TRS-986	Specify whether acceptance limits been set for cleaning verification and are based on following criteria: 1) Visually clean. 2) 10 ppm in another product. 3) 0.1% of the therapeutic dose?		
12.9	WHO TRS-986	Specify whether detergent residues and degradation products are investigated during validation.		
12.10	WHO TRS-986	Whether validation records include: Recovery study data, Analytical method, Acceptance Criteria, Swab recovery test, Signatures of the Quality Assurance Manager, Signature of the employee in charge of cleaning verification from Production and Quality Control.		
13 Manufacturing Operations and Controls:-				
13.1	Sch-M	Whether the contents of all vessels and containers used in manufacture and storage is conspicuously labelled with the name of the products. Batch no, Batch Size, and stage of manufacture along with signature of technical staff.		
13.2	Sch-M	Whether the products not prepared under aseptic conditions are free from pathogens like Salmonella, Escherichia coli, Pyocyanea etc.		
13.3	Sch-M	If yes, pls give brief account of measures taken to assure freedom from pathogens.		
13.4	WHO TRS-986	Verify whether handling of materials and products are carried out in accordance with the relevant SOP'S.		
13.5	WHO TRS-986	Specify Whether any deviation is approved in writing by a designated person and recorded.		

13.6	WHO TRS-986	Is there an approved SOP for In process check?		
13.7	WHO TRS-986	Is the personnel clothing clean, unstained & dust free, including shoes?		
13.8	WHO TRS-986	Is there a cleaning SOP for slippers or shoes that is being used in the manufacturing area?		
13.9	WHO TRS-986	Whether process hold time studies has been carried out for various stages of production		
14 Precautions against mix-up and cross-contaminations:-				
14.1	Sch-M	Whether proper AHU, pressure differential, segregation, status labelling have been provided to prevent mix-up and cross-contamination in manufacturing area		
14.2	Sch-M	Pls specify the areas of dust generation and mechanism involved in controlling the dust		
14.3	Sch-M	Do all the areas have their own independent air locks separately for men and material entry.		
14.4	Sch-M	What criterion of pressure differential has been set for production v/s adjoining areas.		
14.5	Sch-M	Whether processing of sensitive drugs like Beta lactam Antibiotics and Sex Hormones is done in segregated areas with independent AHU and proper pressure differentials along with demonstration of effective segregation of these areas with records.		
14.6	Sch-M	Please specify what measures has been taken to prevent contamination of products with Beta Lactam Antibiotics, Sex hormones and cyto toxic substances.		
14.7	Sch-M	What measures has been taken to prevent mix-ups during various stages of production.		
14.8	Sch-M	Whether equipments use for production are labelled with their current status.		
14.9	Sch-M	Whether packaging lines are independent and adequately segregated.		

14.10	Sch-M	How line clearance is performed. Whether records of line clearance is maintained according to appropriate checklist.		
14.11	Sch-M	Whether separate carton coding area has been provided or online carton coding is performed How carton coding procedure is controlled.		
14.12	Sch-M	Please specify how temperature, humidity and air filtration are controlled in the areas where raw material and/or products are exposed and handled		
14.13	Sch-M	How access of authorized persons to manufacturing areas including packaging is controlled.		
14.14	Sch-M	Whether separate gowning provision is followed before entering the core areas.		
14.15	Sch-M	Whether segregated secured areas for recall or rejected materials or for such material which are to be processed or recovered are provided.		
14.16	Sch-M	Whether various operations are carried out in segregated areas.		
14.17	Sch-M	Are doors of all core areas closed at all times with interlock arrangements?		
14.18	Sch-M	Specify whether any SOP is followed to verify the effectiveness for prevention of cross contamination.		
14.19	WHO TRS-986	Specify whether critical operations are carried out in closed system.		
14.20	WHO TRS-986	Specify the methods followed for product change-over.		
15 Sanitation in the Manufacturing areas:-				
15.1	Sch-M	Specify the cleaning procedure of the manufacturing areas and verify with the SOP in this regard.		
15.2	Sch-M	Whether cleaning procedure is validated.		
15.3	Sch-M	Whether a routine sanitation program is in place.		
15.4	Sch-M	Verify the SOP & the records in this regard.		

15.5	Sch-M	Does the location facilitate cleaning of equipment as well as the cleaning of the areas in which they are installed?		
15.6	Sch-M	Whether production area is adequately lit.		
15.7	Sch-M	Mention lux levels observed in production, visual inspection and other areas.		
15.8	Sch-M	Specify in detail the procedure followed during product changeover.		
16 Equipment: -				
16.1	Sch-M	Whether the equipment are designed aiming to minimize risk of error and permit effective cleaning and maintenance in order to avoid cross contamination & build up of dust.		
16.2	Sch-M	Whether all equipment are provided with log book.		
16.3	Sch-M	Please specify the procedures to clean the equipment after each batch production.		
16.4	Sch-M	Whether validity period for use after the cleaning of equipment is specified.		
16.5	Sch-M	Whether separate area is provided for storage of machine parts etc.		
16.6	Sch-M	Whether balances and other measuring equipments with appropriate range are available in the Raw Material stores & production areas and they are calibrated in accordance with SOP maintained. Specify the calibration schedule of the balances.		
16.7	Sch-M	Specify material of construction of contact parts of the production equipments.		
16.8	Sch-M	Which types of lubricants are used in the equipment. Specify the quality and control reference No. of these lubricants		
16.9	Sch-M	Specify the procedures to remove defective equipments from production areas.		

16.10	WHO TRS-986	Verify whether washing and cleaning of equipment are not a source of contamination.		
16.11	Sch-M	Whether all equipment is provided with an ID NO.		
16.12	WHO TRS-986	Specify the procedures to clean the equipment after each batch production and verify with the SOP.		
16.13	WHO TRS-986	Specify whether CIP or SIP is in place.		
16.14	WHO TRS-986	Specify whether the CIP / SIP system is qualified		
16.15	WHO TRS-986	Are there cleaning agent labelled with a catalogue no. indicating that they were received through the warehouse.		
16.16	WHO TRS-986	Are there records for preparation of cleaning agent?		
17 Production Area for Sterile Preparation				
17.1		Building and Facilities:-		
17.2	Sch-M	Specify the building is devoid of cracks especially in the Critical solutions preparation rooms, Filling rooms, Sealing rooms.		
17.3	Sch-M	Are the locations of services like water, steam, gases etc. Such that the servicing or repairs can be carried out without any threat to the integrity of the facility		
17.4	Sch-M	Specify water lines pose any threat of leakage to the critical area		
17.5	Sch-M	Specify the manufacturing areas clearly separated into following Support Areas: 1) Washing of containers & closures 2) Storage of washed containers & closures 3) Sterilization of containers & closures 4) Preparation of bulk solution (critical/non critical) 5) Change room		

17.6	Sch-M	Specify de-cartoning areas to remove outer cardboard wrappings of primary packaging materials segregated from the washing areas.		
17.7	Sch-M	Specify whether particle shedding materials like wooden pallets, fibre board drums, cardboards etc. are taken into the preparation areas.		
17.8	Sch-M	Specify in the classified areas: 1) Walls are flat, smooth and devoid of recesses. 2) Surface joints like electric sockets, gas points flushed with walls. 3) Joints in the ceiling are properly sealed 4) Air grills and lights flushed with the ceiling. 5) Grade A & B areas devoid of sinks and drains. 6) Doors and windows made up of non shedding materials. 7) Doors open towards higher pressure areas and close automatically due to air pressure.		
17.16	WHO TRS-961 ANNEXE-06	Is there a glass panel between critical area & support area so that all operations in Grade A & B areas can be supervised from support areas?		
17.17	WHO TRS-961 ANNEXE-06	Fire extinguishers are suitably fastened to the walls without gaps.		
17.18	Sch-M	Quality of the furniture used is smooth & washable and made of SS316.		
17.19	Sch-M	Change rooms entrance provided with air locks before entry to the sterile product manufacturing areas.		
17.20	Sch-M	How many change rooms are provided to enter into the critical areas?		

17.2	WHO TRS-961 ANNEXE-06	Specify an appropriate inter- locking system with visual and/or audible warning system installed to prevent the opening of more than one door at a time.		
17.2	Sch-M	Are the critical and support areas provided with intercom telephones or speak phones for communication purposes.		
17.2	Sch-M	Specify the critical areas and support areas provided with suitable air- locks or pass boxes with proper interlocking arrangements for material transfer.		
17.2	WHO TRS-961 ANNEXE-06	Specify whether dynamic pass box is used for material transfer between two different air class.		
17.3	Sch-M	Specify the method of transfer of sterile rubber bungs & aluminum caps to the aseptic area.		
17.3	Sch-M	Specify whether grade A/B area is devoid of sinks and drains.		
18 Air Handling System (Central Air Conditioning):-				
18.1	Sch-M	Specify whether the Air Handling Units for sterile product manufacturing area are separated from those for other areas		
18.2	Sch-M	Give the Background Grade of air for following critical areas: 1) Aseptic filling area 2) Sterilized components unloading area for aseptic filling. 3) Batch manufacturing area for aseptic filling preparations. 4) Component washing and preparation area. 5) Change rooms to enter into Critical area.		

18.3	WHO TRS-961 ANNEXE-06	Specify the steps taken in air handling system to achieve the Grade A, B, C and D of air as per designated classified areas.		
18.4	Sch-M	Specify the recovery time of B & C zone from the time of personnel leaving the room after completion of operations and verify the records in this regard.		
18.5	Sch-M	Specify whether filling operations are challenged initially and there after periodically by simulation trials including sterile media fill.		
18.6	WHO TRS-961 ANNEXE-06	Specify the procedure followed for medial fill and the acceptance criteria.		
18.7	WHO TRS-961 ANNEXE-06	Whether the medial fill trial is based on worst case situation taking into consideration all interventions, activities occurring during normal activity as well as worst case.		
18.8	WHO TRS-961 ANNEXE-06	Whether simulation tests are repeated at defined intervals and after any significant modification to HVAC system, equipment or process.		
18.9	Sch-M	Specify the number of air changes in Grade A/B and Grade C areas.		
18.10	Sch-M	Specify the air velocity maintained in Grade A Laminar Air Flow stations		
18.1	Sch-M	Specify the differential pressure between areas of different environmental standards.		
18.1	Sch-M	Specify type of manometer installed for measurement and verification of Air Pressure Differential.		
18.13	WHO TRS-961	Specify the air classification in final change room to enter A/B area.		

	ANNEXE-06			
19 Environmental Monitoring:-				
19.1	Sch-M	Specify the temperature and humidity maintained in the critical areas.		
19.2	WHO TRS-961 ANNEXE-06	Verify the area qualification records and specify whether the following were taken into consideration: 1) No. of Persons 2) ACPH (Air Changes per hours) 3) Particle count (Static & Dynamic) 4) Viable count (Static & Dynamic) 5) Temperature & Humidity 6) Air Sampling location and interpretation of results (Both viable and non-viable) 7) Whether the above method is in compliance with ISO 14644-1 8) Action and Alert limits for all the above parameters		
19.3	Sch-M	Mention the periodic monitoring frequencies of the followings: 9) Particulate Counts 10) HEPA filters integrity testing 11) Air Change rates 12) Air pressure differentials 13) Temperature and Humidity 14) Microbiological monitoring by settle plates and/ or swabs in Critical areas & Other areas		
19.4	Sch-M	Does a written Environmental Monitoring Program exist?		
19.5	Sch-M	How long the settle plates are exposed in Grade A and other areas.		
19.6	Sch-M	Verify the records of microbiological results also specify whether alert and actions limits are followed or not.		

19.7	Sch-M	What action is taken in case particulate and microbiological monitoring counts exceed the limits?		
19.8	WHO TRS-961 ANNEXE-06	Specify what parameters are reassessed and approved before starting production and in case of major engineering modifications being carried out to the HVAC system of any area.		
20 Garments:				
20.1	Sch-M	Specify type of garments used in critical areas?		
20.2	Sch-M	Specify type of Zips used in garments		
20.3	Sch-M	Whether garments used in critical areas are sterile.		
20.4	Sch-M	Specify the process of sterilization of the garments & the practice followed to carry the sterilised garments to the final change room.		
20.5	Sch-M	Are garments, masks, gloves are changed at every work session?		
20.6	Sch-M	Are the gloves used made of latex or other suitable plastic material		
20.7	Sch-M	Are powder free gloves used in clean rooms		
20.8	Sch-M	Are the gloves long enough to cover the wrists completely and allow the over-all cuff to be tucked in		
20.9	Sch-M	Are the foot-wear used made of plastic or rubber material		
20.10	Sch-M	Are the foot-wear daily cleaned with a bactericide		
20.1	Sch-M	Does the safety goggles / numbered glasses worn inside the critical areas have side extensions		
20.1	Sch-M	Are safety goggles sanitized by a suitable method		
20.1	Sch-M	Specify the garment changing procedure documented		
20.1	Sch-M	Specify whether operators are trained in garment changing procedure.		
20.2	Sch-M	Specify a full size mirror been provided in the final change room to ascertain that the operator has appropriately attired in the garments.		

20.2	WHO TRS-961 ANNEXE-06	Specify how the garments used in clean areas are cleaned and sterilized.		
21 Sanitation:				
21.1	Sch-M	Specify the SOP followed for sanitation of sterile processing facilities and mention the SOP nos.		
21.2	Sch-M	Specify whether employees carrying out the sanitation of critical areas are specially trained for this purpose.		
21.3	Sch-M	Verify the training records.		
21.4	Sch-M	Specify the sanitizing agent/s used.		
21.5	Sch-M	Specify the quality of water used for preparation of sanitising solution.		
21.6	Sch-M	Specify the disinfectant used for hand sprays?		
21.7	Sch-M	Specify whether disinfectant solutions are filtered through membrane into suitable sterile containers or sterilized before use?		
21.8	Sch-M	Specify whether the diluted disinfectants bear 'use before' labels based on microbiological establishment of their germicidal properties & verify the records		
21.9	Sch-M	Specify whether fumigation is carried out in critical areas. If yes, specify fumigating agent and its conc. used.		
21.10	Sch-M	Specify whether any SOP exist for the purpose of fumigation if so mentioned the SOP nos.		
21.1	Sch-M	Specify the cleaning procedure of critical areas.		
21.1	WHO TRS-961 ANNEXE-06	Specify whether particle monitoring in Grade A zones is undertaken for the full duration of critical processing including equipment assembly.		
21.1	WHO TRS-961	Specify whether particle monitoring in Grade B zones is undertaken for the full duration of critical processing.		

	ANNEXE-06			
21.1	Sch-M	Whether more than one sanitizing agent is used in rotation. If yes list the sanitizing agents their concentration and frequency.		
22 Equipment:				
22.1	Sch-M	Specify whether the unit- sterilizers are double ended with suitable inter-locking between the doors.		
22.2	Sch-M	Specify the initial effectiveness of sterilization process established by using microbial spore indicators.		
22.3	Sch-M	Specify whether thermal Mapping of heat sterilizers is carried out on regular basis. Check records.		
22.4	Sch-M	Specify suitable vent filters and recording thermographs provided in autoclaves & dry sterilizers.		
22.5	Sch-M	Specify HEPA filters for cooling air and recording thermographs provided in DHS/Tunnel.		
22.6	WHO TRS-961 ANNEXE-06	Specify whether provisions of CIP or SIP are available.		
22.7	Sch-M	Specify whether pure steams are in use.		
22.8	Sch-M	Specify filter integrity test carried out before and after the filtration process.		
22.9	Sch-M	Specify the material of construction of the equipment & glass containers.		
22.10	Sch-M	Specify the tubing used in critical areas		
22.1	Sch-M	Specify the qualifications of critical equipment.		
22.1	WHO TRS-961 ANNEXE-06	Verify the qualification, protocol and reports for the critical equipment.		
22.1	Sch-M	Specify SOPs available for each equipment for its operation and cleaning.		

22.1	Sch-M	Specify whether the measuring devices attached to equipment calibrated at suitable intervals.		
22.2	Sch-M	Specify whether a written calibration program is available		
22.2	Sch-M	Specify whether calibration status documented and displayed on the equipment and the gauges		
23 Manufacturing Process				
23.1	Sch-M	Specify whether the bulk raw materials and bulk solutions monitored for bio-burden periodically (solutions not to contain more than 100 cfu/ml).		
23.2	Sch-M	Specify the minimum possible time between the preparation of the solution and its sterilization or filtration through microorganism retaining filters followed.		
23.3	Sch-M	Specify the porosity of the filters when any external gases are coming into contact with the sterile product.		
23.4	Sch-M	Specify whether gas cylinders are kept out side of the critical areas.		
23.5	Sch-M	Specify the procedure of sterilization of washed containers.		
23.6	Sch-M	Specify whether the sterilized containers not used within an established time, rinsed with WFI and re-sterilized.		
23.7	Sch-M	Is each lot of the finished product filled in one continuation operation?		
23.8	Sch-M	Specify whether all critical process is validated. Verify the records.		
23.9	WHO TRS-961 ANNEXE-06	Verify the process validation protocol and reports for the critical operation.		
23.10	WHO TRS-961	Specify whether critical operations are carried out in closed system.		

	ANNEXE-06			
24. Aseptic processing and sterilization by filtration:				
24.1	Sch-M	Specify whether the filling area is of Grade A environment with Grade B background.		
24.2	Sch-M	Specify the room classification of solutions preparation area which is sterilized by filtration.		
24.3	Sch-M	Specify the filter used for sterilization of solution by filtration.		
24.4	WHO TRS-961 ANNEXE-06	Specify the maximum possible time used for filtration process.		
24.5	Sch-M	Specify whether integrity of the sterilizing filters is verified before and after use. If so, by which method.		
24.6	WHO TRS-961 ANNEXE-06	Specify whether the personal working in the aseptic area is qualified for clean room procedure or not. If so verify the training records.		
25 Product Containers & Closures:-				
25.1	Sch-M	Specify whether the containers and closures used comply with pharmacopoeia or other specific requirements.		
25.2	Sch-M	Specify whether Specifications, Test methods, Cleaning procedures, Sterilizing procedures etc. are available of the containers/ closures and other component parts of drug packages.		
25.3	Sch-M	Specify whether the container & closures are compatible with the product without affecting its quality and purity. Verify the records.		
25.4	Sch-M	Specify whether containers and the closures are finally washed with WFI before sterilization.		

25.5	Sch-M	Specify whether a written procedure exist for washing of glass ampoules/vials.		
25.6	Sch-M	Specify whether the material quality of the stoppers and closures ensures that it does not affect the quality of the product and avoids the risk of toxicity.		
26 Sterilization				
26.1	Sch-M	Whether the sterilizing processes have been validated (Dry heat, Moist heat, filtration, ETO, ionizations whichever applicable.		
26.2	Sch-M	Whether the validity of the process verified at regular intervals (at least annually)		
26.3	Sch-M	Whether the terminal sterilizer's capacity is sufficient to sterilize one batch completely at one time. If not specify controls and measures taken in lot sterilizations.		
26.4	Sch-M	Whether biological indicators used in monitoring of sterilization.		
26.5	WHO TRS-961 ANNEXE-06	Verify that the probe is placed at the coolest point on the basis of validation studies		
26.6	WHO TRS-961 ANNEXE-06	Verify the qualification, protocol and reports for the sterilizers		
26.7	Sch-M	Whether the biological indicators stored and used as per manufacturer's instructions. Whether quality of BI's checked by positive controls.		
26.8	Sch-M	Whether a clear means of differentiating 'sterilized' from 'unsterilized' products is in place. Specify.		
26.9	Sch-M	Whether the label on the basket / tray or other carrier of product / component clearly states: • Name of the material		

		• Its batch number • Its sterilization status • Indicator (in case it has passed through sterilization process)		
26.10	Sch-M	Whether sterilization records including thermographs and sterilization monitoring slips attached with the Batch Production Record		
27 Sterilization (By Dry Heat)				
27.1	Sch-M	Whether the sterilization cycle recording device of suitable size and precision provided in DHS./ Tunnel		
27.2	Sch-M	Whether the position of temperature probes used for controlling and / or recording determined during validation and (where applicable) been checked against a second independent temperature probe located in the same position		
27.3	Sch-M	Whether the chart forms a part of the batch record.		
27.4	Sch-M	Whether sterilization cycle validated only by biological indicator and chemical indicators or physical validation is also carried out		
27.5	Sch-M	Whether the time allowed reaching the required temperature before commencing the measurement of sterilizing time, separately determined for each type of load.		
27.6	Sch-M	Are adequate precautions taken to protect the load during cooling after it has gone through the high temperature phase of a heat sterilization cycle		
27.7	Sch-M	In case the cooling is affected with any fluid or gas in contact with the product , is it sterilized.		
27.8	Sch-M	Whether the equipment air inlet and outlets been provided with bacteria retaining filters		
27.9	Sch-M	In the process of sterilization by dry heat, does the equipment have: 1) Air circulation facility within the chambers		

		2) Positive pressure to prevent entry of non-sterile air		
27.10	WHO TRS-961 ANNEXE-06	Verify the sterilizer loading pattern & whether is complied with the validated loading pattern.		
27.1	Sch-M	Whether the process of dry heat sterilization intended to remove the pyrogens. If so, has the validation been done with challenge tests using endo-toxins		
28.Sterilization (By Moist Heat)				
28.1	Sch-M	Whether recording of both temperature and pressure carried out to monitor the process		
28.2	Sch-M	Whether the control instrumentation independent of the monitoring instrumentation and recording charts.		
28.3	Sch-M	Whether the equipment has automated control and monitoring system, if so, have these been validated to ensure that critical process requirements are met.		
28.4	Sch-M	Whether the system and cycle faults are recorded inbuilt and also observed by the operator and record maintained.		
28.5	Sch-M	Whether the readings of the thermograph during sterilization cycling are routinely checked by the operator against the reading shown by the dial thermometer fitted with autoclave.		
28.6	Sch-M	Whether the sterilizer fitted with a drain at the bottom of the chamber If so, does the record of temperature at this position is recorded throughout the sterilizing period		
28.7	Sch-M	Are frequent leak tests conducted on the chamber of the autoclave on each day of operation.		
28.8	Sch-M	Whether all items to be sterilized (other than sealed containers) are wrapped for sterilization.		

28.9	Sch-M	Whether the wrapping material allows removal of air and penetration of steam ensuring contact with the sterilizing agent at the required temperature for required time		
28.10	Sch-M	Whether the wrapping prevent contamination after sterilization		
28.1	Sch-M	Whether the steam used for sterilization is of suitable quality and doesn't contain additives at a level which could cause contamination of the product or equipment		
29. Others				
29.1	Sch-M	Specify whether products released only after complete filling and testing.		
29.2	Sch-M	Specify whether result of the tests relating to sterility, bacterial endo-toxins are maintained in the analytical records		
29.3	WHO TRS-961 ANNEXE-06	Whether process hold time studies has been carried out for various stages of production		
30. Documentation and Records				
30.1	Sch-M	Whether all daily documents are filled correctly and timely.		
30.2	Sch-M	How the documents are designed, prepared, reviewed and controlled to provide an audit trail.		
30.3	Sch-M	Whether documents are approved signed and dated by appropriate and authorized person.		
30.4	Sch-M	Whether documents specify title, nature and purpose.		
30.5	Sch-M	Whether documents are regularly reviewed and kept up to date.		
30.6	Sch-M	Whether the records are made at the time of each operation in such a way that all significant activities concerning to the production are traceable.		

30.7	Sch-M	Whether data is recorded by electronic data processing system or by other means. If by electronic data processing system then how access is controlled to enter, modify etc. the data.		
30.8	Sch-M	Whether master formula and detailed operating procedures for each product are available?		
30.9	Sch-M	Specify the duration of retaining the documents after the expiry of the respective product and who is responsible for its maintenance.		
	Do the manufacturing records pertaining to manufacture of Sterile & Non- Sterile products indicate the following details: Serial number of Batch Manufacturing ,Record ,Name of the product, Reference to Master Formula Record, Batch/ Lot number, Batch/ Lot size, Date of commencement and completion of manufacture, Date of manufacture and assigned date of expiry, Date of each step in manufacturing, Names of all ingredients with reference number given by the quality control department ,Quantity of all ingredients, Time and duration of blending, mixing etc. where ever applicable, PH of solutions whenever applicable, Filter integrity testing records, Temperature and humidity records whenever applicable, Records of plate-counts whenever applicable, Results of bacterial endo-toxin and toxicity, Records of weight or volume of drug filled in containers, Bio burden records before sterilisation, Leak test records, Inspection records, Sterilization records including load details, date, duration, temperature, pressure etc. Container washing & testing records, Total number of containers filled, Total number of containers rejected at each stage, Theoretical yield, permissible yield, actual yield and variation there of, Clarification for variation in yield ,beyond permissible yield, Reference number of relevant analytical reports, Details of re-processing, if any, Names of all operators carrying out different activities, Environmental monitoring records, Specimens of different packaging material, Records of destruction of rejected containers and packaging			

	material, and Signature of the competent technical staff responsible for manufacture and testing.			
31 Labels and Other Printed Materials:-				
31.1	Sch-M	Whether the printing is in bright colour and legible on labels and other printed materials?		
31.2	Sch-M	How printed labels (art work) are approved. Verify the SOP.		
31.3	WHO TRS-986	Specify whether cut labels or rolled labels are used.		
31.4	Sch-M	Whether the labels comply with requirements of Rule 96 & 97 & other relevant provisions		
32 Master Formula Records: -				
32.1	Sch-M	How master formula records for each product are prepared, authorized and controlled.		
32.2	Sch-M	Whether master formula is batch size specific.		
32.3	Sch-M	Whether master formula record covers all the points as prescribed in Schedule 'M'.		
32.4	WHO TRS-986	Whether master formula record covered all the points as prescribed in WHO-TRS 986 & PIC/S guidelines		
33 Batch Processing / Manufacturing Records:-				
33.1	Sch-M	Whether the BPR/BMR for each product is prepared on the basis of currently approved master formula.		
33.2	Sch-M	Whether BPR / BMR covered all the points as prescribed in Schedule 'M'		
33.3	WHO TRS-986	Whether BPR / BMR covered all the points as prescribed in WHO-TRS 986 & PIC/S		
33.4	Sch-M	Whether all the documents generated during Batch production are attached with the BPR /BMR		
34 Batch Packaging Records: -				
34.1	Sch-M	Whether authorized packaging instructions for each product of various pack size and type are maintained and complied with.		

34.2	Sch-M	Specify whether all material, equipment, rooms and packaging lines are labelled with an indication of product being processed with batch no.		
34.3	Sch-M	Whether packaging lines are independent and adequately segregated.		
34.4	Sch-M	How line clearance is performed. Whether records of line clearance is maintained according to appropriate checklist.		
34.5	Sch-M	Do the packaging materials arrive on a covered trolley?		
34.6	Sch-M	Are packaging materials verified against a master set to ensure that they are the most recent edition and the correct materials for the batch?		
34.7	Sch-M	Are the quantities of packaging materials verified against the amounts stated as dispensed from the warehouse?		
34.8	WHO TRS-986	Specify the monitoring code (bar code, pinholes etc.) for final packing materials.		
34.9	Sch-M	Is the batch yield calculated immediately upon completion of packaging operation & prior to the introduction of a new batch into the area?		
34.10	Sch-M	Is the yield calculation independently verified by second individual and whether any significant deviation from accepted yield is recorded and investigated?		
34.11	Sch-M	Is any excess printed packaging material destroyed on completion of the batch?		
34.12	Sch-M	Is there a provision in the department for the separation of printed packaging material for destruction & rejected product?		
34.13	Sch-M	Whether Batch packaging record covered all the points as prescribed in Schedule 'M'		
34.14	WHO TRS-986	Whether Batch packaging record covered all the points as prescribed in WHO-TRS 986 & PIC/S		

34.15	Sch-M	Whether all the documents generated during packaging are attached with the Batch packaging record.		
34.16	Sch-M	Whether BPR are based on current master formula record.		
35 Standard Operating Procedure and Records: -				
35.1	Sch-M	Verify the List of SOPs and mention total number of SOPs followed by the firm.		
35.2	Sch-M	Has all the SOPs been displayed.		
35.3	Sch-M	The formats, logs & SOPs are current		
35.4	Sch-M	Is any obsolete copy seen in the Area?		
36 Reprocessing and Recoveries:-				
36.1	Sch-M	Verify the SOP for reprocessing.		
36.2	WHO TRS-986	Whether reprocessed batch is subjected to stability evaluation.		
36.3	Sch-M	Whether the recoveries are added into the subsequent batches. If yes specify the procedures.		
37 Finished Product:-				
37.1	Sch-M	Specify whether finished products are held in quarantine until their final release.		
37.2	Sch-M	Specify the storage arrangement of finished products after final release by QA		
38 Quality Control Area: -				
38.1	Sch-M	Specify whether QC area is independent of production area.		
38.2	Sch-M	Specify the working space provided for QC:		
38.3	Sch-M	Specify the procedure followed for approval/rejection of raw materials, packaging materials, intermediate products and finished products. Verify the SOP and record.		
38.4	Sch-L1	Specify the arrangement provided to protect sensitive electronic balances from vibrations, electrical interference, humidity etc.		

38.5	Sch-L1	Specify the safety measures taken to avoid any accidental hazards in the QC department.		
38.6	Sch-M	Specify whether separate washing and drying area is provided for glassware		
38.7	Sch-L1	Specify which grade of glassware is used in assay procedures and whether they are certified/calibrated. Verify the certificates and calibration records.		
38.8	Sch-M	Specify whether any particular test is outsourced. If so mention the name of laboratory and verify the contract made in this regard.		
39 Microbiology Lab				
39.1	Sch-M	Whether separate AHU's are provided for microbiological testing areas.		
39.2	Sch-M	Whether support areas are under same AHU which is used for sterile area.		
39.3	Sch-M	Briefly describe layout of the microbiology lab (attach copy of the layout if available)		
39.4	Sch-M	Whether entry to the sterile area is through three air lock systems with separate exit		
39.5	WHO TRS-986	Specify whether access in sterile area is controlled, and if so the system followed in this regard		
39.6	Sch-M	Verify the list of equipment used in the microbiological lab and also specify whether these are placed logically and function accurately		
39.7	Sch-M	Specify whether operators are trained in gowning procedures. Verify the training records.		
39.8	Sch-L1	Specify the gowning procedure to enter the sterile area. Verify the entry and exit records.		
39.9	Sch-L1	Specify the air class of sterile areas and whether pressure difference is maintained. Verify the records.		
39.10	WHO TRS-986	Specify whether an environmental monitoring programme is followed with alert and action limit.		

39.1	Sch-M	Specify whether a documented cleaning and disinfection programme is in place.		
39.1	WHO TRS-986	Specify whether a procedure for dealing with spillages in sterile area is in place.		
39.1	WHO TRS-986	Whether separate areas provided for sterility testing, assay of antibiotics & vitamins and MLT in sterile area.		
39.1	Sch-M	Specify the type of workstations (LAF) provided in the sterile area.		
39.2	Sch-M	Whether double door autoclave is provided for transferring of materials from unclassified area to sterile area.		
39.2	WHO TRS-986	Verify the area qualification document for sterile area.		
39.2	WHO TRS-986	Verify the procedure for selection of sampling location and interpretation of results for environmental monitoring of sterile area along with the SOP and documents. (Specify whether the method is in compliance with ISO 14644-1).		
39.2	Sch-L1	Specify whether qualification of all equipment and instruments used in this department is covered under VMP.		
39.2	Sch-L1	Verify the qualification document of major equipment like autoclave/incubator, hot air oven, refrigerator, LAF etc.		
39.20	Sch-L1	Specify the Calibration procedure of temperature measurement devices used in autoclave and incubator. Verify whether it is traceable to standard temperature.		
39.2	Sch-M	Verify the procedure for the handling and disposal of chemical and microbial waste.		
39.2	WHO TRS-986	Specify the procedure followed to verify the validity of the test in case of antibiotic potency testing.		

39.2	WHO TRS-986	Specify whether there is separate autoclave for decontamination.		
39.2	WHO TRS-986	Specify whether the Vendors for dehydrated media is approved and qualified.		
39.3	WHO TRS-986 / IP	Specify whether GPT is carried out for dehydrated media.		
39.3	Sch-L1	Specify whether performance of culture media (recovery or survival maintenance) is carried out and the results meet acceptance criteria.		
39.3	Sch-L1	Specify the source of procurement of reference culture and its maintenance.		
39.3	Sch-L1	Specify the Air Grades for following areas: —Sterility testing room —Microbiological Assay room —MLT room —Airlocks (entry and exit both)		
39.3	Sch-M	Verify the following records: —Log book for the entry/exit in the sterile area —media preparation record —records for water testing (micro) —records for MLT		
39.30	IP	Verify how the concentration of the inoculums is determined.		
39.3	Sch-M	Whether firm has provided microbiology lab for MLT test for nonsterile dosage form. If no how this test is complied.		
40 Quality Control System: -				
40.1	Sch-L1	Specify the source of procurement of various reference standards		
40.2	Sch-L1	How the reference standards are stored, evaluated and maintained.		

40.3	WHO TRS-986	Specify whether authorized access system is followed for reference standards.		
40.4	Sch-L1	Verify the SOP and records for preparation of working standard from the reference standard.		
40.5	Sch-L1	Verify the SOP and records for destruction of unused working standard		
40.6	Sch-M	Verify the sampling SOPs and records for: — starting materials — primary packaging materials — secondary packaging materials — in process materials — finished products — water analysis — wash water analysis — swab analysis — wash water analysis of cleaned garments		
40.7	Sch-M	Specify whether approved specifications are available for all: — starting materials — primary packaging materials — secondary packaging materials — in process materials — finished products — water analysis — wash water analysis — swab analysis — wash water analysis of cleaned garments		
40.8	Sch-L1	Verify whether all approved specifications are based on validation.		
40.9	WHO TRS-986	Is there any SOP for handling of OOS product (out of specification)?		

40.10	WHO TRS-986	Specify the procedure for review of test data & calculations.		
40.1	Sch-L1	Specify whether a designated person is responsible for receipt of samples for testing.		
40.1	Sch-L1	Specify the procedure followed for receiving and recording (logging in). Verify the SOP and records		
40.1	Sch-L1	Specify the procedure for storage and distribution of received samples to different analyst.		
40.1	Sch-L1	Is there a maximum time limit for retention of sample in the laboratory prior to testing?		
40.2	Sch-L1	Specify the procedure followed for preparation, consumption & destruction of volumetric solution. Verify the SOP and records.		
40.2	Sch-L1	Specify whether there is a log book for the preparations of the reagent including name of the analyst, name of the reagent, Calculations, Date of preparation & expiration.		
40.2	Sch-L1	Specify the procedure followed for using GR, LR and AR grade of chemicals / solvents used for calibration & sample testing.		
40.2	Sch-L1	Specify whether respective STP is followed by the analyst for analysis.		
40.2	Sch-L1	Specify the procedure of reporting the result of analysis by the analyst to QC Head.		
40.20	Sch-L1	Specify the procedure followed for storage of samples after testing.		
40.2	Sch-L1	Specify the procedure for retention of samples after testing is completed.		
40.2	Sch-L1	Specify the procedure followed for issuance of COA.		
40.2	Sch-L1	Specify procedures for safe removal of waste from the laboratory.		
41 Analytical Method Validation (AMV):-				

41.1	IP	Specify whether following Characteristics are considered during validation of analytical methods: — Specificity — Linearity — Range — Accuracy — Precision — Detection — Limit — Quantification — Limit — Robustness. — Solution Stability/Filter Study		
42 HPLC Calibration				
42.1	IP	Verify the records of calibration of following parameters: — Calibration of pump. — Calibration of Gradient proportionate valve (GPV). — Calibration of Auto injector. — Calibration of Detector. — Temperature calibration for Column oven and — Sample Trays compartment. — Auto Sampler Carry over. — Manual injector calibration — System suitability		
43 Dissolution Apparatus Calibration				
43.1	IP	Verify the records of calibration of following parameters: — Checking of RPM — Checking of Temperature — Checking of distance between inside bottom of the vessel & paddle		

		— Checking of distance between inside bottom of the vessel & Basket — Checking Wobbling of paddle — Checking of Wobbling of Basket — Checking of Timer: Calibrate against standard stop watch — Performance verification test **[Verify whether dissolution is calibrated against standard prednisolone tablets]**		
44 UV-VIS				
44.1	IP	Verify the records of calibration of following parameters: — Control of wavelengths (Wavelength accuracy) — Control of absorbance (Photometric accuracy) — Limit Of Stray Light — Resolution Power — Resolution (second order derivative spectrum) — CELLS Verification — I0 flatness — Calibration of Visible Wavelength — Calibration of absorbance reproducibility for visible wavelength — Photometric linearity at 430nm		
46 FTIR				
46.1	IP	Verify the records of calibration of following parameters: — Verification of the wave number scale — Control of resolution performance		
47 TOC Analyser+				
47.1	USP	Verify the records of calibration of following parameters: — System suitability:		

		— Calibration (Four point calibration)		
48 Stability Studies				
48.1	Sch-M	Specify whether stability study is carried out in the QC and if so, is there separate area for Stability Chamber for stability studies. How many Stability Chambers have been provided? Specify whether shelf life of the product is fixed on the basis of stability studies.		
48.2	WHO TRS-986	Verify the qualification documents of all the stability chambers.		
48.3	WHO TRS-986	Specify whether a written programme for ongoing stability determination is in place.		
48.4	WHO TRS-986	Specify whether a complete description of stability study is available.		
48.5	WHO TRS-986	Verify the stability calendar along with stability protocol and documents. Attach the copy of stability calendar		
48.6	WHO TRS-986	Specify whether the stability protocol indicates complete set of testing parameters and methods.		
48.7	WHO TRS-986	Specify whether summary of all generated data from the study are retained.		
48.8	WHO TRS-986	Specify the testing schedule for each product		
48.9	WHO TRS-986	Specify whether stability study is performed after any significant changes in process equipment, packaging materials etc.		
48.10	WHO TRS-986	Specify the validation method for stability chambers		
48.1	WHO TRS-986	Specify the Temperature and humidity for real times studies carried out for fixing shelf life of drug in the country.		
49 Quality assurance:-				
49.1	Sch-M	Mention the documents prepared and maintained by QA department		

49.2	Sch-M	Specify the responsibility of the QA Head.		
49.3	Sch-M	Specify the procedure followed by QA department to ensure the implementation of all SOPs in the plant.		
49.4	Sch-M	Verify the total list of SOPs maintained by QA and how QA ensure that no obsolete SOP is in circulation.		
49.5	WHO TRS-986	Specify whether any procedure is followed for preparation of SOPs and its circulation to all concerned. How master, controlled and uncontrolled copy of SOPs are processed.		
49.6	WHO TRS-986	Mention the change control procedures & examine three recent change control forms.		
49.7	WHO TRS-986	Specify the procedures followed to ensure CAPA process. Verify the SOP and three recent records in this regard.		
49.8	WHO TRS-986	How deviation are controlled. Verify SOP and three recent deviations. Specify whether all deviations are reported and records maintained.		
49.9	Sch-M	Is the production batch record and release test results reviewed for accuracy and completeness before a batch/lot of finished product is released?		
49.10	Sch-M	Verify the checklist and SOP in this regard.		
49.1	Sch-M	Whether QA is involved in control of starting materials, intermediate products, bulk products, process controls, calibrations, validation and release of finish goods.		
50 Annual Product Quality Review (APQR):-				
50.1	WHO TRS-986	Specify Whether Annual Product Quality review is carried out for each product		
50.2	WHO TRS-987	Specify whether following criteria are considered for review: — Starting materials and packaging materials — Critical in-process controls and finished product results; — All significant deviations or non-conformance		

		— All changes made to the processes or analytical methods; — Results of the stability monitoring programme and any adverse trends — All quality-related returns, complaints and recalls and the investigations performed at the time — Adequacy of any other previous corrective actions on product process or equipment — The qualification status of relevant equipment and utilities e.g. HVAC, water, or compressed gases		
50.3	WHO TRS-988	Verify whether Cp and CpK values are calculated and what is the acceptance criteria fixed.		
51 Product Recalls:-				
51.1	Sch-M	Specify the product recall system.		
51.2	Sch-M	Verify the procedure followed to handle the recalled products		
51.3	Sch-M	Are distribution records available for a prompt recall of products from the market?		
51.4	Sch-M	Verify the SOP for recall of products clearly defining responsibility, procedure reporting, reconciliation etc.		
52 Complaints and Adverse Reactions:-				
52.1	Sch-M	Are complaints, whether received in oral or written form, documented in writing, and retained in a designated file?		
52.2	WHO TRS-988	Are complaints reviewed on a timely basis by the Quality Assurance unit?		
52.3	WHO TRS-988	Is CAPA process followed in response to each complaint documented?		
52.4	WHO TRS-988	Specify whether system of route cause analysis is followed by the firm on the complaint of adverse drug reaction.		
52.5	Sch-M	Specify the review system for complaints concerning the quality of products.		

52.6	Sch-M	How records of complaint and adverse reactions maintained.		
52.7	Draft Rules	Whether the firm has provided Pharmacovigilance department for analysing complaints of adverse drugs reactions resulting from the use of a drug.		
52.8	Sch-M	Are there any criteria for action to be taken on the basis of nature of complaint / adverse reaction?		
53 Site Master File:-				
53.1	Sch-M	Whether all the relevant information has been included in the site master file.		
53.2	Sch-M	Whether quality policy has been included in the site master file.		
53.3	Sch-M	Verify whether all information as per schedule M		
53.4	WHO TRS-988	Verify whether all information as per WHO TRS 986 and PIC/S document.		
54 Validation				
54.1	WHO TRS-988	Specify the validation policy of the company		
54.2	WHO TRS-988	Whether a Validation Master Plan has been prepared.		
54.3	Sch-M	Verify resources and those responsible for its implementation.		
54.4	WHO TRS-988	Identify the systems and processes to be validated as per VMP		
54.5	WHO TRS-988	Verify whether documentation, standard operating procedures (SOPs), Work Instructions and Standards (applicable for national and international) are incorporated in VMP		
54.6	WHO TRS-988	Validation list for facilities/equipment, processes / procedure and products.		
54.7	WHO TRS-988	Specify whether key approval criteria are mentioned in the VMP & how record and conclusion of such validation studies are prepared and maintained.		

54.8	WHO TRS-988	Verify Protocol format for each validation activity, including re-validation and reasonable unforeseen events (power failures, system crash and recovery, filter integrity failure.		
54.9	WHO TRS-988	Whether validation calendar is specified in VMP.		
54.10	Sch-M	Specify whether the critical processes validated Prospectively, retrospectively or concurrently.		
54.1	WHO TRS-988	In case electronic data processing systems are used, are these validated?		
54.1	WHO TRS-988	Please specify whether periodical challenge tests performed on the system to verify reliability.		
54.1	Sch-M	Are the validation studies performed according to pre-defined protocols?		
54.1	Sch-M	Is a written report summarized, results and conclusions prepared and maintained?		
54.2	WHO TRS-988	Is the validity of the critical processes and procedures established based on a validation study?		
54.2	WHO TRS-988	Are criteria established to assess the changes originating a revalidation?		
54.2	WHO TRS-988	Are trend analyses performed to assess the need to re-validate in order to assure the processes and procedures continue to obtain the desired results?		
55 Internal Quality / GMP Audit Programme				
55.1	Sch-M	Does a formal auditing function exist in the Quality Assurance department?		
55.2	Sch-M	Does a written SOP specify who shall conduct audits and qualifications (education, training, and experience) for those who conduct audits?		
55.3	Sch-M	Does a written SOP specify the scope and frequency of audits and how such audits are to be documented?		

55.4	WHO TRS-988	Specify whether record is maintained for CAPA on the basis of self quality audit / inspection and whether same is reviewed by the management		
56 Pharmaceutical Development				
56.1	ICH/Q-8-PICS	Whether there is Research and Development facility available.		
56.2	ICH/Q-8-PICS	Whether formulation development facility up to development of exhibit batches available.		
56.3	ICH/Q-8-PICS	Whether firm hires consultants for technology transfer. If so details thereof.		
56.4	ICH/Q-8-PICS	Whether firm has adopted latest tools (quality by design) to develop new products.		
57 Quality Risk Assessment System:-				
57.1	ICH/Q-9-PICS	Whether the firm has adopted QRM principle to mitigate risk involved in pharmaceutical development, manufacturing and distribution. If yes specify which guidelines are followed in this regard.		
57.2	ICH/Q-9-PICS	Whether firm has policy document on QRM. Specify document number and its effective date.		
57.3	ICH/Q-9-PICS	Which known principles have been adopted to analyse risks e.g. FMEA, HAZOP, HACCP, FTA etc.		
57.4	ICH/Q-9-PICS	Whether risk priority number (RPN) is calculated based on severity, probability and detectability. If so, what is the criteria of acceptance.		
57.5	ICH/Q-9-PICS	How many products, process etc. have been analysed for risk. Give brief.		
58 Data Integrity				
58.1	Sch-M	Whether the records are completed at the time of the operation and are legible maintained with raw data if applicable.		
58.2	Sch-L1	Whether the firm has software based manufacturing and testing equipment		

58.3	Sch-L1	Whether the individuals are provided log in IDs for access. All login and logout information should be available.		
58.4	Sch-L1	Whether rights to work, amend, modify, delete are specified in written document.		
58.5	Sch-L1	Whether right to access and modify are with two different individuals. If yes how QA is involved in modification of data.		
58.6	Sch-L1	Whether audit trails related to project creation (study creation), project (study) modification, deletion etc. are available.		
58.7	Sch-L1	Whether the data is backed up at regular intervals. If yes what is the written back up policy. The data backup must be server based.		
58.8	Sch-L1	How Excel sheets are validated if calculation are done in Excel sheet.		
58.9	Sch-L1	Whether the firm has QA SOP for review of data integrity or audit trail. If yes how the modification and deletions are reviewed.		
59 Pharmaceutical Quality Management System (PQS)				
59.1	WHO TRS-986	Specify the management responsibility defined as per the quality manual		
59.2	WHO TRS-986	Specify the Procedures followed for continual improvement of process performance and product quality		
59.3	WHO TRS-986	Specify the performance indicators presently followed by the firm to monitor the effectiveness of PQS like product quality monitoring, CAPA, change management and management review		
59.4	WHO TRS-987	whether purchases are also included under PQS		
59.5	WHO TRS-986	Specify whether life cycle approach is followed		

59.6	WHO TRS-986	Give synopsis of last to management review meeting held by the firm		

List of Observations/Deficiencies:

1) **Critical:**

   1.1:

   1.2:

2) **Major:**

   2.1:

   2.2:

3) **Others:**

   3.1:

   3.2:

   3.3:

Concluding Remarks:

Name and Signatures of the Inspecting officials:

			Quality Rating			
S.No	**Reference**		**2**	**1**	**0**	**X**
1 Building and premises: -						
1.1	Sch-M,	Specify whether the whole facility is separated, dedicated and is not a part of any other non-drug facility.	the whole facility was found separated, dedicated and is not a part of any other non-drug facility. Even no other category of drugs like sex hormones, beta lactam, cyto-toxic, spore forming are manufactured in the same campus	the whole facility was found separated, dedicated and is not a part of any other non-drug facility.	Non drug items like nutraceuticals was found manufactured along with general drug item	1) The manufacturing facilities for potent drugs such as sex hormones, beta-lactam and cytotoxic are common with general drugs. 2) Some of the critical areas of manufacturing are exposed directly with the environment
1.2	Sch-M,	Specify whether the surroundings of manufacturing area is clean and as per the SOP prescribed in this regard. (Mention the SOP nos.)	Situated in eco-friendly zone with less than 50% FAR with the surroundings in the campus is free from dust and planned greeneries.	Situated in industrial area and not effected by other industries.	Situated in industrial area and obnoxiou fumes, smoke is produced in the surroundings.	NA
1.3	Sch-M,	Describe the pest, insects, birds and rodents control system followed in the premises. Specify pest control schedule- area wise, along with materials and methods used.	NA	Agreement copy and SOP in place.	Neither agreement copy nor SOP available.	Pest infestation, rodents and birds found in the manufacturing premises
1.4	Sch-M,	What measures have been taken to make Interior surface (of walls, floors, and ceilings) smooth and free from cracks, and to permit easy cleaning Specify material of construction and finish for walls, ceiling, floor, coving etc. i.e. whether Epoxy or PU coated, kota / granite stone with epoxy sealed joints, solid / GI / gypsum / cal. Silicate board ceiling with epoxy, PU or any other pre-fabricated panel (GRP, powder coated SS or Aluminium etc.) paint.	Made of RCC and layout is such so that uni-flow system of man and material is maintained and interior surfaces are smooth, free from cracks and permits easy cleaning. Maintenance of hygienic conditions is excellent and proper documents are available. All the manufacturing and surrounding corridors including change rooms are made of epoxy flooring and interior surfaces are free from any cracks or joints.	Made of RCC and interior surfaces are smooth, free from cracks and permits easy cleaning.	Cracks are observed at many places of non critical areas of manufactured	

			Quality Rating			
S.No	Reference		2	1	0	X
1.5	Sch-M,	Specify the lux level maintained in various parts of the premise (Storage area, manufacturing area specially visual inspection, Laboratory areas etc.).	400-500 lux in the processing area 300-400 lux in ancillary areas 200-300 lux in storage area More then 500 lux in inspection areas For photo sensitive products monochromatic light is used	400-500 lux in the processing area 300-400 lux in ancillary areas 200-300 lux in storage area More then 500 lux in inspection areas	Less then 500 lux in inspection areas Less then 400 lux in processing area	NA
1.6	Sch-M,	Specify the air handling system used in various areas i.e. stores, production, packing, QC areas.	Totally dedicated AHU for each operation.	Separate AHU for critical area.	All manufacturing and ancillary areas is under same AHU	No AHU is provided in the manufacturing areas or where raw materials and/or products are exposed.
1.7	Sch-M,	Specify drainage system which prevents back flow and entry of insects and rodents into the premises. Specify number and location of drains installed.	GMP drains with cleaning records and SOP in place. Drawing is also available specifying the number and location of drains.	GMP drains with cleaning records and SOP in place.	No GMP drain in the critical areas	There are open drain(s) in the critical areas where the products are exposed.
2 Ancillary areas: -						
2.1	Sch-M,	Specify the position of rest and refreshment rooms and mention whether they are separated and not leading directly to the manufacturing and warehouse areas.	NA	Separate and outside the manufacturing area	Inside the manufacturing area	NA
2.2	Sch-M,	Are there general change rooms in plant? specify number of washing station & toilets provided for number of users.	NA	Separate and outside the manufacturing area Separate for male and female	Inside the manufacturing area	NA
2.3	Sch-M,	Specify whether primary clean garments are provided for each personnel entering the factory premises.	Clean Garments are provided to all employees as well as visitors with proper Identification	Factory Garments are provided to employees only	No Clean Garments are provided as primary gowning	NA
2.4	Sch-M,	Is there in-house general laundry for garment washing / cleaning? If not how garment washing is carried out and monitored.	In House Laundry facility is in place with proper SOP, monitoring and audit facility	In House / out source Laundry facility specific for pharmaceuticals garments is in place	No proper Cleaning facility (use of common washer man)	NA
2.5	Sch-M, Para	Whether change room facilities separated for both sexes.	NA	Change room facilities was found separated for both sexes.	Change room facilities was found not separated for both sexes.	NA
2.6	Sch-M, Para	Whether maintenance workshop is separated and away from production.	NA	Maintenance workshop is separated and far away from production	Maintenance workshop is separated but adjacent to the production area	NA
3 Security system:-						
3.1	WHO TRS	Is the men & material movement inside the factory premises, observed & checked through security system.	Written security policy was found maintained with SOP.	NA	NA	NA
3.2	WHO TRS	Is CCTV available to control the Entry & Exit from Factory premises?	CCTV is available to control the Entry & Exit from Factory premises and is regularly monitored	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
3.3	WHO TRS	Is there a system for identifying persons visiting the factory ? How?	Persons are identified through to photo and Biometrics	NA	NA	NA
3.4	WHO TRS	What is the precautionary activity taken for the movement of carriers i.e. vehicles?	Movement of carriers inside the plant is guided and controlled by the security persons	NA	NA	NA
4 Water & Compressed air system: -						
4.1	Sch-M, Para	Verify whether a current drawing of the water system showing all equipment in the system from inlet to the points of use is available.	Schematic drawing of water system was found in the PW generation area showing all the equipment and location of various sampling and users' points.	Schematic drawing of water system was found in the PW generation area but not showing location of various sampling and users' points.	No schematic drawing of water system was found in place	NA
4.1.1	Sch-M, Para	Specify the MOC of the water storage tank (Both PW & WFI) and its pipe line.	MOC of the holding vessels & circulation pipelines of purified water was found of SS316L with certification	MOC of the holding vessels & circulation pipelines of purified water was found of SS316 with certification	MOC of the holding vessels & circulation pipelines of purified water was found of SS316	NA
4.1.2	Sch-M, Para	Specify weather storage tank for WFI is steam jacketed.	NA	WFI storage tank was found steam jacketed.	WFI storage tank was found without steam jacketed.	NA
4.2	Sch-M, Para	Specify whether water system validation/qualification has been carried out as per protocol and reports have been prepared and maintained.	NA	Water system qualification (IQ, OQ & PQ) was found carried out and records maintained.	Water system qualification (IQ, OQ & PQ) was not found carried out.	1) Purified water system is ill maintained and data in respect of its quality is falsified. 2) WFI system and pure steam system of parenteral unit are ill maintained and data in respect of their quality is falsified.
4.3	WHO TRS-970	Whether IQ protocol include at least facility review, equipment specification vs. design, welding roughness testing on pipelines, absence of dead points / section in the pipelines, pipe and tank passivation, drawings, SOP for operations, cleaning, sanitation, maintenance and calibration of gadgets. Whether its report includes Conclusion / Summary, Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.	All the details were found in the IQ protocol and records found maintained	NA	NA	NA
4.4	WHO TRS-970	Whether OQ protocol includes at least System production capacity (L/min), Flow type and water rate, Valve operation, Alarm system operation and Controls operation? Whether its report includes Conclusion / Summary, operations performed Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.	All the details were found in the OQ protocol and records found maintained	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
4.5	WHO TRS-970	Please specify whether Phase 1, Phase 2 and Phase 3 studies carried as part of PQ stages?	Phase 1, Phase 2 and Phase 3 studies were found carried out as part of PQ stages	NA	NA	NA
4.6	WHO TRS-970	Phase 1: Whether the operations parameters, cleaning and sanitation procedures & frequencies defined. Whether daily sampling records for every pre-treatment point and usage point for a period of 2 to 4 weeks maintained and SOP's prepared.	Operations parameters, cleaning & sanitation procedures and frequencies was found defined. Daily sampling records for every pre-treatment point and usage point for a period of 2 to 4 weeks maintained and SOP's prepared.	NA	NA	NA
4.7	WHO TRS-970	PHASE 2: Whether daily sampling records for every pre-treatment point and usage point for a period of 4 to 5 weeks after Phase 1 maintained and reviewed.	Daily sampling records for every pre-treatment point and usage point for a period of 4 to 5 weeks after Phase 1 was found maintained and reviewed.	NA	NA	NA
4.8	WHO TRS-970	PHASE 3: Whether weekly sampling records available of every usage point for a one-year period.	Weekly sampling records of every usage point for a one-year period was available.	NA	NA	NA
4.9	Sch-M	Specify source of raw water and give details of treatment processes, sampling points, distribution and storage system for raw and purified water. Verify whether the Raw Water holding tank was sanitised as per specified SOP.	Following treatment processes are in the water purification system for PW: —Raw water storage —Sodium hypochlorite dosing —Multimedia filtration —Softener (2 nos, one for standby) —Soft water storage tank —cartridge filter 150 micron —SMBS dosing, —ADH dosing (for anti scaling), —Auto pH correction (using NAOH), —Double pass RO —EDI —Ultra Filtration — PW storage tank with vent filter Provisions for—cartridge filter 5 micron, UV disinfection was found placed in the circulation loop.	Following treatment processes are in the water purification system for PW: —Raw water storage —Sodium hypochlorite dosing —Multimedia filtration —Softener —Soft water storage tank —cartridge filter 150 micron —SMBS dosing, —ADH dosing (for anti scaling), —Auto pH correction (using NAOH), Mixed Bed — PW storage tank	Following treatment processes are in the water purification system for PW: —Raw water storage —Sodium hypochlorite dosing — Sand and Charcoal filter —Softener —Ion exchange treatment — PW storage tank	Potable water was found outsourced without any records/validation regarding any further treatment and/or analysis before use.
4.10	Sch-M	Verify whether the softener column is regenerated as per the specified SOP.	NA	Column generation as per written criteria	Column generation without any written criteria	NA

			Quality Rating			
S.No	Reference		2	1	0	X
4.11	Sch-M	Specify whether the quality of potable water used for the preparation of purified water meets the requirement of Schedule M in respect of microbiological limit.	The quality of water was found assessed for seasonal variation for microbiological limit and records found maintained and complies with the requirement of schedule M	The quality of water was found complies with the requirement of schedule M for microbiological limit and records found maintained.	No records were available	NA
4.12	Sch-M	Specify whether the quality of Purified Water used for the preparation of WFI meets the requirement of IP/BP/USP.	NA	Quality of Purified Water used for the preparation of WFI was found comply with the requirement of IP/BP/USP.	No records were available	NA
4.13	Sch-M	What is the process for preparation of Water for Injection (WFI)?	Purified water is fed in to multicolumn distillation plant fitted with on line TOC analyser and conductivity meter with PLC control. The WFI so obtained is stored in steam jacketed SS316L vessel with constant circulation loop at elevated temperature.	Purified water is fed in to multicolumn distillation plant and the WFI so obtained is stored in steam jacketed SS316 vessel.	Purified water is fed in to multicolumn distillation plant and the WFI so obtained is stored in SS316 vessel.	NA
4.14	Sch-M	Specify the process of sanitisation of SS storage tank of WFI.	NA	Raw Water holding tank was found cleaned by passing pure steam for 1/2 hour as per SOP	No SOP was found in this regard	NA
4.15	Sch-M	Specify whether the quality of WFI meets the requirement of IP/BP/USP & Schedule M.	NA	Quality of WFI meets the requirement of IP/BP/USP & Schedule M and records found maintained	No records were available	NA
4.16	Sch-M	Specify whether WFI is used for: 1) Bulk preparations of liquid injections 2) Final rinse of product containers for sterile preparations. 3) Final rinse of machine parts (for sterile preparations) 4) Preparation of disinfectant solutions for use in critical areas (for sterile preparations.)	NA	It was observed that WFI is used for: 1) Bulk preparations of liquid injections 2) Final rinse of product containers for sterile preparations. 3) Final rinse of machine parts (for sterile preparations) 4) Preparation of disinfectant solutions for use in critical areas (for sterile preparations.)	It was observed that WFI is used for only Bulk preparations of liquid injections	NA
4.17	Sch-M	How bio burden in purified water & WFI are controlled / reduced (Mention the SOP no. followed in this regard).	Bio Burden in purified water was found controlled by passing through UV radiation in addition maintaining recirculation through loop system	Bio Burden in purified water was found controlled by passing through UV radiation.	No control regarding Bio Burden in purified water was found.	NA
4.17.1	Sch-M	Specify whether WFI has been stored and circulated above 70 degree centigrade.	NA	It was observed that WFI is stored and circulated above 70 degree centigrade.	It was observed that WFI is not stored and circulated above 70 degree centigrade.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
4.18	WHO TRS-970	Verify whether the circulation rate of purified water & WFI is at least twice the storage capacity of the holding vessels per hour.	Circulation rate of purified water & WFI was found more then twice the storage capacity of the holding vessels per hour and the pump capacity is commensurate with the circulation rate	NA	NA	NA
4.19	WHO TRS-970	Verify the Dead leg of non returned valve at the discharge point.	Less than 3D	NA	NA	NA
4.20	WHO TRS-970	Specify how the circulation loop is sanitised. Verify the SOP.	Circulation loop is sanitised by passing pure steam for 15 to 30 minutes.	NA	NA	NA
4.21	WHO TRS-970	Specify whether spray ball is used to wet the surface of head space in the storage vessel.	Spray ball is used to wet the surface of head space in the storage vessel.	NA	NA	NA
4.22	WHO TRS-970	Specify whether pressure release valves are provided in the storage vessel.	pressure release valves are provided in the storage vessel.	NA	NA	NA
4.23	Sch-M	How water tanks are cleaned periodically and records maintained thereof.	NA	Water tanks were found cleaned periodically and records found maintained thereof.	No records were available	NA
4.24	WHO TRS-970	Specify whether on line TOC test is available for WFI & PW.	On line TOC analyser is available for WFI and PW	NA	NA	NA
4.25	PIC/S Guidelines	Specify whether replacement of Air Vent filters on the purified/WFI water tank is carried out as per relevant SOP. Whether the provision to keep dry the vent filter is made.	Replacement of Air Vent filters on the purified water/WFI tank was found carried out as per relevant SOP.	NA	NA	NA
4.26	Sch-M	Specify the arrangement for preparation of pure steam & its use.	NA	PSG was found provided for preparation of pure steam	PSG was found not provided for preparation of pure steam	NA
4.27	Sch-M	Specify whether pure steam (condensate) used in production meets the microbiological specification of not more than 10 cfu/100ml and IP/BP/USP specifications of WFI.	NA	Pure steam (condensate) used in production meets the microbiological specification of not more than 10 cfu/100ml and IP/BP/USP specifications of WFI.	No records were available	NA
4.28	WHO TRS-970	Verify PQ of the PSG.	PQ of PSG was found carried out and records found maintained	NA	NA	NA
4.29	Sch-M	Specify the system in place for the compressed gases / air used in the facility.	NA	Compressed air generation system was found in place with arrangement of filtration before use in coating operation and drying.	Compressed air is not filtered before use in coating operation and drying.	Unfiltered gases used during filling of injectable or eye preparations
4.30	ISO/PICS	Verify the qualification documents of compressed air system specially where it comes in contact with product or primary container.	Qualification documents of compressed air system specially where it comes in contact with product or primary container was verified and founds satisfactory	NA	NA	NA

			Quality Rating			
S.No	Reference		2	1	0	X
4.31	WHO TRS-970	Specify whether action and alert limits are followed based on qualification of water and compressed Air system.	Action and alert limits are found followed based on qualification of water and compressed Air system.	NA	NA	NA
5 Disposal of waste(Ambient protection):-						
5.1	Sch-M	Specify the system of disposal of sewage, and effluents (solid, liquid, and gas) from the manufacturing site.(Enclosed the copy of NOC obtained from State Pollution control board in this regard.)	Centralized dust extraction system along with AHU for air, Scrubber system for gases / air, ETP for effluents along with NOC from State Pollution Control Board.	AHU with localized dust extraction system and ETP along with NOC from State Pollution Control Board.	No such system was found in place.	NA
5.2	Sch-M	Mention the procedure for storage and disposal of rejected drugs and applicable SOP.	NA	Segregated lock and key storage and disposal in compliance to written norms	No such SOP was found in place although segregated area is provided	NA
5.3	Sch-M	Whether adequate records are maintained for the disposal of waste.	NA	Records maintained for the disposal of waste was found adequate.	No record could be produced in this regard.	NA
5.4	Sch-M	Whether provision for disposal of bio-medical waste made as per the provisions of the Bio Medical Waste (Management and Handling) Rules 1996.	NA	It was observed that provision for disposal of bio-medical waste made as per the provisions of the Bio Medical Waste (Management and Handling) Rules 1996.	No such provision was found in place.	NA
6 Health, clothing and sanitation of workers: -						
6.1	Sch-M	Whether all personnel prior to employment have undergone medical examination including eye examination and are all free from Tuberculosis, skin and other communicable or contagious diseases & thereafter at regular intervals.	NA	Medical examination of all personal was found carried out prior to employment and all records found maintained	No records were available	NA
6.2	Sch-M	Whether investigational reports, e.g. of X rays etc. preserved. Whether records of such medical examination are maintained thereof	NA	Records regarding all investigational reports are found maintained	No records were available	NA
6.3	Sch-M	Specify whether employees report their illness to the supervising authority before entering into the production area.	NA	It was observed that employees report their illness to the supervising authority before entering into the production area.	No such system was found in place	NA
6.4	Sch-M	Specify whether person from infectious disease is barred to enter into production area.	NA	It was observed that person from infectious disease is barred to enter into production area.	No such system was found in place	NA
6.5	Sch-M	Specify if any unhygienic practise is observed within the manufacturing areas.	NA	No unhygienic practise is observed within the manufacturing areas during inspection	Unhygienic practise is observed in a manufacturing area during inspection	NA
6.6	Sch-M	Whether all personnel are trained to ensure high level of personal hygiene. Mention the SOP no. followed in this regard.	NA	All personnel were found trained to ensure high level of personal hygiene and respective SOP is followed	Neither any training record nor any SOP was found in place.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
6.7	Sch-M	Specify whether cross over bench is in place in the change room and if so whether it rules out the possibility of dust particle entering the clean side.	NA	Cross over bench was found in place in the change room and it rules out the possibility of dust particle entering the clean side.	Although cross over bench was found in place in the change room but can not prevent dust particle entering the clean side	NA
6.8	Sch-M	Whether arrangements provided for cleaning of outside dust and dirt from foot.	NA	Arrangement was found provided for cleaning of outside dust and dirt from foot.	No such arrangement was found provided	NA
7 Training:-						
7.1	Sch-M	Specify whether basic training on GMP is provided to all personnel attached to production and quality control activity at the time of induction.	NA	Basic training on GMP was found provided to all personnel attached to production and quality control activity at the time of induction and records found maintained	No such record could be produced during inspection	NA
7.2	Sch-M	Specify whether specific training related to the job duty are provided to all personnel at the time of induction.	Training need are identified all personnel and training calendar is in place. The training imparted is assessed for its effectiveness.	Specific training related to the job duty was found provided to all personnel at the time of induction and records found maintained	No such record could be produced during inspection	NA
7.3	WHO TRS-986	Specify whether continuous training is provided.	It was observed that whenever there is a change in SOP, complete training was found provided to the concerned person before implementing the new SOP	NA	NA	NA
7.4	WHO TRS-986	Specify whether concept of QA and its importance is part of training session.	Concept of QA and its importance was found a part of training session.	NA	NA	NA
7.5	WHO TRS-986	Are all the persons associated with various production activities properly trained as per guidelines provided in WHO working document. Verify the assessment records of the training of few selected people who are associated with critical operations and procedure	Yes all the persons associated with various production activities properly trained as per guidelines provided in WHO working document. The training records of some of the persons working in critical areas/operation were Verified	NA	NA	NA
8 Warehousing Area:-						
8.1	WHO TRS-986	Is access to the area restricted to authorised personnel only.	Biometric system for access in place	NA	NA	NA
8.2	Sch-M	Whether adequate areas have been allocated for warehousing of Raw Materials, intermediates, Packaging Material, products in quarantine, finish products, rejected or returned products. How are these areas marked or segregated. Please specify the total area provided for warehousing.	NA	It was observed that adequate areas with respect to stock volume have been allocated for warehousing of Raw Materials, intermediates, Packaging Material, products in quarantine, finish products, rejected or returned products. These areas were found properly marked and segregated.	Due to inadequacy of the storage area materials was found stored in manufacturing and other ancillary area not meant for the storage.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
8.3	Sch-M	How the warehousing areas being maintained to have good storage conditions. Are they clean and dry and maintained within specified temperature limits?	NA	The warehousing areas are maintained to have good storage conditions. The cleaning schedule and records are found maintained. The humidity and temperature are as per the storage requirements and there records are maintained.	The storage area is clean and having required temperature for storage however records are not in placed.	Storage condition was found unhygienic with accumulation of dust, dirt, pest manifestation, fungal growth, water stagnation and materials dumped without any identification labels.
8.4	WHO TRS-986	Is there any SOP defining maximum exposure time at room temperature for thermo labile materials i.e. prior to storage in a refrigerator.	maximum exposure time at room temperature for thermo labile materials was found followed as per the written document	NA	NA	NA
8.5	Sch-M	Specify the storage arrangement provided for materials which are sensitive to temperature, humidity and light and how the parameters are monitored. Is cold room or deep freezers required for storage of goods?	NA	It was observed that all sensitive materials are stored in cold room or deep freezers and monitored at regular interval and records maintained	No such arrangement was found provided	NA
8.6	WHO TRS-986	Verify the Thermal mapping of the cold rooms or deep freezers	Thermal mapping of the cold rooms and deep freezers were verified and found that probes for monitoring are placed at all strategic points including hotspots	NA	NA	NA
8.7	Sch-M	Whether receiving and dispatch bays are maintained to protect in coming and out going materials.	NA	Receiving and dispatch bays were found covered.	Receiving and dispatch bays were found not covered.	NA
8.8	Sch-M	How incoming materials are treated and cleaned before entry into the plant. Please specify the cleaning system for the outer surface of the container.	Tunnel was found provided to clean the outer surface of the container of incoming materials.	Vacuum cleaner was found used to clean the outer surface of the container of incoming materials.	No such arrangement was found provided	NA
8.9	Sch-M	How quarantined materials are segregated from other materials. How access to quarantined area is restricted.	Location of the materials is guided through SAP or ERP System with records. The access to quarantined area is allowed to identified person by access cards.	Quarantined materials are kept in the separate rooms before sampling and then shifted to the room for under test materials and access to these areas are controlled.	The quarantined material is segregated by labelling only and there is no control on access to these areas	NA
8.10	Sch-M	Specify the system followed for storing passed raw materials.	NA	All containers of passed raw materials are properly labelled and identified.	The passed raw material are stored batch wise but not identified.	NA
8.11	Sch-M	Whether proper racks, bins and platforms have been provided for the storage.	NA	Proper racks, bins and platforms was found provided for the storage.	Proper racks, bins and platforms was not found provided for the storage.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
8.12	WHO TRS-986	What is the control on entry of material and men into the sampling area? Whether reverse LAF have been provided for sampling. Whether log book for sampling booth maintained.	The sampling area has access control with PAL and MAL arrangements. Reverse LAF has been provided for sampling and log book of sampling booth is maintained.	NA	NA	NA
8.13	Sch-M	Specify the storage arrangement provided for primary packaging materials.	NA	Proper racks and bin were found provided with temperature and humidity control.	Primary packaging materials are found stored with other secondary packaging material or with raw materials.	NA
8.14	Sch-M	Specify the arrangements provided to sample the primary packaging materials foils, bottles, etc. which are used as such.	NA	Primary packaging Materials are sampled under LAF in a specified area	No specific arrangement was found provided	NA
8.15	WHO TRS-986	Specify sampling plan used.	100 % sampling for identification of API & Excipients and complete analysis following sampling procedure prescribed in WHO TRS 929. Well defined SOP in this regard was found in place and followed meticulously.	100 % sampling for API but $\sqrt{n} + 1$ for excipients	No sampling plan is used	NA
8.16	WHO TRS-986	Which type of sampling tools are used and how they are cleaned, dried and maintained.	Scoops, Spears, Dip tubes, Thieves etc. made of SS-316 as prescribed in WHO TRS 929 are used. Used sampling tools are cleaned in a separate washing area following the specified SOP	NA	NA	NA
8.17	WHO TRS-986	How containers are cleaned before and after sampling. (Specify whether the sampling is carried out as per the current SOP).	Outer surface of each container was found mopped before and after sampling following the specified SOP in this regard	NA	NA	NA
8.18	Sch-M	What provisions have been made for segregated storage of rejected, recalled or returned materials or products. How is the access to these areas restricted?	NA	It was observed that restricted & segregated area is provided for rejected material. The Area was found controlled with authorised access.	No segregated area is provided	NA
8.19	Sch-M	How printed secondary packaging materials are stored in safe, separate and in secure manner.	NA	Separate area is provided for secondary packaging materials with authorised access	No separate area was found provided	NA
8.20	Sch-M	How printed packaging materials, product leaflets etc. are stored separately to avoid chances of mix-up?	NA	Printed packaging materials, product leaflets etc. are stored separately in almirahs under lock to avoid chances of mix-up	Storage arrangement can rule out the possibility the chances of mix-up.	NA
8.21	Sch-M	How labels, cartons, boxes, circulars, inserts and leaflets are controlled. ?	NA	Proper stock register is maintained along with issue records following specified SOP	No SOP was found in this regard	NA

			Quality Rating			
S.No	Reference		2	1	0	X
8.22	Sch-M	How records of receipt of all labelling and packaging materials are maintained.	NA	Proper stock register is maintained along with issue records following specified SOP	Neither any SOP nor any stock register was found	NA
8.23	Sch-M	Whether unused packaging materials return to the store or destroyed.	NA	Unused labels and cartons with batch no printed is destroyed and without batch no is returned to the store after proper reconciliation.	No records were available	NA
8.24	Sch-M	How returned/unused packaging material like foils is controlled so as to prevent contamination and cross- contamination.	NA	Unused primary packaging materials like Aluminium Foils etc. are properly packed, sealed, labelled and kept in a separate intermediate store in secured condition.	Returned to the store without proper packing and sealing	NA
8.25	Sch-M	Specify the arrangement provided for dispensing of starting materials.	NA	Reverse LAF has been provided for dispensing and log book of dispensing booth is maintained.	Dispensing is carried out in the storage area without any control	NA
8.26	WHO TRS-986	What is the control on entry of material and men into the dispensing area? Whether reverse LAF have been provided for dispensing with back ground clean air supply.	The dispensing area has access control with PAL and MAL arrangements and reverse phase LAF provided in a class C background	NA	NA	NA
8.27	WHO TRS-986	Whether pressure differential is maintained between the dispensing and adjacent areas.	The dispensing area is observed under negative pressure of 15 pa in comparison with the adjacent PAL & MAL	NA	NA	NA
8.28	WHO TRS-986	Specify the pressure differential maintained.	10-15 pa pressure differential was found maintained.	NA	NA	NA
8.29	Sch-M	Examine the record of the daily check of balances in the dispensing area.	NA	It was observed that balances in the dispensing area are checked daily and records are maintained.	NA	NA
8.30	WHO TRS-986	How containers are cleaned before and after dispensing. Who carries out the dispensing?	Outer surface of each container was found mopped before and after dispensing following the specified SOP in this regard. Designated qualified person is carry out the dispensing operation.	NA	NA	NA
8.31	WHO TRS-986	Specify whether appropriate air velocity is maintained in sampling & dispensing areas which rule out any influence in the balance readings placed inside the RLAFs Benches.	Appropriate air velocity was found maintained in sampling & dispensing areas which rule out any influence in the balance readings placed inside the RLAFs Benches.	NA	NA	NA
8.32	Sch-M	Specify whether the dispensing is carried out as per the current SOP.	NA	Dispensing was found carried out as per the current SOP.	No SOP was found in this regard	NA

S.No	Reference		Quality Rating			
			2	1	0	X
8.33	Sch-M	Specify whether dispensed material for each batch of final product are kept together and conspicuously labelled.	NA	Dispensed material for each batch of final product was found kept together and conspicuously labelled.	Dispensed material for each batch was found not conspicuously labelled.	NA
8.34	Sch-M	What steps are taken against spillage, breakage and leakage of containers?	NA	SOP was found in place for handling of spillage, breakage and leakage of containers in the warehouse area.	No SOP was found in this regard	NA
8.35	Sch-M	How highly hazardous, poisonous and explosive materials, narcotics, and psychotropic drugs are handled and stored. How these areas are safe and secure.	NA	In segregated area with all safety features	No segregated area was found provided	NA
9 Raw Materials: -						
9.1	Sch-M	Please specify the procedures followed for receiving and processing of in-coming materials (Starting materials and packing material). Verify the SOP.	NA	SOP was found in place for receiving and processing of in-coming materials (Starting materials and packing material)	No SOP was found in this regard	NA
9.2	Sch-M	Whether first in / first out or first expiry principal has been adopted.	NA	First in first out (FIFO) / first expiry (FIFE) principal was found adopted.	No such system was found in place	NA
9.3	Sch-M	How they are labelled and stored as per their status – Under Test, Approved and Rejected	NA	Under Test, Approved and Rejected materials are labelled as per specified SOP .	No such SOP was found in place	NA
9.4	Sch-M	Whether incoming materials are purchased from approved vendors.	NA	Incoming materials were found purchased from approved vendors.	Incoming materials are not always purchased from approved vendors.	NA
9.5	Sch-M	Whether list of approved vendors is available to the user.	NA	Approved vendors' list is available in the receiving area	Approved vendors' list is not available in the receiving area	NA
9.6	WHO TRS-986	Specify the norms of vendor qualification.	A questionnaire is sent to the vendor, after getting satisfactory response against questionnaire, the vendor for API is audited given approval if all the parameters found complied. SOP for vendor selection criteria was found followed.	NA	NA	NA
9.7	Sch-M	How damaged containers are identified recorded and segregated	NA	SOP for identification and segregation of damaged containers for starting materials was found in place .	No SOP for identification and segregation of damaged containers for starting materials was found in place .	NA
9.8	Sch-M	Whether each batch of a consignment is considered for sampling, testing and release.	NA	It was observed that each batch of a consignment is considered for sampling, testing and release.	No such system was found followed	NA
9.9	WHO TRS-986	Whether all the containers of each batch of starting materials sampled for identification test.	It was observed that identity test is carried out by FTNIR for each container and pooled sample for other tests.	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
9.10	Sch-M	Whether labels of raw material in the storage area have information like ; (a) designated name of the product and the internal code reference, where applicable, and analytical reference number; (b) manufacturer's name, address and batch number; (c) the status of the contents (e.g. quarantine, under test,released,approved, rejected); and (d) The manufacturing date, expiry date and re-test date.	NA	All relevant information was found available on the labels.	All relevant information was found not available on the labels.	NA
9.11	Sch-M	Whether separate areas are provided for under test, approved and rejected materials.	NA	separate and segregated areas was found provided for under test, approved and rejected materials.	No such segregation was found in place	NA
9.12	Sch-M	How the containers from which samples have been drawn labelled.	NA	Containers from which samples was drawn found labelled as per specified SOP.	No such system was found in place	NA
9.13	Sch-M	Please specify the procedures by which it is ensured that the raw materials which has been released by the Quality Control Department and which are within their shelf life are going to be used in the product.	Electronically controlled system	Bin card system	No specific system was found followed	NA
10 Production Area for Non Sterile preparation:-						
10.1	WHO TRS-986	Verify whether access to production area is restricted to authorised personnel only.	Access control was found in place to enter production area. List of authorised personnel was found in place in place..	NA	NA	NA
10.2	WHO TRS-986	Whether the facility is provided with a well-sealed structure with no air leakage through ceilings, cracks or service penetrations.	The facility was found provided with a well-sealed structure with no air leakage through ceilings, cracks or service penetrations.	NA	NA	NA
10.3	WHO TRS-986	Whether entry and exit doors, for materials and personnel, have an interlock mechanism or other appropriate system to prevent the opening of more than one door at a time.	It was observed that entry and exit doors for all PAL & MAL have interlock arrangement.	NA	NA	NA
10.4	WHO TRS-986	Specify the procedures for entry of maintenance people into the production area.	Specific SOP was found prepared and followed for entry of maintenance people into the production area.	NA	NA	NA
10.5	WHO TRS-986	Whether the change rooms have an arrangement with step-over/cross-over bench.	Step-over/cross-over bench was found provided in all the change room.	NA	NA	NA
10.6	Sch-M	Is there any cris cross flow of materials and men?	NA	NO cris cross flow of materials and men was observed within the manufacturing areas during inspection	Cris cross flow of materials and men was observed within the manufacturing areas during inspection	NA

S.No	Reference		Quality Rating 2	1	0	X
10.7	Sch-M	Whether the premises and equipment are appropriately designed and installed to facilitate cleaning and decontamination.	NA	The premises and equipment are appropriately designed and installed to facilitate cleaning and decontamination.	Design of the premises and installation of equipment do not facilitate cleaning and decontamination.	NA
10.8	WHO TRS-986	Specify the position of IPQC lab in the manufacturing area.	IPQC lab was found in a separate enclosed cubical in the manufacturing area.	NA	NA	NA
10.9	Sch-M	Specify whether non storage areas are used for storage of any material.	NA	No such observation was found	Yes materials was found stored in non storage areas.	NA
10.10	WHO TRS-986	Specify the provisions for storage of dirty, washed and cleaned equipment in process areas.	SOP was found in place which prescribes provisions of storage of dirty, washed and cleaned equipment in process areas.	NA	NA	NA
10.11	Sch-M	Specify how service lines are identified for nature of supply and direction of the flow.	NA	Fixed Pipe work was found labelled with colour code to indicate the contents & direction of flow.	service lines are not identified for nature of supply and direction of the flow.	NA
10.12	WHO TRS-986	Whether service lines in production areas are through service pendants. If not, how they are placed so as to avoid accumulation of dust.	It was observed that Service lines (purified water, compressed air and electrical wires) are concealed in a service pendant..	NA	NA	NA
11 Air Handling Systems (HVAC):-						
11.1	WHO TRS-986	Please specify whether following parameters are qualified: (IQ,OQ,PQ) — temperature — relative humidity — supply air quantities for all diffusers — return air or exhaust air quantities — room air change rates — room pressures (pressure differentials) — room airflow patterns — unidirectional flow velocities —filter penetration tests (HEPA) — room particle counts — room clean-up rates — microbiological air and surface counts where appropriate — operation of de-dusting — warning/alarm systems	Following parameters were found qualified and documents are maintained (IQ,OQ,PQ) — temperature — relative humidity — supply air quantities for all diffusers — return air or exhaust air quantities — room air change rates — room pressures (pressure differentials) — room airflow patterns — unidirectional flow velocities —filter penetration tests (HEPA) — room particle counts — room clean-up rates — microbiological air and surface counts where appropriate — operation of de-dusting — warning/alarm systems	NA	NA	NA
11.2	WHO TRS-986	Verify the SOPs for AHUs operation and cleaning.	SOPs for AHUs operation and cleaning was verified and found satisfactory.	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
11.3	WHO TRS-986	Specify whether the facilities and premises have following basic air-handling characteristics: a) The absence of direct venting of air to the outside. b) Whether the facility is maintained at a negative air pressure to the environment. c) The precaution taken to prevent the infiltration into the core areas. d) Whether appropriate air pressure alarm systems as well as alert and action limit is provided. e) The type of HEPA filters used in the HVAC system f) Whether the change rooms are supplied with same quality of air as supplied to the working area. g) The measures taken to prevent air flow from the primary packing area to the secondary packing area.	Following basic air-handling characteristics were found in the system of the facilities. a) The absence of direct venting of air to the outside. b) Whether the facility is maintained at a negative air pressure to the environment. c) The precaution taken to prevent the infiltration into the core areas. d) Whether appropriate air pressure alarm systems as well as alert and action limit is provided. e) The type of HEPA filters used in the HVAC system f) Whether the change rooms are supplied with same quality of air as supplied to the working area. g) The measures taken to prevent air flow from the primary packing area to the secondary packing	NA	NA	NA
11.4	WHO TRS-986	Whether HVAC system description includes: 1) Schematic drawings detailing the filters and their specifications 2) Number of air changes per hour 3) pressure gradients	It was observed that the HVAC system includes following description: 1) Schematic drawings detailing the filters and their specifications 2) Number of air changes per hour	NA	NA	NA
11.5	WHO TRS-986	Specify the emergency power systems in case of power failure.	Standby Generator with UPS	NA	NA	NA
11.6	WHO TRS-986	Specify whether recirculated air is used. If yes, specify the proportion of fresh air supplied.	10-12 % of ambient air is used	NA	NA	NA
11.7	WHO TRS-986	Whether risk assessment study has been carried out in case of return air/ recirculated air system. Verify the records thereof.	It was observed that risk assessment was carried out in this regard and records found maintained.	NA	NA	NA
11.8	WHO TRS-986	Specify what precaution has been taken during filter change of AHUs.	Filters are taken in polythene bags and sealed before taking into cleaning area. Dedicated filter cleaning area was found provided. Bag-in-bag-out system is also followed.	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
11.9	WHO TRS-986	Whether all exhaust systems from the facility, including dust extraction systems, vacuum system exhaust, fluid bed drier exhaust, coating pan exhaust, etc., are passed through safe change filter housings and wet scrubber before being exhausted to the atmosphere.	All exhaust systems from the facility, including dust extraction systems, vacuum system exhaust, fluid bed drier exhaust, coating pan exhaust, etc., was found passed through safe change filter housings and wet scrubber before being exhausted to the atmosphere.	NA	NA	NA
11.10	WHO TRS-986	Whether all exhaust points outside the building are located as far as possible from air entry points, exit points and at a high level, to minimize the possibility of re-entrainment of exhaust air.	All exhaust points outside the building are located at distance and at a high level from air entry points of air to minimize the possibility of re-contaminant of incoming air.	NA	NA	NA
11.11	WHO TRS-986	Whether the return air ducts are checked periodically for dust accumulation.	Duct Cleaning system was found in place	NA	NA	NA
11.11	Sch-M	Whether the dust collectors are located in a room maintained at a negative pressure.	NA	Dust collectors were found located in a room maintained at a negative pressure.	No such system was found in place.	NA
11.12	WHO TRS-986	Whether the filters cleaning facility is maintained at negative pressure.	Filters cleaning facility was found maintained at negative pressure.	NA	NA	NA
11.13	WHO TRS-986	Whether records for safe disposal of all contaminated filters and dust are maintained.	Records for safe disposal of all contaminated filters and dust was found maintained.	NA	NA	NA
11.15	WHO TRS-986	Specify whether total No. of AHUs used to cover the whole production Area is commensurate with the requirements	Total No of AHUs used to cover the whole production Area is commensurate with the requirements.	NA	NA	NA
11.16	WHO TRS-986	Specify the Terminal Air Filter of various core areas.	HEPA	NA	NA	NA
11.17	WHO TRS-986	Specify the no. of Air Change maintained in various core areas.	NLT 20 ACPH	NA	NA	NA
11.18	WHO TRS-986	Specify the pressure balancing to segregate different areas.	Difference of 15 pa was found maintained as pressure balancing to segregate different areas.	NA	NA	NA
11.19	WHO TRS-986	Are the returns risers cleaned during Product Change Over?	Returns risers were found cleaned during Product Change Over as per the prescribed SOP	NA	NA	NA
11.20	WHO TRS-986	Verify if the AHU's / HVAC systems have been shut down. If yes the reasons there of such as cleaning & maintenance & the procedures for re-initiation / re-start of the systems	Whenever there is shut down of AHUs for preventive maintenance or break down, requalification was found carried out before carrying out normal production.	NA	NA	NA
12 Cleaning Validation:-						

			Quality Rating			
S.No	Reference		2	1	0	X
12.1	Sch-M	Is a validation performed to confirm cleaning effectiveness?	NA	Validation was found performed to confirm cleaning effectiveness	Validation was found not performed to confirm cleaning effectiveness	NA
12.2	WHO TRS-986	Does the protocol define the selection criteria for products or groups of products subject to cleaning validation?	Protocol prepared in this regard was found established the selection criteria for products or groups of products subject to cleaning validation	NA	NA	NA
12.3	WHO TRS-986	Is data produced supporting the conclusion that residues were removed to an acceptable level?	Documents produced during inspection concluded that residues were removed to an acceptable level	NA	NA	NA
12.4	WHO TRS-986	Specify whether the validation is implemented to verify cleaning of: 1)Surfaces in contact with the product 2) After a change in product 3) Between shift batches.	Validation protocol was found mentioned descriptively to verify cleaning of 1)Surfaces in contact with the product 2) After a change in product 3) Between shift batches.	NA	NA	NA
12.5	WHO TRS-986	Specify whether the Validation Strategy include contamination risks & equipment storage time.	It was observed that validation strategy include contamination risks & equipment storage time.	NA	NA	NA
12.6	WHO TRS-986	Whether Quality Control responsible of the sampling for cleaning verification?	It was observed that QA/QC is responsible for sampling of cleaning verification	NA	NA	NA
12.7	WHO TRS-986	Whether personnel engaged in cleaning, sampling etc. trained.	The Personnel engaged in cleaning, sampling etc. was found adequately trained.	NA	NA	NA
12.8	WHO TRS-986	Specify whether acceptance limits been set for cleaning verification and are based on following criteria: 1) Visually clean. 2) 10 ppm in another product. 3) 0.1% of the therapeutic dose?	It was observed that following criteria has been set: 1) Visually clean criteria is followed for manufacturing of same product of different batch number 2) 10 ppm criteria is followed during product change over of similar dosage form 3) 0.1% of the therapeutic dose criteria is followed during product change over from smaller to larger dosage form	NA	NA	NA
12.9	WHO TRS-986	Specify whether detergent residues and degradation products are investigated during validation.	It was observed that detergent residues and degradation products are investigated during validation.	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
12.10	WHO TRS-986	Whether validation records include : Recovery study data, Analytical method, Acceptance Criteria, Swab recovery test, Signatures of the Quality Assurance Manager, Signature of the employee in charge of cleaning verification from Production and Quality Control.	It was observed that validation records contain Recovery study data, Analytical method, Acceptance Criteria, Swab recovery test, Signatures of the Quality Assurance Manager, Signature of the employee in charge of cleaning verification from Production and Quality Control.	NA	NA	NA
13 Manufacturing Operations and Controls:-						
13.1	Sch-M	Whether the contents of all vessels and containers used in manufacture and storage is conspicuously labelled with the name of the products. Batch no, Batch Size, and stage of manufacture along with signature of technical staff.	NA	It was observed that the contents of all vessels and containers used in manufacture and storage is conspicuously labelled with the name of the products. Batch no, Batch Size, and stage of manufacture along with signature of technical staff.	It was observed that the contents of all vessels and containers used in manufacture and storage is not conspicuously labelled with the name of the products. Batch no, Batch Size, and stage of manufacture along with signature of technical staff.	NA
13.2	Sch-M	Whether the products not prepared under aseptic conditions are free from pathogens like Salmonella, Escherichia coli, Pyocyanea etc.	NA	Products not prepared under aseptic conditions was found tested for absence of pathogens like Salmonella, Escherichia coli, Pyocyanea etc.	Products not prepared under aseptic conditions was found not tested for absence of pathogens like Salmonella, Escherichia coli, Pyocyanea etc.	NA
13.3	Sch-M	If yes, pls give brief account of measures taken to assure freedom from pathogens.	NA	MLT was found carried out	MLT was found not carried out	NA
13.4	WHO TRS-986	Verify whether handling of materials and products are carried out in accordance with the relevant SOP'S.	It was observed that handling of materials and products are carried out in accordance with the relevant SOP'S.	NA	NA	NA
13.5	WHO TRS-986	Specify Whether any deviation is approved in writing by a designated person and recorded.	It was observed that any deviation during any stage of manufacturing operation is approved in writing by a designated person and recorded.	NA	NA	NA
13.6	WHO TRS-986	Is there an approved SOP for In process check?	Approved SOP for In process check was found in place	NA	NA	NA
13.7	WHO TRS-986	Is the personnel clothing clean, unstained & dust free, including shoes?	It was observed that the garments including shoes used by the employees are clean, unstained & dust free,	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
13.8	WHO TRS-986	Is there a cleaning SOP for slippers or shoes that is being used in the manufacturing area?	Cleaning SOP for slippers or shoes that is being used in the manufacturing area was found in place	NA	NA	NA
13.9	WHO TRS-986	Whether process hold time studies has been carried out for various stages of production	Process hold time studies was found carried out for various stages of production	NA	NA	NA
13.10	Sch-M	Specify whether all critical activities of production and testing is carried out under the direct supervision of competent technical staff.	NA	All critical activities of production and testing was found carried out under the direct supervision of competent technical staff.	Some of the critical activities of production and testing was found carried out under the direct supervision of competent technical staff.	The critical activities of production and testing is carried out without direct supervision of competent technical staff.
14 Precautions against mix-up and cross-contaminations:-						
14.1	Sch-M	Whether proper AHU, pressure differential, segregation, status labelling have been provided to prevent mix-up and cross-contamination in manufacturing area	NA	AHU, pressure differential, segregation, status labelling were found provided to prevent mix-up and cross-contamination in manufacturing area	AHU, pressure differential, segregation, status labelling were found not provided to prevent mix-up and cross-contamination in manufacturing area	NA
14.2	Sch-M	Pls specify the areas of dust generation and mechanism involved in controlling the dust	NA	Dust collectors were found installed in granulation, coating, compression and powder filling area to control the dust generated during manufacturing.	Dust collectors were found not installed in granulation, coating, compression and powder filling area to control the dust generated during manufacturing.	NA
14.3	Sch-M	Do all the areas have their own independent air locks separately for men and material entry.	NA	Independent air locks separately for men and material entry was found provided in all areas.	Independent air locks separately for men and material entry was found not provided in all areas.	NA
14.4	Sch-M	What criteria of pressure differential has been set for production v/s adjoining areas.	NA	Criteria of pressure differential was found set for production v/s adjoining areas.	Criteria of pressure differential was found not set for production v/s adjoining areas.	NA
14.5	Sch-M	Whether processing of sensitive drugs like Beta lactam Antibiotics and Sex Hormones is done in segregated areas with independent AHU and proper pressure differentials along with demonstration of effective segregation of these areas with records.	NA	Processing of sensitive drugs like Beta lactam Antibiotics and Sex Hormones was found carried out in separate dedicated areas with independent AHU and proper pressure differentials along with demonstration of effective segregation of these areas with records.	Processing of sensitive drugs like Beta lactam Antibiotics and Sex Hormones was found carried out in segregated areas in the same facility with independent AHU and proper pressure differentials along with demonstration of effective segregation of these areas with records.	Processing of sensitive drugs like Beta lactam Antibiotics and Sex Hormones was found carried out in the same facility without independent AHU and proper pressure differentials

S.No	Reference		Quality Rating			
			2	1	0	X
14.6	Sch-M	Please specify what measures has been taken to prevent contamination of products with Beta Lactam Antibiotics, Sex hormones and cyto toxic substances.	NA	Beta Lactam Antibiotics, Sex hormones and cyto toxic substances were found manufactured in a separate dedicated facility with dedicated arrangements for raw materials store, sampling & dispensing operations.	Beta Lactam Antibiotics, Sex hormones and cyto toxic substances were found manufactured in a s dedicated area with common arrangements for raw materials store, sampling & dispensing operations.	Beta Lactam Antibiotics, Sex hormones and cyto-toxic substances were found manufactured in a same facility without any dedicated area with common arrangements for raw materials store, sampling & dispensing operations.
14.7	Sch-M	What measures has been taken to prevent mix-ups during various stages of production.	NA	Line clearance was found obtained before proceeding every stages of manufacturing operations.	Line clearance was found not obtained before proceeding every stages of manufacturing operations	NA
14.8	Sch-M	Whether equipments use for production are labelled with their current status.	NA	Equipment use for production were found labelled with their current status.	No status label was found affixed with the equipment use in manufacturing process	NA
14.9	Sch-M	Whether packaging lines are independent and adequately segregated.	NA	Packaging lines were found independent and adequately segregated.	Packaging lines were found neither independent nor adequately segregated	NA
14.10	Sch-M	How line clearance is performed. Whether records of line clearance is maintained according to appropriate checklist.	NA	Line clearance was found performed according to the prescribed SOP and records of line clearance was found maintained according to the appropriate checklist.	Records of line clearance could not produce during inspection	NA
14.11	Sch-M	Whether separate carton coding area has been provided or online carton coding is performed How carton coding procedure is controlled.	NA	Separate carton coding area / online carton coding was found provided.	Separate carton coding area was found not provided.	NA
14.12	Sch-M	Please specify how temperature, humidity and air filtration are controlled in the areas where raw material and/or products are exposed and handled	NA	Temperature, humidity and air filtration are controlled through AHU in the areas where raw material and/or products are exposed and handled	Temperature, humidity and air filtration are not controlled through AHU in the areas where raw material and/or products are exposed and handled	NA
14.13	Sch-M	How access of authorized persons to manufacturing areas including packaging is controlled.	NA	List of authorized persons to enter manufacturing areas including packaging was found in place and records found maintained in this regard.	Access of authorized persons to manufacturing areas including packaging is found not controlled.	NA
14.14	Sch-M	Whether separate gowning provision is followed before entering the core areas.	NA	Secondary gowning procedure was found followed before entering the core areas	Secondary gowning procedure was found not followed before entering the core areas	NA

S.No	Reference		Quality Rating			
			2	1	0	X
14.15	Sch-M	Whether segregated secured areas for recall or rejected materials or for such material which are to be processed or recovered are provided.	NA	Segregated secured areas for recall or rejected materials or for such material which are to be processed or recovered was found provided.	Segregated secured areas for recall or rejected materials or for such material which are to be processed or recovered was found not provided.	NA
14.16	Sch-M	Whether various operations are carried out in segregated areas.	NA	Various operations were found carried out in segregated areas	Various operations were found not carried out in segregated areas	NA
14.17	Sch-M	Are doors of all core areas closed at all times with interlock arrangements?	NA	Doors of all core areas were found closed at all times with interlock arrangements	Doors of all core areas were found not closed at all times with interlock arrangements	NA
14.18	Sch-M	Specify whether any SOP is followed to verify the effectiveness for prevention of cross contamination.	NA	Specific SOP was found in place and followed to verify the effectiveness for prevention of cross contamination.	No specific SOP was found in place to verify the effectiveness for prevention of cross contamination.	NA
14.19	WHO TRS-986	Specify whether critical operations are carried out in closed system.	It was observed that all critical operations are carried out in closed system.	NA	NA	NA
14.20	WHO TRS-986	Specify the methods followed for product change-over.	Specific SOP was found prepared and followed for product change over.	NA	NA	NA
15 Sanitation in the Manufacturing areas:-						
15.1	Sch-M	Specify the cleaning procedure of the manufacturing areas and verify with the SOP in this regard.	NA	Specified SOP for cleaning procedure of the manufacturing areas was found in place and followed. Records found maintained in this regard.	Neither any SOP nor any records for cleaning procedure of the manufacturing areas was found in place.	NA
15.2	Sch-M	Whether cleaning procedure is validated.	NA	Cleaning procedure was found validated.	Cleaning procedure was found not validated.	NA
15.3	Sch-M	Whether a routine sanitation program is in place.		Routine sanitation program was found in place	Routine sanitation program was found not in place	NA
15.4	Sch-M	Verify the SOP & the records in this regard.	NA	SOP & records regarding sanitation program was verified and found satisfactory.	Neither any SOP nor any records regarding sanitation program was found in place.	NA
15.5	Sch-M	Does the location facilitate cleaning of equipment as well as the cleaning of the areas in which they are installed?	NA	Equipment was found installed in such location which facilitate cleaning of the areas as well as the equipment.	Location of equipment installation do not facilitate cleaning of the areas as well as the equipment.	NA
15.6	Sch-M	Whether production area is adequately lit.	NA	Production area was found adequately lit.	Lux level in the production area was found adequate.	NA
15.7	Sch-M	Mention lux levels observed in production, visual inspection and other areas.	NA	Production Area - 400 to 500 Lux, visual inspection area- 500 to 600 Lux and other areas 200 to 400 Lux	No specific Lux level was found maintained	NA
15.8	Sch-M	Specify in detail the procedure followed during product changeover.	NA	Specific SOP was found in place and followed.	No specific SOP was found in place in this regard	NA
16 Equipment: -						

S.No	Reference		Quality Rating			
			2	1	0	X
16.1	Sch-M	Whether the equipment are designed aiming to minimize risk of error and permit effective cleaning and maintenance in order to avoid cross contamination & build up of dust.	NA	It was observed that the equipment are designed aiming to minimize risk of error and permit effective cleaning and maintenance in order to avoid cross contamination & build up of dust.	No such measures was found taken.	NA
16.2	Sch-M	Whether all equipment are provided with log book.	NA	All equipment was found provided with log book.	Log book was found not maintained for each equipment	NA
16.3	Sch-M	Please specify the procedures to clean the equipment after each batch production.	NA	Specific SOP was found in place and followed to clean the equipment after each batch production	No SOP was found in place and followed to clean the equipment after each batch production	NA
16.4	Sch-M	Whether validity period for use after the cleaning of equipment is specified.	NA	Validity period for use after the cleaning of equipment was found specified.	Validity period for use after the cleaning of equipment was found not specified.	NA
16.5	Sch-M	Whether separate area is provided for storage of machine parts etc.	NA	Separate area was found provided for storage of machine parts etc.	No separate area is provided for storage of machine parts etc.	NA
16.6	Sch-M	Whether balances and other measuring equipments with appropriate range are available in the Raw Material stores & production areas and they are calibrated in accordance with SOP maintained. Specify the calibration schedule of the balances.	NA	Balances and other measuring equipment with appropriate range were available in the Raw Material stores & production areas and they were found calibrated in accordance with SOP maintained. Calibration schedule of the balances was found mentioned in the SOP. Record of calibration was found maintained.	Balances and other measuring equipments with appropriate range are available in the Raw Material stores & production areas but they are not found calibrated and no SOP was found in place in this regard.	NA
16.7	Sch-M	Specify material of construction of contact parts of the production equipments.	NA	MOC of contact parts of all the manufacturing equipment was found made up of SS-316	MOC of contact parts of all the manufacturing equipment was found not made up of SS-316	The material of construction of the equipment is not suitable. e.g., found rusted, cracked, leaking etc.
16.8	Sch-M	Which types of lubricants are used in the equipment. Specify the quality and control reference No. of these lubricants	NA	Food grade lubricants was found in use.	Food grade lubricants was found not in use.	NA
16.9	Sch-M	Specify the procedures to remove defective equipments from production areas.	NA	Specific SOP was found in place in this regard.	No specific SOP was found in place in this regard.	NA
16.10	WHO TRS-986	Verify whether washing and cleaning of equipment are not a source of contamination.	Washing and cleaning of equipment was found not a source of contamination.	NA	NA	NA
16.11	Sch-M	Whether all equipment is provided with an ID NO.	NA	All equipment was found provided with an ID No.	All equipment was found not provided with an ID No.	NA
16.12	WHO TRS-986	Specify the procedures to clean the equipment after each batch production and verify with the SOP.	Specific SOP was found in place in this regard	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
16.13	WHO TRS-986	Specify whether CIP or SIP is in place.	CIP/SIP was found in place	NA	NA	NA
16.14	WHO TRS-986	Specify whether the CIP / SIP system is qualified	CIP/SIP system was found qualified.	NA	NA	NA
16.15	WHO TRS-986	Are there cleaning agent labelled with a catalogue no. indicating that they were received through the warehouse.	Cleaning agent was found labelled with a catalogue no. indicating that they were received through the warehouse.	NA	NA	NA
16.16	WHO TRS-986	Are there records for preparation of cleaning agent?	Records for preparation of cleaning agent was found in place.	NA	NA	NA
17 Production Area for Sterile Preparation						
17.1		Building and Facilities:-				
17.2	Sch-M	Specify the building is devoid of cracks especially in the Critical solutions preparation rooms, Filling rooms, Sealing rooms.	NA	Building was found devoid of cracks especially in the Critical solutions preparation rooms, Filling rooms, Sealing rooms.	Cracks are observed in non critical areas.	Wide cracks on walls/floor/ceiling or fungal growth or cobwebs, or insects infestations seen in filling areas of parenteral or eye drop preparations
17.3	Sch-M	Are the location of services like water, steam, gases etc. Such that the servicing or repairs can be carried out without any threat to the integrity of the facility	NA	Location of services like water, steam, gases etc. Such that the servicing or repairs can be carried out without any threat to the integrity of the facility	Location of services like water, steam, gases etc. can not rule out the threat to the integrity of the facility during servicing or repairs.	NA
17.4	Sch-M	Specify water lines pose any threat of leakage to the critical area	NA	Water lines do not pose any threat of leakage to the critical area	Threat of leakage to the critical area can not ruled out from water lines.	NA
17.5	Sch-M	Specify the manufacturing areas clearly separated into following Support Areas: 1) Washing of containers & closures 2) Storage of washed containers & closures 3) Sterilization of containers & closures 4) Preparation of bulk solution (critical/non critical) 5) Change room	NA	Manufacturing area was found clearly separated into following Support Areas: 1) Washing of containers & closures 2) Storage of washed containers & closures 3) Sterilization of containers & closures 4) Preparation of bulk solution (critical/non critical) 5) Change room	Following support areas was found not clearly separated. 1) Washing of containers & closures 2) Storage of washed containers & closures 3) Sterilization of containers & closures 4) Preparation of bulk solution (critical/non critical) 5) Change room	NA
17.6	Sch-M	Specify de-cartoning areas to remove outer cardboard wrappings of primary packaging materials segregated from the washing areas.	NA	De-cartoning areas to remove outer cardboard wrappings of primary packaging materials was found segregated from the washing areas.	De-cartoning areas to remove outer cardboard wrappings of primary packaging materials was found not segregated from the washing areas.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
17.7	Sch-M	Specify whether particle shedding materials like wooden pallets, fibre board drums, cardboards etc. are taken into the preparation areas.	NA	No particle shedding materials like wooden pallets, fibre board drums, cardboards etc. are taken into the preparation areas.	Particle shedding materials like wooden pallets, fibre board drums, cardboards etc. was found in the preparation areas.	NA
17.8	Sch-M	Specify in the classified areas: 1) Walls are flat, smooth and devoid of recesses. 2) Surface joints like electric sockets, gas points flushed with walls. 3) Joints in the ceiling are properly sealed 4) Air grills and lights flushed with the ceiling. 5) Grade A & B areas devoid of sinks and drains. 6) Doors and windows made up of non shedding materials. 7) Doors open towards higher pressure areas and close automatically due to air pressure.	NA	In the classified area following observations were noted : 1) Walls are flat, smooth and devoid of recesses. 2) Surface joints like electric sockets, gas points flushed with walls. 3) Joints in the ceiling are properly sealed 4) Air grills and lights flushed with the ceiling. 5) Grade A & B areas devoid of sinks and drains. 6) Doors and windows made up of non shedding materials. 7) Doors open towards higher pressure areas and close automatically due to air pressure.	In the classified area some of the following points were found not complied with : 1) Walls are flat, smooth and devoid of recesses. 2) Surface joints like electric sockets, gas points flushed with walls. 3) Joints in the ceiling are properly sealed 4) Air grills and lights flushed with the ceiling. 5) Grade A & B areas devoid of sinks and drains. 6) Doors and windows made up of non shedding materials. 7) Doors open towards higher pressure areas and close automatically due to air pressure.	NA
17.16	WHO TRS-961 ANNEXE-06	Is there a glass panel between critical area & support area so that all operations in Grade A & B areas can be supervised from support areas?	Glass panel between critical area & support area was found so that all operations in Grade A & B areas can be supervised from support areas	NA	NA	NA
17.17	WHO TRS-961 ANNEXE-06	Fire extinguishers are suitably fastened to the walls without gaps.	Fire extinguishers were found suitably fastened to the walls without gaps.	NA	NA	NA
17.18	Sch-M	Quality of the furniture used is smooth & washable and made of SS316.	NA	Quality of the furniture used was found smooth & washable and made of SS316.	Quality of the furniture used was found not smooth & washable	NA
17.19	Sch-M	Change rooms entrance provided with air locks before entry to the sterile product manufacturing areas.	NA	Three change rooms were found provided with air locks before entry to the sterile product manufacturing areas.	Three change rooms were found not provided with air locks before entry to the sterile product manufacturing areas	NA
17.20	Sch-M	How many change rooms are provided to enter into the critical areas?	NA	Three	Less than three	NA
17.21	WHO TRS-961 ANNEXE-06	Specify an appropriate inter- locking system with visual and/or audible warning system installed to prevent the opening of more than one door at a time.	Appropriate inter- locking system with visual and/or audible warning system was found installed to prevent the opening of more than one door at a time	Na	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
17.22	Sch-M	Are the critical and support areas provided with intercom telephones or speak phones for communication purposes.	NA	Critical and support areas were found provided with intercom telephones or speak phones for communication purposes.	Critical and support areas was found not provided with intercom telephones or speak phones for communication purposes.	NA
17.23	Sch-M	Specify the critical areas and support areas provided with suitable air- locks or pass boxes with proper interlocking arrangements for material transfer.	NA	Critical areas and support areas were found provided with suitable air- locks or pass boxes with proper interlocking arrangements for material transfer.	Critical areas and support areas were found not provided with suitable air- locks or pass boxes with proper interlocking arrangements for material transfer.	NA
17.24	WHO TRS-961 ANNEXE-06	Specify whether dynamic pass box is used for material transfer between two different air class.	Dynamic pass box was found used for material transfer between two different air class	NA	NA	NA
17.25	Sch-M	Specify the method of transfer of sterile rubber bungs & aluminium caps to the aseptic area.	NA	Specific SOP was found in place and followed for transfer of sterile rubber bungs & aluminium caps to the aseptic area.	No specific SOP was found in place and followed for transfer of sterile rubber bungs & aluminium caps to the aseptic area.	NA
17.26	Sch-M	Specify whether grade A/B area is devoid of sinks and drains.	NA	Grade A/B area was found devoid of sinks and drains	Sinks and drains was found provided in grade A/B area.	NA
18 Air Handling System (Central Air Conditioning):-						
18.1	Sch-M	Specify whether the Air Handling Units for sterile product manufacturing area are separated from those for other areas	NA	Air Handling Units for sterile product manufacturing area was found separated from those for other areas	Air Handling Units for sterile product manufacturing area was found not separated from those for other areas	NA
18.2	Sch-M	Give the Background Grade of air for following critical areas: 1) Aseptic filling area 2) Sterilized components unloading area for aseptic filling. 3) Batch manufacturing area for aseptic filling preparations. 4) Component washing and preparation area. 5) Change rooms to enter into Critical area.	NA	Background grade of air for following critical areas were found as given below: 1) Aseptic filling area- Grade B 2) Sterilized components unloading area for aseptic filling-Grade B 3) Batch manufacturing area for aseptic filling preparations-Grade B 4) Component washing and preparation area-Grade C 5) Change rooms to enter into Critical area-Grade B	Background grade of air for following critical areas were found not complied with the requirements prescribed in Schedule M.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
18.3	WHO TRS-961 ANNEXE-06	Specify the steps taken in air handling system to achieve the Grade A, B, C and D of air as per designated classified areas.	As per the qualification records submitted it was observed that following steps were taken to achieve the Grade A, B, C and D of air as per designated classified areas: Grade-A - Vertical LAF Grade-B - 60 % ceiling is covered under HEPA and keeping ACPH more than 60 Grade C & D - Keeping appropriate ACPH	NA	NA	NA
18.4	Sch-M	Specify the recovery time of B & C zone from the time of personnel leaving the room after completion of operations and verify the records in this regard.	Recovery time of B & C zone from the time of personnel leaving the room after completion of operations was found less than 20 minutes from the available records.	Recovery time of B & C zone from the time of personnel leaving the room after completion of operations was found less than 30 minutes from the available records.	No records regarding recovery time of B & C zone from the time of personnel leaving the room after completion of operations could be produced.	NA
18.5	Sch-M	Specify whether filling operations are challenged initially and there after periodically by simulation trials including sterile media fill.	NA	Filling operations were found challenged initially and there after periodically by simulation trials including sterile media fill	Filling operations were found challenged initially but not there after periodically by simulation trials including sterile media fill	Media fill studies are not performed for aseptic products in simulated conditions as per Rules.
18.6	WHO TRS-961 ANNEXE-06	Specify the procedure followed for medial fill and the acceptance criteria.	Specific SOP was found prepared & followed as prescribed in WHO TRS-961, Annex-06	NA	NA	NA
18.7	WHO TRS-961 ANNEXE-06	Whether the medial fill trial is based on worst case situation taking into consideration all interventions, activities occurring during normal activity as well as worst case.	Medial fill trial was found based on worst case situation taking into consideration all interventions, activities occurring during normal activity as well as worst case.	NA	NA	NA
18.8	WHO TRS-961 ANNEXE-06	Whether simulation tests are repeated at defined intervals and after any significant modification to HVAC system, equipment or process.	Simulation tests was repeated at defined intervals and after any significant modification to HVAC system, equipment or process.	NA	NA	NA
18.9	Sch-M	Specify the number of air changes in Grade A/B and Grade C areas.	NA	Number of air changes in Grade A/B and Grade C areas was found NLT 20	No records could be produced in this regard	NA
18.10	Sch-M	Specify the air velocity maintained in Grade A Laminar Air Flow stations	NA	Air velocity was found maintained 100 $\pm$ 10 feet per minute in Grade A Laminar Air Flow stations	No records could be produced in this regard	NA
18.11	Sch-M	Specify the differential pressure between areas of different environmental standards.	NA	15 pa was found maintained as differential pressure between areas of different environmental standards	No records could be produced in this regard	NA

S.No	Reference		Quality Rating			
			2	1	0	X
18.12	Sch-M	Specify type of manometer installed for measurement and verification of Air Pressure Differential.	NA	Magneheilic Manometer was found installed for measurement and verification of Air Pressure Differential.	Manometer installed for measurement and verification of Air Pressure Differential was found faulty.	NA
18.13	WHO TRS-961 ANNEXE-06	Specify the air classification in final change room to enter A/B area.	Grade-B	NA	NA	NA
19 Environmental Monitoring:-						
19.1	Sch-M	Specify the temperature and humidity maintained in the critical areas.	Temperature and humidity is maintained through automated building management system or any other suitable system and is recorded continuously as retrievable and printable data.	Temperature and humidity is maintained and periodically monitored with suitably calibrated instruments and recorded with predefined intervals as per SOP.	Temperature and humidity is not maintained consistently as per specified limits. Temperature and humidity not always recorded periodically as evidence.	1. Suitable arrangements are not made for maintaining temperature and humidity in critical areas. 2. The viable counts are not performed as per rules. The microbial counts were found well above the limits however reported within limits. 3. The HEPA filter integrity test (smoke testing), particulate monitoring in air, air change rates tests are not performed as per Rules.
19.2	WHO TRS-961 ANNEXE-06	Verify the area qualification records and specify whether the following were taken into consideration : 1) No. of Persons 2) ACPH (Air Changes per hours) 3) Particle count (Static & Dynamic) 4) Viable count (Static & Dynamic) 5) Temperature & Humidity 6) Air Sampling location and interpretation of results (Both viable and non-viable) 7) Whether the above method is in compliance with ISO 14644-1 8) Action and Alert limits for all the above parameters	Area Qualification performed with predefined protocols taking into account following parameters 1) No. of Persons 2) ACPH (Air Changes per hours) 3) Particle count (Static & Dynamic) 4) Viable count (Static & Dynamic) 5) Temperature & Humidity 6) Air Sampling location and interpretation of results (Both viable and non-viable) 7) Whether the above method is in compliance with ISO 14644-1 8) Action and Alert limits for all the above parameters	NA	NA	NA

			Quality Rating			
S.No	Reference		2	1	0	X
19.3	Sch-M	Mention the periodic monitoring frequencies of the followings: 1) Particulate counts 2) HEPA filters integrity testing 3) Air Change rates 4) Air pressure differentials 5) Temperature and Humidity 6) Microbiological monitoring by settle plates and/ or swabs in Critical areas & Other areas	NA	Periodic monitoring frequencies of the following parameters were observed as detailed below: 1) Particulate counts-6 Monthly 2) HEPA filters integrity testing-Yearly 3) Air Change rates-6 Monthly 4) Air pressure differentials-Daily 5) Temperature and Humidity-Daily 6) Microbiological monitoring by settle plates and/ or swabs in Critical areas & Other areas-Daily	1) Frequency of monitoring not followed as required 2) Air change rate calculations not proper 3) No immediate actions taken on adverse results 4) The monitoring results are not in desired limits.	1.The monitoring not done as per the pre-specified SOPs 2.The monitoring data is manipulated/falsified 3.There is gross deviation from the pre-specified limits 4. The corrective actions are inadequate and deviations from the limits are not justified/explained. 5.The production activity is performed under non-compliant conditions
19.4	Sch-M	Does a written Environmental Monitoring Program exist?	NA	SOP for environmental monitoring programme was found available for clean areas " In operation"	Witten environmental monitoring programme was available but not adequate in compliance with Schedule M.	NA
19.5	Sch-M	How long the settle plates are exposed in Grade A and other areas.	NA	Individual settle plates are exposed for not less than two hrs. in Grade B,C and D areas and not less than 30 mins in Grade A area.	Settle plates exposed for less time than specified.	NA
19.6	Sch-M	Verify the records of microbiological results also specify whether alert and actions limits are followed or not.	Trend analysis for microbiological monitoring is performed with respect to predefined alert and action limits/	SOP was found specified alert and action limits and within the limits specified in Sch.M. The limits are monitored and followed.	Records proves that the alert and actions limits are not followed.	NA
19.7	Sch-M	What action is taken in case particulate and microbiological monitoring counts exceed the limits?	NA	SOP for corrective action is available in case particulate and microbiological monitoring count exceeds the limits. For the incidences of exceeding limits appropriate corrective and preventive action is taken so which may not impact product quality.	Corrective and preventive actions not taken adequately for the incidences where particulate, microbial monitoring values exceed the limits.	NA
19.8	WHO TRS-961 ANNEXE-06	Specify what parameters are reassessed and approved before starting production and in case of major engineering modifications being carried out to the HVAC system of any area.	Specific SOP was found prepared and followed in this regard.	NA	NA	NA
20 Garments:						

S.No	Reference		Quality Rating			
			2	1	0	X
20.1	Sch-M	Specify type of garments used in critical areas?	NA	Garments used are made of non-shredding and tight wave material. The garments not are not shedding fibres or particulate matter.	Garments are not made of non-shredding and tight wave material. The garments are shedding fibres or particulate matter.	NA
20.2	Sch-M	Specify type of Zips used in garments	NA	Zips are made up from plastic material and not damaged.	Zips are not made from plastic material and some garments in	NA
20.3	Sch-M	Whether garments used in critical areas are sterile.	NA	The garments sued in critical areas are clean and sterilized.	Garments in use are not properly cleaned and sterilized	NA
20.4	Sch-M	Specify the process of sterilization of the garments & the practise followed to carry the sterilised garments to the final change room.	Validated load pattern with pressure -vacuum cycle, Bowie dick test is performed periodically.	Garments were found sterilized after dipping in 70% IPA solution followed by air- drying & moist autoclaving. The sterilized garments was found taken to the final change room in sealed condition	Garments were found sterilized by moist autoclaving but no precaution is taken to avoid further contamination during carry over the same to final change room.	NA
20.5	Sch-M	Are garments,masks,gloves are changed at every work session?	NA	Garments,masks,gloves were found changed at every work session.	No such system was found followed.	NA
20.6	Sch-M	Are the gloves used made of latex or other suitable plastic material	NA	Gloves used in clean rooms are made of latex or plastic material.	Gloves used in clean rooms are made not of latex or plastic material.	NA
20.7	Sch-M	Are powder free gloves used in clean rooms	NA	Powder free gloves used in clean rooms	powder free gloves are not used in clean rooms	NA
20.8	Sch-M	Are the gloves long enough to cover the wrists completely and allow the over-all cuff to be tucked in	NA	The gloves are long enough to cover the wrists completely and over-all cuff is tucked in.	The gloves are not long enough to cover the wrists completely and over-all cuff is tucked in.	NA
20.9	Sch-M	Are the foot-wear used made of plastic or rubber material	NA	Foot-wear used are made from plastic or rubber material which is not shredding and easy for cleaning	Foot-wear used are not made from plastic or rubber material and does not permit easy cleaning.	NA
20.10	Sch-M	Are the foot-wear daily cleaned with a bactericide	Foot-wears are cleaned and sterilized before use.	Foot-wears are cleaned and disinfected with suitable disinfectants.	Foot-wears are not cleaned and disinfected with suitable disinfectants daily.	1. Sterile garments are not used in aseptic area. 2. Unclean foot wears are used in critical areas.
20.11	Sch-M	Are the safety goggles / numbered glasses worn inside the critical areas and have side extensions	NA	Safety goggles with side extensions are used.	Safety goggles does not have side extensions.	NA
20.12	Sch-M	Are safety goggles sanitized by a suitable method	NA	Safety goggles are sanitized with suitable disinfectant .	Safety goggles are not sanitized before use.	NA
20.13	Sch-M	Specify the garment changing procedure and SOPs	NA	SOP for garment changing is available.	Procedure for garment changing not documented as followed practically.	NA
20.14	Sch-M	Specify whether operators are trained in garment changing procedure.	NA	Personnel are adequately trained for garment change procedure.	Personnel are not properly trained for garment change procedure.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
20.15	Sch-M	if full size mirror has been provided in the final change room to ascertain that the operator has appropriately attired in the garments.	NA	The full size mirror is provided in the final change room.	The full size mirror is provided in the final change room. Mirror is provided but it is cracked.	NA
20.16	WHO TRS-961 ANNEXE-06	Specify how the garments used in clean areas are cleaned and sterilized.	Specific SOP was found in place for cleaning of Garments used in clean areas. In in-house laundry facility and sterilization was found with validated cycle.	NA	NA	NA
21 Sanitation:						
21.1	Sch-M	Specify the SOP followed for sanitisation of sterile processing facilities and mention the SOP nos.	NA	Detailed SOP/SOPs is available with the procedure for sanitization, frequency of sanitization, concentration of sanitizing agent, rotation policy of sanitizing agent, preparation of sanitizing agent and maintenance of sanitization record.	SOP for sanitizing procedure is not adequate with respect to procedure for sanitization, frequency of of sanitizing agent, rotation policy of sanitizing agent, preparation of sanitizing agent and maintenance of sanitization record.	NA
21.2	Sch-M	Specify whether employees carrying out the sanitation of critical areas are specially trained for this purpose.	NA	The sanitization activity is performed by trained personnel(including contractual staff) .The periodic training is imparted to personnel on change/modification of the	Not all the personnel including contractual staff is trained to carry out the sanitization activity.	NA
21.3	Sch-M	Verify the training records.	NA	Periodic training records are maintained including the assessment and further retraining if required. Instructions for cleaning and sanitization available in a language that is understood by the user and concern staff trained in same language	Training records not maintained for the all concern staff including contractual staff. Training not imparted on the procedure change or disinfectant change or introduction of new equipment for sanitization.	NA
21.4	Sch-M	Specify the sanitizing agent/s used.	NA	Sanitization agents used in accordance with SOP and is used in rotation and concentration of it same as recommended by manufacturer of sanitizing agent and the dilution is validated with its efficacy test. Records of rotational of use of sanitization is maintained.	Sanitation agent not used in rotation as defined in SOP. The concentration of sanitizing agent not complying as recommended by manufacturer and the dilution is not validated with its efficacy test	NA
21.5	Sch-M	Specify the quality of water used for preparation of sanitising solution.	NA	Distilled water freshly collected from distilled water plant or water maintained above 70 degree	Disinfectants are diluted with distilled water which is not collected freshly or with water that	NA
21.6	Sch-M	Specify the disinfectant used for hand sprays?	NA	70 % Iso propyl alcohol or alcohol was found used for hand disinfectant	Iso propyl alcohol or alcohol is not used for hand spray (disinfection)	NA

S.No	Reference		Quality Rating			
			2	1	0	X
21.7	Sch-M	Specify whether disinfectant solutions are filtered through membrane into suitable sterile containers or sterilized before use?	Disinfectants and detergents are monitored for microbial contamination; dilutions are in previously cleaned containers and are only be stored for defined periods unless sterilized. Disinfectants and detergents used in Grade A and B areas are sterilized before use.	Disinfectant solutions are sterilized by membrane filtration or any other suitable method(if available) and is stored in the sterile containers.	Sterilized disinfectants are not stored in sterile containers. The sterilization procedure is not properly followed (i.e. selection of suitable sterilization grade filter or any other ineffective sterilization procedure is adopted). The sterilization records not effectively maintained etc.	NA
21.8	Sch-M	Specify whether the diluted disinfectants bear 'use before' labels based on microbiological establishment of their germicidal properties & verify the records	NA	Use before period for the diluted disinfectant is established based on the efficacy test of diluted disinfectant (i.e. Disinfectant validation by microbial challenge). Based on the validation used before date is mentioned in the documents and label of the containers.	Containers of the diluted disinfectants does not bear 'USE BEFORE" Label based on the microbial efficacy test (validation). Use before date is not established for the concentration actually used. Use before date for all disinfectants is not established.	NA
21.9	Sch-M	Specify whether fumigation is carried out in critical areas. If yes, specify fumigating agent and its conc. used.	NA	Fumigation(with Formaldehyde or other equally effective fumigant) is performed in case of major civil modification or as per conditions mentioned in SOP.	SOP for fumigation not followed. Fumigation is routinely done in place of routine sanitization procedure. Fumigant used not mentioned SOP.	NA
21.10	Sch-M	Specify whether any SOP exists for the purpose of fumigation if so mention the SOP nos.	NA	Detailed SOP for fumigation is available with procedure of fumigation & defumigation, concentration/quantity of fumigant viz viz area of the clean room, precautions to be taken during fumigation etc.	SOP of fumigation is deficient with respect to procedure of fumigation & defumigation, concentration/quantity of fumigant viz area of the clean room, precautions to be taken during fumigation etc.	NA
21.11	Sch-M	Specify the cleaning procedure of critical areas.	NA	Detailed SOP with procedure of cleaning of critical area, dilution and quantity of diinfectant, type of disinfectants & rotation schedule is available and record of that is maintained.	No SOP was found followed in this regard.	NA
21.12	WHO TRS-961 ANNEXE-06	Specify whether particle monitoring in Grade A zones is undertaken for the full duration of critical processing including equipment assembly.	Continuous particle monitoring system is installed in Grade A at appropriate location as per risk based assessment	NA	NA	NA
21.13	WHO TRS-961 ANNEXE-06	Specify whether particle monitoring in Grade B zones is undertaken for the full duration of critical processing.	Continuous particle monitoring system is installed in Grade B at appropriate location as per risk based assessment	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
21.14	Sch-M	Whether more than one sanitizing agent is used in rotation. If yes list the sanitizing agents their concentration and frequency.	NA	Sanitizing agent/class of agent used on rotational basis.	Sanitization agents not used in rotation and same agent/or class of agent used.	NA
22 Equipment:						
22.1	Sch-M	Specify whether the unit- sterilizers are double ended with suitable inter-locking between the doors.	NA	Double door sterilizer are installed with effective interlocking system between both the doors. Unloading side is in the clean room where the sterilized material will be used or conveyed to other clean rooms for use.	Sterilizers do not have door interlocking system. Unloading side is not opening in clean room.	NA
22.2	Sch-M	Specify the initial effectiveness of sterilization process established by using microbial spore indicators.	NA	Suitable microbial spores are used to establish effectiveness of sterilization process, (as mentioned in IP) e.g. 1) For Moist heat-Bacillus Stereo thermophillus 2) For Dry heat sterilization: Bacillus Substilis var-niger 3) For Eto-Basillus Substilis var-niger. 6 log reduction observed after sterilization procedure. The appropriate no of microbial spore indicator units are distributed through out the sterilizer.	1) Suitable microbial indicator as per the type of sterilization procedure not used for establishment of effectiveness of sterilization process. 2) The population of spores are not adequate. 3) The appropriate no of microbial spore indicators are not distributed throughout the load. 4) After sterilization cycle the spores indicators are not tested adequately to establish 6log reduction. 5) Before use The microbial spore indicators are not stored as per manufacturer's recommendations.	1) Effectiveness of sterilization process not established by using microbial spore indicators. 2) The spore indicators used have inadequate population or no spore population. 3) Post sterilization testing of the spore strips is not performed to establish 10 log reduction.
22.3	Sch-M	Specify whether thermal Mapping of heat sterilizers is carried out on regular basis. Check records.	NA	Thermal mapping of the sterilizers are performed at least once a year by adequate number of calibrated independent probes for all type loads. The sterilization parameters like temperature, duration, pressure(where ever applicable) are established during thermal mapping are followed during routine sterilization(as per established SOP). The sterilization cycle is controlled by temperature probe which is place at coolest spot which established during thermal mapping.	1) Thermal mapping of the sterilizers are not performed at least once a year. 2) No. of external probes used are not adequate 3) The external probes used for validation are not calibrated 4) The sterilization cycle is not controlled by coolest spot prob. 5) The established parameters during validation are not used in routine sterilization process.	NA

			Quality Rating			
S.No	Reference		2	1	0	X
22.4	Sch-M	Specify if suitable vent filters and recording thermographs are provided for autoclaves & dry heat sterilizers.	Autoclave is installed with continuous temperature recording data logger and the data is retrievable and non editable.	Suitable sterilizing grade hydrophobic vent filters are installed on autoclave on the unloading i.e. Clean roll side. Each cycle temperature is recorded with continuously through thermograph or printout.	1) Vent filters are installed are not suitable to sterilize air. 2) Vent filters not installed at unloading site. 3) The vent filters not periodically changed. 4) The vent filter periodic integrity test not performed. 5) Continuous temperature recording system or thermograph not installed 6) The thermographs are not legible 7) Thermograph not recording temperature of control	NA
22.5	Sch-M	Specify whether cool air is passed through HEPA filter and recording thermographs provided in DHS/Tunnel.	DHS/Tunnel is installed with continuous temperature recording data logger and the data is retrievable and non editable.	1) Suitable HEPA filters are installed for cooling air and tested for integrity periodically. 2) Each cycle temperature is recorded with continuously through thermograph or printout.	1) HEPA filters not installed appropriately 2) Periodic integrity test of HEPA filter not performed 3) The thermograph is not recording temperature properly(Not legible) 4) Thermograph not recording temperature of control prob.	NA
22.6	WHO TRS-961 ANNEXE-06	Specify whether provisions of CIP or SIP are available.	Provision for Cleaning in place or sterilization in place is available for the non moving equipment, tanks etc.(cleaning and sterilization procedure adopted is validated)	NA	NA	NA
22.7	Sch-M	Specify whether pure steam is in use.	NA	Clean steam or pure steam is used to sterilize the product contact parts/accessories. They steam used is sterile and pyrogen free. It does not contains additives.	Pure steam is not used to sterilize the product contact parts/accessories.	NA
22.8	Sch-M	Specify if filter integrity test is carried out before and after the sterile filtration process.	NA	Integrity test of Membrane filters (0.22 micron or 0.45 micron) is carried out before use and after use by suitable method like bubble point, diffusive flow or pressure hold test with the values recommended by filter manufacture.	1) Integrity test either before or after use not carried out. 2) Parameters of integrity testing not same as recommended by Manufacturer. 3) The records of integrity test not preserved 4) Procedure followed for integrity test not in line with SOP.	NA

			Quality Rating			
S.No	Reference		2	1	0	X
22.9	Sch-M	Specify the material of construction of the equipment & type of glass containers	NA	The construction material used for the parts which are in direct contact with products and the manufacturing vessel are of SS 316 which washable and sterilizable. Glass containers is of Borosilicate.	The MOC of the parts which are in product contact is SS but not SS316. The glass containers are not made from Borosilicate glass.	NA
22.10	Sch-M	Specify the tubing used in critical areas	NA	Tubing used are of capable of being washed and sterilized. Made up of inert material.	Tubing used is washable but not sterilizable.	NA
22.11	Sch-M	Specify the qualifications of critical equipment.	Equipments are qualified with predefined protocols.	Critical equipments are identified. Installation qualification been done of all the equipments by the engineers (with the support of production and quality assurance personnel). Equipments performance qualification is performed by validation.	Qualifications are not adequately performed.	NA
22.12	WHO TRS-961 ANNEXE-06	Verify the qualification, protocol and reports for the critical equipment.	Details qualification protocol with reports available	NA	NA	NA
22.13	Sch-M	Specify SOPs available for each equipment for its operation and cleaning.	NA	Each equipment is operated as per standard operating procedure made in accordance with equipment manual. The Cleaning of equipment is performed as per the SOP.	SOP for equipment operation and cleaning not adequate. The actual operations carried out does not reflect in SOP.	NA
22.14	Sch-M	Specify whether the measuring devices attached to equipment calibrated at suitable intervals.	NA	Measuring devices attached to equipments are calibrated at predefined intervals.	Calibration schedule not followed, intervals not strictly adhered	NA
22.15	Sch-M	Specify whether a written calibration program is available	NA	Calibration schedule is in place with frequency of calibration. The schedule is followed and calibration tag available on the equipment/instrument displaying calibration status of it.	1) Instruments are calibrated but written calibration programme not available. . 2) The calibration tags are not in legible condition. 3) Calibration not performed adequately.	NA

			Quality Rating			
S.No	Reference		2	1	0	X
22.16	Sch-M	Specify whether calibration status documented and displayed on the equipment and the gauges	NA	Each instrument has calibration status tag. Calibration documents are matching with the calibration label on the instrument.	As per documents instrument is calibrated but no calibration tag on the instrument. The calibration SOP is deviated	1) Calibration data for the instruments/ equipment is falsified. 2) The calibration status label and calibration document are not matching
23 Manufacturing Process						
23.1	Sch-M	Specify whether the bulk raw materials and bulk solutions monitored for bio-burden periodically (solutions not to contain more than 100 cfu/ml).	NA	Bio burden of bulk raw material is periodically monitored with predefined frequency. Bio-burden of bulk solutions before filtration is monitored periodically (limit : 100 cfu/ml)	No SOP was found prepared and followed in this regard.	NA
23.2	Sch-M	Specify the minimum possible time between the preparation of the solution and its sterilization or filtration through microorganism retaining filters followed.	NA	Maximum time from preparation of bulk batch to filtration through microorganism retaining filter is defined. The allowed time gap is based on the master manufacturing formula	The sterilization by filtration of bulk through the microorganism retaining membrane filter is performed beyond the predefined time.	NA
23.3	Sch-M	Specify the porosity of the filters when any external gases are coming into contact with the sterile product.	NA	The external gases which are coming in contact with the sterile product are filtered through two 0.22 micron hydrophobic filters connected in series. This filters are tested for integrity.	1) The external gases not filtered through two 0.22 micron filters in series. 2) Integrity test of gas filters not performed.	NA
23.4	Sch-M	Specify whether gas cylinders are kept out side of the critical areas.	NA	Gas cylinders are kept out side of the critical areas and gases are carried at the point of use by suitable pipes.	Gas cylinders are not kept out side of the critical areas and gases are not carried at the point of use by suitable pipes	NA
23.5	Sch-M	Specify the procedure of sterilization of washed containers.	NA	The washed containers are sterilized with suitably validated procedure (documented in operation SOP) and validated load patterns are followed in routine.	The procedure adopted for sterilization is not adequately validated, all load pattern are not defined. Established parameters during validation are violated.	NA
23.6	Sch-M	Specify whether the sterilized containers not used within an established time, rinsed with WFI and re-sterilized.	NA	Hold time before use of sterilised containers are defined based on the validation. If within specified time the sterilised containers are not used, they are again rinsed with WFI and re-sterilized as per SOP.	1) The sterilized containers used beyond the established hold time. 2) The containers/load does not bear use before date after sterilization. 3) The containers are re-sterilized after established hold time without rinsing with WFI. 4) The seal/packing of the containers is not intact up	NA

S.No	Reference		Quality Rating			
			2	1	0	X
23.7	Sch-M	Is each lot of the finished product filled in one continuation operation?	NA	Finished product is filled in in one continuous operation. In case where one batch is filled using more than operation , each lot is tested separately for sterility and held separately till sterility test results are known.	Finished product is not filled in continuous operation. The lots not segregated. The sterility test performed as whole batch.	NA
23.8	Sch-M	Specify whether all critical process is validated. Verify the records.	NA	The critical process parameters are identified, the testing procedure to establish the quality by maintaining critical parameters is defined and Process validation is performed with predefined protocol.	1) Critical process validated but all the critical parameters are not validated or Verified. 2) The established critical parameters are not followed during routine process.	NA
23.9	WHO TRS-961 ANNEXE-06	Verify the process validation protocol and reports for the critical operation.	Process validation protocol and reports for some critical operations was verified during inspection and found comply with the norms specified in WHO TRS.	NA	NA	NA
23.10	WHO TRS-961 ANNEXE-06	Specify whether critical operations are carried out in closed system.	All critical operations were found carried out in closed system.	NA	NA	NA
24. Aseptic processing and sterilization by filtration:						
24.1	Sch-M	Specify whether the filling area is of Grade A environment with Grade B background.	NA	Ascetic Filling and preparation is done in Grade A with grade B background . Grade of area is established by area validation taking into account viable and non viable particle count, ACPH, Air velocity and differential pressures.	1) Critical individual activities during filling process e.g. rubber closer addition in to hopper, conveying sterilized vials/accessories to filling station etc. are not carried out in Grade A. 2) The grade of area is not appropriately established by validation and certified area layout with classification not available.	NA
24.2	Sch-M	Specify the room classification of solutions preparation area which is sterilized by filtration.	NA	Preparation of solution which are to be sterilized by filtration was found carried out in Grade C environment, and for aseptic filling the operation was found carried out in Grade A environment with Grade B background.	The grade of area is not appropriately established by validation and certified area layout with classification not available.	NA
24.3	Sch-M	Specify the filter used for sterilization of solution by filtration.	NA	Solution was found sterilized by filtration through a non-fibre releasing, sterilizing grade cartridge/membrane filter of nominal pore size of 0.22 micron for aseptic filling whereas 0.45 micron porosity is used for terminally sterilized products.	Solution filtered through fibre releasing filter and pore size of filter is not defined or no evidence for pore size available.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
24.4	WHO TRS-961 ANNEXE-06	Specify the maximum possible time used for filtration process.	It was observed that the maximum possible time used for filtration was established through validation.	NA	NA	NA
24.5	Sch-M	Specify whether integrity of the sterilizing filters is verified before and after use. If so, by which method.	NA	Integrity test of sterilizing filters is carried out before use and after use by suitable method like bubble point, diffusive flow or pressure hold test with the values recommended by filter manufacture.	1) Integrity test either before or after use not carried out. 2) Parameters of integrity testing not same as recommended by Manufacturer. 3) The records of integrity test not preserved 4) Procedure followed for integrity test not in line with SOP.	NA
24.6	WHO TRS-961 ANNEXE-06	Specify whether the personal working in the aseptic area are qualified for clean room procedure or not. If so verify the training records.	It was observed that the personal working in the aseptic area are qualified for clean room procedure through appropriate training and the training record was found maintained.	NA	NA	NA
25 Product Containers & Closures:-						
25.1	Sch-M	Specify whether the containers and closures used comply with pharmacopoeia or other specific requirements.	NA	Container/closure was found suitable for the product filled (specific requirements) and in accordance with pharmacopoeia	Containers and closures use do not comply with pharmacopoeia requirements	Recycled /second hand containers and closures are used for primary packaging.
25.2	Sch-M	Specify whether Specifications, Test methods, Cleaning procedures, Sterilizing procedures etc. are available of the containers/ closures and other component parts of drug packages.	NA	Specifications , test methods are available in compliance with pharmacopoeia. Validated cleaning and sterilization procedure area available for containers and closures.	1) Specification are not available for containers and closures. 2) All lots of container and closures are not tested before use for production 3) Cleaning/sterilization of containers are not appropriately performed. 4) Containers and closured which are out of specification used for production. 5) Second hand containers and closures are used	NA
25.3	Sch-M	Specify whether the container & closures are compatible with the product without affecting its quality and purity. Verify the records.	NA	The containers and closures are compatible with the product without affecting quality and purity which is established through validation and product stability testing.	The container & closures are not compatible with the product and affecting its quality and purity. e.g.absorbtion of preservative by the closures.	NA
25.4	Sch-M	Specify whether containers and the closures are finally washed with WFI before sterilization.	NA	WFI is used for final washing/rinsing of the containers and closures before sterilization.	The containers and closures not washed with WFI	NA

S.No	Reference		Quality Rating			
			2	1	0	X
25.5	Sch-M	Specify whether a written procedure exist for washing of glass ampoules/vials.	NA	SOP is available for washing of glass vials and ampoules. Parameters of washing are established through vial washing procedure validation.	No SOP for washing. The quality of water used is not as per SOP e.g. PW used in place of WFI	NA
25.6	Sch-M	Specify whether the material quality of the stoppers and closures ensures that it does not affect the quality of the product and avoids the risk of toxicity.	NA	Biological and physico chemical testing is performed on the closures before use. The effect on quality is established through validation and stability testing.	Material used for stoppers /closure is not as per pharmacopeia. The material is not inert.	NA
26 Sterilization						
26.1	Sch-M	Whether the sterilizing processes have been validated (Dry heat, Moist heat, filtration, ETO, ionizations whichever applicable.	NA	Sterilization process validated by thermal mapping, biological indicators, endotoxin challenge(as applicable) and parameters for sterilization are established for day to day operations.	Validation not performed.	NA
26.2	Sch-M	Whether the validity of the process verified at regular intervals (at least annually)	NA	It was observed that sterilization process is validated as per predefined protocol at least once a year.	Validation not performed.	NA
26.3	Sch-M	Whether the terminal sterilizer's capacity is sufficient to sterilize one batch completely at one time. If not specify controls and measures taken in lot sterilizations.	NA	It was observed that the terminal sterilizer's capacity is sufficient to sterilize one batch completely at one time. If sterilization is performed in different lot,tracebility was found well maintained by documentation and each lot was found tested separately for all parameters including sterility and the lots kept separately.	The maximum capacity of the sterilizer is not defined based on loading pattern and type of packaging. Each sterilized lot was found not tested for sterility . Sterility testing was found performed on combined lots only and not on the individual lots sterilized.	NA
26.4	Sch-M	Whether biological indicators used in monitoring of sterilization.	NA	Suitable biological indicators was found used for monitoring of the sterilization cycle.	Biological indicators not used for the monitoring of sterilization cycle.	NA
26.5	WHO TRS-961 ANNEXE-06	Verify that the probe is placed at the coolest point on the basis of validation studies	The probes were found placed at the coolest point on the basis of validation studies.	NA	NA	NA
26.6	WHO TRS-961 ANNEXE-06	Verify the qualification, protocol and reports for the sterilisers	Protocols for qualification of sterilizers was found well defined and reports available	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
26.7	Sch-M	Whether the biological indicators stored and used as per manufacturers instructions. Whether quality of BI's checked by positive controls.	NA	The BI's are stored as per manufacturer's instruction. The quality of BI's ascertained by positive control during microbial analysis.	Biological indicators not stored as per manufacturers recommendations. The media used for verification BI with positive control is not same as recommended by manufacturer.	NA
26.8	Sch-M	Whether a clear means of differentiating 'sterilized' from 'unsterilized' products is in place. Specify.	NA	The sterilized and unsterilized products were found stored in well segregated area where possibility of accidental mix-ups is complete avoided. The status is properly indicated on label. There is uniflow of material movement from unsterilized product storage area to sterilized product storage area after process of sterilization only.	Sterilized and unsterilized product stored haphazardly without proper segregation . Status labels are ambiguous . There are chances of mix-up due to the practices followed.	NA
26.9	Sch-M	Whether the label on the basket / tray or other carrier of product / component clearly states: • Name of the material • Its batch number • Its sterilization status Indicator (in case it has passed through sterilization process)	NA	The carrier/basket /tray has clear-cut identification with name of material, Batch no.,sterilization states. Appropriate sterilization indicator is used for each load and it is preserved as evidence of sterilization.	The carrier/basket /tray do not have status label indicating sterilization status, name of material, Its batch/lot number. Indicator not placed during sterilization. Indicator not preserved.	NA
26.10	Sch-M	Whether sterilization records including thermographs and sterilization monitoring slips attached with the Batch Production Record	NA	Thermographs and Sterilization indicators are preserve and are part of Batch processing record. These records are reviewed for batch release.	Manual temperature recording available but thermographs are not preserved. Sterilization monitoring slips not attached with Batch records and not preserved. The thermographs and sterilization monitoring slips not reviewed for batch release. (No signatures)	NA
27 Sterilization (By Dry Heat)						
27.1	Sch-M	Whether the sterilization cycle recording device of suitable size and precision provided in DHS./ Tunnel	NA	DHS./ Tunnel was found provided with recording device of suitable size and precision for sterilization cycle recording.	DHS./ Tunnel was found not provided with recording device of suitable size and precision for sterilization cycle recording.	NA

			Quality Rating			
S.No	Reference		2	1	0	X
27.2	Sch-M	Whether the position of temperature probes used for controlling and / or recording determined during validation and (where applicable) been checked against a second independent temperature probe located in the same position	NA	The temperature probe(RTD or thermocouple) was found placed at coolest spot determined during validation by independent calibrated prob. The temperature of same probe was found recorded and the recording is continuous through the cycle/	The control probe was found not at exactly same position of coolest point. The temperature recording was found not continuous. The validation was found not performed by independent probe at the same position/suitable position that of control probe	NA
27.3	Sch-M	Whether the chart forms a part of the batch record.	NA	Temperature Chart/ Thermograph was found part of batch record.	Temperature Chart/ Thermograph was found not part of batch record. Thermograph not preserved.	NA
27.4	Sch-M	Whether sterilization cycle validated only by biological indicator and chemical indicators or physical validation is also carried out	NA	Sterilization cycle validated physically by thermal mapping along with biological and chemical indicators. During validation sterilization parameters are established e.g. 1) For DHS Temperature, duration, positive pressure 2) For tunnel , temperature,duration,speed of conveyor etc.	Physical verification by thermal mapping for heat distribution and heat penetration was found not carried out.	The sterilizers are not studied for heat distribution / penetration. Effectiveness of sterilization process not established by using microbial spore indicators.
27.5	Sch-M	Whether the time allowed reaching the required temperature before commencing the measurement of sterilizing time, separately determined for each type of load.	NA	Lag time was found determined for all load types. The lag rimes was found specified in SOP for routine sterilization	The sterilization time is measured without considered established lag time.	NA
27.6	Sch-M	Are adequate precautions taken to protect the load during cooling after it has gone through the high temperature phase of a heat sterilization cycle	NA	Adequate precaution was found taken to protect the load during cooling after it has gone through the high temperature phase of a heat sterilization cycle.	No adequate precaution was found taken to protect the load during cooling after it has gone through the high temperature phase of a heat sterilization cycle.	NA
27.7	Sch-M	In case the cooling is affected with any fluid or gas in contact with the product , is it sterilized.	NA	Cooling air was found filtered through HEPA filters	Cooling air was found not filtered through HEPA filters	NA
27.8	Sch-M	Whether the equipment air inlet and outlets been provided with bacteria retaining filters	NA	Inlet and outlet was found provided with HEPA filters.	Inlet and outlet was found not provided with HEPA filters.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
27.9	Sch-M	In the process of sterilization by dry heat, does the equipment have: 1 Air circulation facility within the chambers 2 Positive pressure to prevent entry of non-sterile air	NA	1) Efficient blowers/fans was found provided for air circulation in sterilizer. 2) Positive pressure was found maintained in the chamber which is monitored by magnahelic gauges with established differential pressure limits.	1) Air circulation is not effective due to faulty or inefficient blower system 2) The positive pressure not monitored through out the sterilization cycle. 3) The limits for differential pressure not adequately established. 4) No records of positive pressure	NA
27.10	WHO TRS-961 ANNEXE-06	Verify the sterilizer loading pattern & whether is complied with the validated loading pattern.	Validated load pattern with pressure -vacuum cycle, was found established. Bowie dick test was found performed periodically.	NA	NA	NA
27.11	Sch-M	Whether the process of dry heat sterilization intended to remove the pyrogens If so, has the validation been done with challenge tests using endo-toxins	NA	Endotoxin challenge test was found performed to ensure three log reduction.	Endotoxin challenge test was found not performed to ensure three log reduction.	NA
28.Sterilization (By Moist Heat)						
28.1	Sch-M	Whether recording of both temperature and pressure carried out to monitor the process	NA	Temperature and pressure was found monitored as per specified SOP	Temperature and pressure was found not monitored as per specified SOP	NA
28.2	Sch-M	Whether the control instrumentation independent of the monitoring instrumentation and recording charts.	NA	There are multiple probes inside chamber. Probe at coolest point is controlling probe and other probes are monitoring prob. Recording is done with the controlling probe values	No monitoring done in routine sterilization except with controlling prob. Recording throughout the chamber not performed for uniform sterilization in routine.	NA
28.3	Sch-M	Whether the equipment has automated control and monitoring system, if so, have these been validated to ensure that critical process requirements are met.	NA	Equipment have automated control system and monitoring . Which ensures sterilization temperature, duration and pressure as per the established parameters. Effective alarm system is installed to notice the discrepancies during sterilization process. The automated system is validation for performance	1) Automated control and monitoring system is not properly functioning and manual interventions required. 2) Validation does not included alarm testing	NA
28.4	Sch-M	Whether the system and cycle faults are recorded inbuilt and also observed by the operator and record maintained.	NA	System and cycle faults were found recorded in-built. System and cycle faults are noticed and alarmed to operator. The suitable alarm record system available. With critical faults the cycle is aborted or appropriate action is taken by system	System and cycle faults are not recorded.	NA

			Quality Rating			
S.No	Reference		2	1	0	X
28.5	Sch-M	Whether the readings of the thermograph during sterilization cycling are routinely checked by the operator against the reading shown by the dial thermometer fitted with autoclave.	NA	Operator was found recording the temperature in checklist or BMR during the sterilization cycle after defined time interval.	Operator was found not recorded temperature / or missed the entries in checklist or BMR during the sterilization cycle.	NA
28.6	Sch-M	Whether the sterilizer fitted with a drain at the bottom of the chamber If so, does the record of temperature at this position is recorded through out the sterilizing period	NA	The sterilizer was found fitted with drain and the drain temperature is recorded through the sterilizing period.	The drain temperature was found not recorded through out the sterilization cycle.	NA
28.7	Sch-M	Are frequent leak tests conducted on the chamber of the autoclave on each day of operation.	NA	Leak test with prespecified limits as per SOP was found performed daily.	Leak test with prespecified limits as per SOP was found not performed daily.	NA
28.8	Sch-M	Whether all items to be sterilized (other than sealed containers) are wrapped for sterilization.	NA	All items were found wrapped in suitable steam penetrable wrappers.	Items to be sterilized are not wrapped during sterilization. The wrapping paper does not withstand stem sterilization	NA
28.9	Sch-M	Whether the wrapping material allows removal of air and penetration of steam ensuring contact with the sterilizing agent at the required temperature for required time	NA	The items to be sterilized, other than products in sealed containers, was found wrapped in a material that allows the removal of air and the penetration of steam but prevents recontamination after sterilization. Specially designed autoclavable stainless steel containers, that allow steam to enter and air to leave are used. All parts of the load are in contact with saturated steam at the required temperature for the specified time.	Wrapping paper does not allow the penetration of steam adequately.	NA
28.10	Sch-M	Whether the wrapping prevent contamination after sterilization	NA	It was observed that the wrapping prevent contamination after sterilization	It was observed that the wrapping may not prevent contamination after sterilization	NA

S.No	Reference		Quality Rating			
			2	1	0	X
28.11	Sch-M	Whether the steam used for sterilization is of suitable quality and doesn't contain additives at a level which could cause contamination of the product or equipment	NA	The steam generating boilers and distribution systems is validated and the monitoring is done by suitable laboratory analysis of the steam and feed water samples; There is periodic maintenance of the steam generating equipment and the distribution pipe-lines until point of use. Steam used for STERILIZATION is tested for (chemical, microbiological and endotoxin analysis of condensate and physical examination of steam (such as dryness, superheat, and non-condensable gases) and does not contain additives at a level that could cause contamination of the product or equipment. Steam used for sterilization is tested regularly	The quality of steam used for sterilization that comes in direct contact with the product to be sterilized was found not verified. There is no testing performed to check the quality of steam.	NA
29. Others						
29.1	Sch-M	Specify whether products released only after complete filling and testing.	NA	Products were found released only after complete filling and testing.	Products were found released before complete filling and testing.	NA
29.2	Sch-M	Specify whether result of the tests relating to sterility, bacterial endo-toxins are maintained in the analytical records	NA	Result of the tests relating to sterility, bacterial endo-toxins was found maintained in the analytical records	Result of the tests relating to sterility, bacterial endo-toxins was not available but products were found released	Batches failing initial sterility test are released for sale on the basis of a second test without proper investigation.
29.3	WHO TRS-961 ANNEXE-06	Whether process hold time studies has been carried out for various stages of production	Process hold time studies was found carried out for various stages of production	NA	NA	NA
30. Documentation and Records						
30.1	Sch-M	Whether all daily documents are filled correctly and timely.	NA	Daily documents was found filled correctly and timely.	Daily documents was found not filled correctly and timely.	NA
30.2	Sch-M	How the documents are designed, prepared, reviewed and controlled to provide an audit trail.	NA	Specific SOP was found prepared and followed in this regard.	No specific SOP was found prepared and followed in this regard.	NA
30.3	Sch-M	Whether documents are approved signed and dated by appropriate and authorized person.	NA	Documents was found approved, signed and dated by appropriate and authorized person.	Documents was found not approved, signed and dated by appropriate and authorized person.	NA
30.4	Sch-M	Whether documents specify title, nature and purpose.	NA	Yes	No	NA
30.5	Sch-M	Whether documents are regularly reviewed and kept up to date.	NA	Documents was found regularly reviewed and kept up to date as per the specified SOP.	Documents was found not regularly reviewed and kept up to date as per the specified SOP.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
30.6	Sch-M	Whether the records are made at the time of each operation in such a way that all significant activities concerning to the production are traceable.	NA	Records was found made at the time of each operation in such a way that all significant activities concerning to the production are traceable.	Records was found not made at the time of each operation.	NA
30.7	Sch-M	Whether data is recorded by electronic data processing system or by other means. If by electronic data processing system then how access is controlled to enter, modify etc. the data.	NA	Data was found properly recorded through electronic system with proper access control.	Data was found not properly recorded.	NA
30.8	Sch-M	Whether master formula and detailed operating procedures for each product are available?	NA	Master formula and detailed operating procedures for each product was available.	Master formula and detailed operating procedures for each product was not available.	No written Master Formula Records.
30.9	Sch-M	Specify the duration of retaining the documents after the expiry of the respective product and who is responsible for its maintenance.	NA	1 year after expiry of the product and QA is responsible for its maintenance.	No records could be produced in this regard	NA
		Do the manufacturing records pertaining to manufacture of Sterile & Non- Sterile products indicate the following details: Serial number of Batch Manufacturing ,Record ,Name of the product, Reference to Master Formula Record, Batch/ Lot number, Batch/ Lot size, Date of commencement and completion of manufacture, Date of manufacture and assigned date of expiry, Date of each step in manufacturing, Names of all ingredients with reference number given by the quality control department ,Quantity of all ingredients, Time and duration of blending, mixing etc. where ever applicable, PH of solutions whenever applicable, Filter integrity testing records, Temperature and humidity records whenever applicable, Records of plate-counts whenever applicable, Results of bacterial endo-toxin and toxicity, Records of weight or volume of drug filled in containers, Bio burden records before sterilisation, Leak test records, Inspection records, Sterilization records including load details, date, duration, temperature, pressure etc. Container washing & testing records, Total number of containers filled, Total number of containers rejected at each stage, Theoretical yield, permissible yield, actual yield and variation there of, Clarification for variation in yield ,beyond permissible yield, Reference number of relevant analytical reports, Details of re-processing, if any, Names of all operators	NA	All relevant records as specified under Sch.M was found maintained. Some of the records verified during inspection and found satisfactory.	All relevant records as specified under Sch.M was found not maintained.	NA
31 Labels and Other Printed Materials:-						
31.1	Sch-M	Whether the printing is in bright colour and legible on labels and other printed materials?	NA	Printing on labels and other printing materials was found bright in colour and legible	Printing on labels and other printing materials was found not bright in colour and legible	NA
31.2	Sch-M	How printed labels (art work) are approved. Verify the SOP.	NA	Specified SOP was found in place in this regard.	No specified SOP was found in place in this regard.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
31.3	WHO TRS-986	Specify whether cut labels or rolled labels are used.	Rolled labels were found used	NA	NA	NA
31.4	Sch-M	Whether the labels comply with requirements of Rule 96 & 97 & other relevant provisions	NA	Labels were found comply with requirements of Rule 96 & 97 & other relevant provisions in all respects	Labels were found not comply with requirements of Rule 96 & 97 & other relevant provisions in all respects	NA
32 Master Formula Records: -						
32.1	Sch-M	How master formula records for each product are prepared, authorized and controlled.	NA	Master formula records for each product was found prepared, authorized and controlled as prescribed in Sch.M	Master formula records for each product was found not prepared, authorized and controlled as prescribed in Sch.M	NA
32.2	Sch-M	Whether master formula is batch size specific.	NA	Master formula was found batch size specific	Master formula was found not batch size specific	NA
32.3	Sch-M	Whether master formula record covers all the points as prescribed in Schedule 'M'.	NA	Master formula record was found covers all the points as prescribed in Schedule 'M'.	Master formula record was found not covers all the points as prescribed in Schedule 'M'.	No written Master Formula Records.
32.4	WHO TRS-986	Whether master formula record covered all the points as prescribed in WHO-TRS 986 & PIC/S guidelines	Master formula record was found covered all the points as prescribed in WHO-TRS 986 & PIC/S guidelines	NA	NA	NA
33 Batch Processing / Manufacturing Records:-						
33.1	Sch-M	Whether the BPR/BMR for each product is prepared on the basis of currently approved master formula.	NA	BPR/BMR for each product was found prepared on the basis of currently approved master formula.	BPR/BMR for each product was found not prepared on the basis of currently approved master formula.	NA
33.2	Sch-M	Whether BPR / BMR covered all the points as prescribed in Schedule 'M'	NA	BPR / BMR was found covered all the points as prescribed in Schedule 'M'	BPR / BMR was found not covered all the points as prescribed in Schedule 'M'	NA
33.3	WHO TRS-986	Whether BPR / BMR covered all the points as prescribed in WHO-TRS 986 & PIC/S	BPR / BMR was found covered all the points as prescribed in WHO-TRS 986 & PIC/S	NA	NA	NA
33.4	Sch-M	Whether all the documents generated during Batch production are attached with the BPR /BMR	NA	All the documents generated during Batch production was found attached with the BPR /BMR	All the documents generated during Batch production was found not attached with the BPR /BMR	NA
34 Batch Packaging Records: -						
34.1	Sch-M	Whether authorized packaging instructions for each product of various pack size and type are maintained and complied with.	NA	Authorized packaging instructions for each product of various pack size and type were found maintained and complied with.	Authorized packaging instructions for each product of various pack size and type were found not maintained and complied with.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
34.2	Sch-M	Specify whether all material, equipment, rooms and packaging lines are labelled with an indication of product being processed with batch no.	NA	All material, equipment, rooms and packaging lines were found labelled with an indication of product being processed with batch no.	All material, equipment, rooms and packaging lines were found not labelled with an indication of product being processed with batch no.	NA
34.3	Sch-M	Whether packaging lines are independent and adequately segregated.	NA	Packaging lines were found independent and adequately segregated.	Packaging lines were found not independent and adequately segregated.	NA
34.4	Sch-M	How line clearance is performed. Whether records of line clearance is maintained according to appropriate checklist.	NA	Specific SOP was found in place in this regard and records found maintained.	NO Specific SOP was found in place in this regard and records found not maintained.	NA
34.5	Sch-M	Do the packaging materials arrive on a covered trolley?	NA	Packaging materials was found arrive on a covered trolley	Packaging materials was found not arrive on a covered trolley	NA
34.6	Sch-M	Are packaging materials verified against a master set to ensure that they are the most recent edition and the correct materials for the batch?	NA	Packaging materials were found verified against a master set to ensure that they are the most recent edition and the correct materials for the batch.	Packaging materials were found not verified against a master set to ensure that they are the most recent edition and the correct materials for the batch.	NA
34.7	Sch-M	Are the quantities of packaging materials verified against the amounts stated as dispensed from the warehouse?	NA	Quantities of packaging materials was found verified against the amounts stated as dispensed from the warehouse	Quantities of packaging materials was found not verified against the amounts stated as dispensed from the warehouse	NA
34.8	WHO TRS-986	Specify the monitoring code (bar code, pinholes etc.) for final packing materials.	Monitoring code (bar code, pinholes etc.) for final packing materials was found followed as per prescribed SOP.	NA	NA	NA
34.9	Sch-M	Is the batch yield calculated immediately upon completion of packaging operation & prior to the introduction of a new batch into the area?	NA	Batch yield was found calculated immediately upon completion of packaging operation & prior to the introduction of a new batch into the area	Batch yield was found not calculated immediately upon completion of packaging operation & prior to the introduction of a new batch into the area	NA
34.10	Sch-M	Is the yield calculation independently verified by second individual and whether any significant deviation from accepted yield is recorded and investigated?	NA	Yield calculation was found independently verified by second individual and any significant deviation from accepted yield is recorded and investigated.	Yield calculation was found not independently verified by second individual and any significant deviation from accepted yield is not recorded and investigated.	NA
34.11	Sch-M	Is any excess printed packaging material destroyed on completion of the batch?	NA	Excess printed packaging material was found destroyed on completion of the batch	No records could be produced in this regard	NA

S.No	Reference		Quality Rating			
			2	1	0	X
34.12	Sch-M	Is there a provision in the department for the separation of printed packaging material for destruction & rejected product?	NA	Specific SOP was found in place in this regard.	No specific SOP was found in place in this regard.	NA
34.13	Sch-M	Whether Batch packaging record covered all the points as prescribed in Schedule 'M'	NA	Batch packaging record was found covered all the points as prescribed in Schedule 'M'	Batch packaging record was found not covered all the points as prescribed in Schedule 'M'	NA
34.14	WHO TRS-986	Whether Batch packaging record covered all the points as prescribed in WHO-TRS 986 & PIC/S	Batch packaging record was found covered all the points as prescribed in WHO-TRS 986 & PIC/S	NA	NA	NA
34.15	Sch-M	Whether all the documents generated during packaging are attached with the Batch packaging record.	NA	All the documents generated during packaging was found attached with the Batch packaging record.	All the documents generated during packaging was found not attached with the Batch packaging record.	NA
34.16	Sch-M	Whether BPR are based on current master formula record.	NA	BPR was found based on current master formula record.	BPR was found not based on current master formula record.	NA
35 Standard Operating Procedure and Records: -						
35.1	Sch-M	Verify the List of SOPs and mention total number of SOPs followed by the firm.	NA	All relevant SOPs were found in place.	More SOPs are required to be prepared.	NA
35.2	Sch-M	Has all the SOPs been displayed.	NA	All SOPs found displayed.	All SOPs found not displayed.	NA
35.3	Sch-M	The formats, logs & SOPs are current	NA	Formats, logs & SOPs were found current and updated.	Formats, logs & SOPs were found not current and updated.	NA
35.4	Sch-M	Is any obsolete copy seen in the Area?	NA	No obsolete copy was seen in the Area	Some obsolete copy was seen in the Area	NA
36 Reprocessing and Recoveries:-						
36.1	Sch-M	Verify the SOP for reprocessing.	NA	Specific SOP was found in place for reprocessing.	No specific SOP was found in place for reprocessing.	NA
36.2	WHO TRS-986	Whether reprocessed batch is subjected to stability evaluation.	Reprocessed batch was found subjected to stability evaluation.	NA	NA	NA
36.3	Sch-M	Whether the recoveries are added into the subsequent batches. If yes specify the procedures.	NA	Specific SOP was found in place to add recoveries into subsequent batches.	No specific SOP was found in place to add recoveries into subsequent batches.	NA
37 Finished Product:-						
37.1	Sch-M	Specify whether finished products are held in quarantine until their final release.	NA	Finished products were found held in quarantine until their final release.	Finished products were found not held in quarantine until their final release.	NA
37.2	Sch-M	Specify the storage arrangement of finished products after final release by QA	NA	Adequate storage arrangement was found provided for finished products after final release by QA.	Storage arrangement was found inadequate for finished products.	NA
38 Quality Control Area: -						

			Quality Rating			
S.No	Reference		2	1	0	X
38.1	Sch-M	Specify whether QC area is independent of production area.	NA	QC area was found independent of production area.	QC area was found adjacent to production area.	NA
38.2	Sch-M	Specify the working space provided for QC:	NA	Adequate working space was found provided for QC.	Working space provided for QC was found inadequate.	NA
38.3	Sch-M	Specify the procedure followed for approval/rejection of raw materials, packaging materials, intermediate products and finished products. Verify the SOP and record.	NA	Specific SOP was found in place in this regard and records found maintained.	No specific SOP was found in place in this regard.	NA
38.4	Sch-L1	Specify the arrangement provided to protect sensitive electronic balances from vibrations, electrical interference, humidity etc.	NA	Temperature and humidity control room was found provided to protect sensitive electronic balances from vibrations, electrical interference, humidity etc.	Temperature and humidity control room was found not provided to protect sensitive electronic balances from vibrations, electrical interference, humidity etc.	NA
38.5	Sch-L1	Specify the safety measures taken to avoid any accidental hazards in the QC department.	NA	Proper safety measures like Air showers etc. was found provided to avoid any accidental hazards in the QC department.	No safety measures like Air showers etc. was found provided to avoid any accidental hazards in the QC department.	NA
38.6	Sch-M	Specify whether separate washing and drying area is provided for glassware	NA	Separate washing and drying area was found provided for glassware	No separate washing and drying area was found provided for glassware	NA
38.7	Sch-L1	Specify which grade of glassware is used in assay procedures and whether they are certified/calibrated. Verify the certificates and calibration records.	NA	Certified and calibrated glassware was found provided.	Certified and calibrated glassware was found not provided.	NA
38.8	Sch-M	Specify whether any particular test is outsourced. If so mention the name of laboratory and verify the contract made in this regard.	NA	Outsource laboratory was found mentioned in the licence.	Outsource laboratory was found not mentioned in the licence.	NA
39 Microbiology Lab						
39.1	Sch-M	Whether separate AHU's are provided for microbiological testing areas.	NA	Separate AHU's was found provided for microbiological testing areas.	Separate AHU's was found not provided for microbiological testing areas.	NA
39.2	Sch-M	Whether support areas are under same AHU which is used for sterile area.	NA	Support areas were found under different AHU.	Support areas were found under same AHU which is used for sterile area.	NA
39.3	Sch-M	Briefly describe layout of the microbiology lab (attach copy of the layout if available)	NA	Layout of the microbiology lab was found satisfactory.	Layout of the microbiology lab was found not satisfactory.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
39.4	Sch-M	Whether entry to the sterile area is through three air lock systems with separate exit	NA	Entry to the sterile area was found through three air lock systems with separate exit	Entry to the sterile area was not found through three air lock systems with separate exit	NA
39.5	WHO TRS-986	Specify whether access in sterile area is controlled, and if so the system followed in this regard	Access in sterile area was found controlled through access control (Biometric) system.	NA	NA	NA
39.6	Sch-M	Verify the list of equipment used in the microbiological lab and also specify whether these are placed logically and function accurately	NA	Equipment used in the microbiological laboratory was found adequate and comply with the requirements.	Equipment used in the microbiological laboratory was found not adequate and comply with the requirements.	NA
39.7	Sch-M	Specify whether operators are trained in gowning procedures. Verify the training records.	NA	Operators were found trained in gowning procedures. Training records found maintained.	Operators were found not trained in gowning procedures.	NA
39.8	Sch-L1	Specify the gowning procedure to enter the sterile area. Verify the entry and exit records.	NA	Specific SOP for gowning procedure to enter the sterile area was found in place and records found maintained.	No specific SOP for gowning procedure to enter the sterile area was found in place.	NA
39.9	Sch-L1	Specify the air class of sterile areas and whether pressure difference is maintained. Verify the records.	NA	Pressure differential was found maintained in the sterile areas.	Pressure differential was found not maintained in the sterile areas.	NA
39.10	WHO TRS-986	Specify whether an environmental monitoring programme is followed with alert and action limit.	Environmental monitoring programme was found followed with alert and action limit.	NA	NA	NA
39.11	Sch-M	Specify whether a documented cleaning and disinfection programme is in place.	NA	Documented cleaning and disinfection programme was found in place.	No documented cleaning and disinfection programme was found in place.	NA
39.12	WHO TRS-986	Specify whether a procedure for dealing with spillages in sterile area is in place.	Procedure for dealing with spillages in sterile area was found in place.	NA	NA	NA
39.13	WHO TRS-986	Whether separate areas provided for sterility testing, assay of antibiotics & vitamins and MLT in sterile area.	Separate areas was found provided for sterility testing, assay of antibiotics & vitamins and MLT in sterile area.	NA	NA	NA
39.14	Sch-M	Specify the type of workstations (LAF) provided in the sterile area.	NA	Vertical LAF was found provided.	Vertical LAF was found not provided.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
39.15	Sch-M	Whether double door autoclave is provided for transferring of materials from unclassified area to sterile area.	NA	Double door autoclave was found provided for transferring of materials from unclassified area to sterile area.	Double door autoclave was found not provided for transferring of materials from unclassified area to sterile area.	NA
39.16	WHO TRS-986	Verify the area qualification document for sterile area.	Qualification documents for sterile area including IQ.OQ.& PQ was found in place.	NA	NA	NA
39.17	WHO TRS-986	Verify the procedure for selection of sampling location and interpretation of results for environmental monitoring of sterile area along with the SOP and documents. (Specify whether the method is in compliance with ISO 14644-1).	The procedure presently followed was found in compliance with ISO 14644-1	NA	NA	NA
39.18	Sch-L1	Specify whether qualification of all equipment and instruments used in this department is covered under VMP.	NA	Qualification of all equipment and instruments used in this department was found covered under VMP.	Qualification of all equipment and instruments used in this department was found not covered under VMP.	NA
39.19	Sch-L1	Verify the qualification document of major equipment like autoclave/incubator, hot air oven, refrigerator, LAF etc.	NA	Qualification document of major equipment like autoclave/incubator, hot air oven, refrigerator, LAF etc. were verified and found satisfactory.	No document could be produced in this regard.	NA
39.20	Sch-L1	Specify the Calibration procedure of temperature measurement devices used in autoclave and incubator. Verify whether it is traceable to standard temperature.	NA	Calibration procedure of temperature measurement devices used in autoclave and incubator was found elaborately specified in a SOP and it is traceable to standard temperature.	No such procedure was found followed.	NA
39.21	Sch-M	Verify the procedure for the handling and disposal of chemical and microbial waste.	NA	Specific SOP was found in place for the handling and disposal of chemical and microbial waste.	No SOP was found in this regard	NA
39.22	WHO TRS-986	Specify the procedure followed to verify the validity of the test in case of antibiotic potency testing.	Judicial limits of error was found calculated as per standard statistical analysis.	NA	NA	NA
39.23	WHO TRS-986	Specify whether there is separate autoclave for decontamination.	Separate autoclave for decontamination was found provided.	NA	NA	NA
39.24	WHO TRS-986	Specify whether the Vendors for dehydrated media is approved and qualified.	Vendors for dehydrated media was found approved and qualified.	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
39.25	WHO TRS-986 / IP	Specify whether GPT is carried out for dehydrated media.	GPT was found carried out for dehydrated media	NA	NA	NA
39.26	Sch-L1	Specify whether performance of culture media (recovery or survival maintenance) is carried out and the results meet acceptance criteria.	NA	Performance of culture media (recovery or survival maintenance) was found carried out and the results meet acceptance criteria.	Performance of culture media (recovery or survival maintenance) was found not carried out.	NA
39.27	Sch-L1	Specify the source of procurement of reference culture and its maintenance.	NA	Reference culture was found procured from Microbial Institute of Technology, Chandigarh (MIT)	No procurement records could be produced.	NA
39.28	Sch-L1	Specify the Air Grades for following areas: —Sterility testing room —Microbiological Assay room —MLT room —Airlocks (entry and exit both)	NA	Sterility testing room-Grade A Microbiological Assay room-Grade A MLT room-Grade A Airlocks (entry and exit both)-Grade B,C & D	No documents could be produces regarding air grades in the following classified area : —Sterility testing room —Microbiological Assay room —MLT room —Airlocks (entry and exit both)	NA
39.29	Sch-M	Verify the following records: —Log book for the entry/exit in the sterile area —media preparation record —records for water testing (micro) —records for MLT	NA	Following records were checked and found satisfactory and updated. —Log book for the entry/exit in the sterile area —media preparation record —records for water testing (micro) —records for MLT	Records regarding the following were found not updated —Log book for the entry/exit in the sterile area —media preparation record —records for water testing (micro) —records for MLT	NA
39.30	IP	Verify how the concentration of the inoculums is determined.	NA	Concentration of the inoculums was found determined as prescribed in IP.	Concentration of the inoculums was found not determined as prescribed in IP.	NA
39.31	Sch-M	Whether firm has provided microbiology lab for MLT test for nonsterile dosage form. If no how this test is complied.	NA	The firm was found carry out MLT in their on testing lab for which Microbiology lab has been set up.	Neither any microbiology laboratory has been set up nor the test for MLT is outsourced	NA
40 Quality Control System: -						
40.1	Sch-L1	Specify the source of procurement of various reference standards	NA	IPC, Ghaziabad BP USP	Could not produce any document in this regards.	NA
40.2	Sch-L1	How the reference standards are stored, evaluated and maintained.	NA	Specific SOP was found in place in this regard.	No specific SOP was found in place in this regard.	NA
40.3	WHO TRS-986	Specify whether authorized access system is followed for reference standards.	Authorized access system was found followed for reference standards.	NA	NA	NA

			Quality Rating			
S.No	Reference		2	1	0	X
40.4	Sch-L1	Verify the SOP and records for preparation of working standard from the reference standard.	NA	Specific SOP was found in place in this regard.	No specific SOP was found in place in this regard.	NA
40.5	Sch-L1	Verify the SOP and records for destruction of unused working standard	NA	Specific SOP was found in place in this regard.	No specific SOP was found in place in this regard.	NA
40.6	Sch-M	Verify the sampling SOPs and records for: —starting materials —primary packaging materials —secondary packaging materials —in process materials —finished products —water analysis —wash water analysis —swab analysis —wash water analysis of cleaned garments	NA	All the relevant SOPs and related records were found in place.	No specific SOP was found in place in this regard.	NA
40.7	Sch-M	Specify whether approved specifications are available for all: —starting materials —primary packaging materials —secondary packaging materials —in process materials —finished products —water analysis —wash water analysis —swab analysis —wash water analysis of cleaned garments	NA	All the relevant approved specification and related records were found in place.	Approved specification and related records were found in place.	NA
40.8	Sch-L1	Verify whether all approved specifications are based on validation.	NA	All approved specifications were found based on validation.	All approved specifications were found not based on validation.	NA
40.9	WHO TRS-986	Is there any SOP for handling of OOS product (out of specification)?	SOP for handling of OOS product (out of specification) was found in place.	NA	NA	NA
40.10	WHO TRS-986	Specify the procedure for review of test data & calculations.	Specific SOP was found in place for review of test data & calculations.	NA	NA	NA
40.11	Sch-L1	Specify whether a designated person is responsible for receipt of samples for testing.	NA	Designated person was found responsible for receipt of samples for testing.	No designated person was found responsible for receipt of samples for testing.	NA
40.12	Sch-L1	Specify the procedure followed for receiving and recording (logging in). Verify the SOP and records	NA	Specific SOP was found in place in this regard.	No specific SOP was found in place in this regard.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
40.13	Sch-L1	Specify the procedure for storage and distribution of received samples to different analyst.	NA	Specific SOP was found in place for storage and distribution of received samples to different analyst.	No specific SOP was found in place in this regard.	NA
40.14	Sch-L1	Is there a maximum time limit for retention of sample in the laboratory prior to testing?	NA	Maximum time limit for retention of sample in the laboratory prior to testing was found mentioned in the relevant SOP.	No specific SOP was found in place in this regard.	NA
40.15	Sch-L1	Specify the procedure followed for preparation, consumption & destruction of volumetric solution. Verify the SOP and records.	NA	Specific SOP was found in place for preparation, consumption & destruction of volumetric solution. Verify the SOP and records.	No specific SOP was found in place in this regard.	NA
40.16	Sch-L1	Specify whether there is a log book for the preparations of the reagent including name of the analyst, name of the reagent, Calculations, Date of preparation & expiration.	NA	Log book for the preparations of the reagent including name of the analyst, name of the reagent, Calculations, Date of preparation & expiration log books was found in place.	No log book was found in place.	NA
40.17	Sch-L1	Specify the procedure followed for using GR, LR and AR grade of chemicals / solvents used for calibration & sample testing.	NA	Specific SOP was found in place for using GR, LR and AR grade of chemicals / solvents used for calibration & sample testing.	No specific SOP was found in place in this regard.	NA
40.18	Sch-L1	Specify whether respective STP is followed by the analyst for analysis.	NA	Respective STP was found followed by the analyst for analysis.	No STP was found followed.	NA
40.19	Sch-L1	Specify the procedure of reporting the result of analysis by the analyst to QC Head.	NA	Specific SOP was found followed for reporting the result of analysis by the analyst to QC Head.	No specific SOP was found in place in this regard.	NA
40.20	Sch-L1	Specify the procedure followed for storage of samples after testing.	NA	Specific SOP was found followed for storage of samples after testing.	No specific SOP was found in place in this regard.	NA
40.21	Sch-L1	Specify the procedure for retention of samples after testing is completed.	NA	Specific SOP was found followed for retention of samples after testing is completed.	No specific SOP was found in place in this regard.	NA
40.22	Sch-L1	Specify the procedure followed for issuance of COA.	NA	Specific SOP was found followed for issuance of COA.	No specific SOP was found in place in this regard.	NA
40.23	Sch-L1	Specify procedures for safe removal of waste from the laboratory.	NA	Specific SOP was found followed for safe removal of waste from the laboratory.	No specific SOP was found in place in this regard.	NA
40.24		Specify whether raw materials, intermediates and finished product testing is carried out as per specifications and raw data is maintained.	NA	Raw materials, intermediates and finished product testing was found carried out as per specifications and raw data was found maintained.	Raw materials, intermediates and finished product testing was found carried out partially and raw data not maintained.	1) Raw material testing, intermediate testing or finished product testing was found not carried out. 2) Raw data was found falsified

S.No	Reference		Quality Rating 2	1	0	X
41 Analytical Method Validation (AMV):-						
41.1	IP	Specify whether following Characteristics are considered during validation of analytical methods: — Specificity — Linearity — Range — Accuracy — Precision — Detection Limit — Quantification Limit — Robustness. —Solution Stability/Filter Study	NA	Following Characteristics were found considered during validation of analytical methods: — Specificity — Linearity — Range — Accuracy — Precision — Detection Limit — Quantification Limit — Robustness. —Solution Stability/Filter Study	Following Characteristics were found not considered during validation of analytical methods: — Specificity — Linearity — Range — Accuracy — Precision — Detection Limit — Quantification Limit — Robustness. —Solution Stability/Filter Study	NA
42 HPLC Calibration						
42.1	IP	Verify the records of calibration of following parameters: — Calibration of pump. — Calibration of Gradient proportionate valve (GPV). — Calibration of Auto injector. — Calibration of Detector. — Temperature calibration for Column oven and — Sample Trays compartment. — Auto Sampler Carry over. — Manual injector calibration — System suitability	NA	Records of calibration of following parameters were verified and found complied with IP: — Calibration of pump. — Calibration of Gradient proportionate valve (GPV). — Calibration of Auto injector. — Calibration of Detector. — Temperature calibration for Column oven and — Sample Trays compartment. — Auto Sampler Carry over. — Manual injector calibration — System suitability	Records of calibration of following parameters were verified and found not complied with IP: — Calibration of pump. — Calibration of Gradient proportionate valve (GPV). — Calibration of Auto injector. — Calibration of Detector. — Temperature calibration for Column oven and — Sample Trays compartment. — Auto Sampler Carry over. — Manual injector calibration — System suitability	NA
43 Dissolution Apparatus Calibration						

			Quality Rating			
S.No	Reference		2	1	0	X
43.1	IP	Verify the records of calibration of following parameters: —Checking of RPM —Checking of Temperature —Checking of distance between inside bottom of the vessel & paddle —Checking of distance between inside bottom of the vessel & Basket —Checking Wobbling of paddle —Checking of Wobbling of Basket —Checking of Timer: Calibrate against standard stop watch —Performance verification test **[Verify whether dissolution is calibrated against standard prednisolone tablets]**	NA	Records of calibration of following parameters verified and found complied with IP : —Checking of RPM —Checking of Temperature —Checking of distance between inside bottom of the vessel & paddle —Checking of distance between inside bottom of the vessel & Basket —Checking Wobbling of paddle —Checking of Wobbling of Basket —Checking of Timer: Calibrate against standard stop watch —Performance verification test Dissolution was found calibrated against standard prednisolone tablets	Records of calibration of following parameters verified and found not complied with IP : —Checking of RPM —Checking of Temperature —Checking of distance between inside bottom of the vessel & paddle —Checking of distance between inside bottom of the vessel & Basket —Checking Wobbling of paddle —Checking of Wobbling of Basket —Checking of Timer: Calibrate against standard stop watch —Performance verification test Dissolution was found not calibrated against standard prednisolone tablets	NA
44 UV-VIS						
44.1	IP	Verify the records of calibration of following parameters: —Control of wavelengths (Wavelength accuracy) —Control of absorbance (Photometric accuracy) —Limit Of Stray Light —Resolution Power —Resolution (second order derivative spectrum) —CELLS Verification —I0 flatness —Calibration of Visible Wavelength —Calibration of absorbance reproducibility for visible wavelength —Photometric linearity at 430nm	NA	Records of calibration of following parameters verified and found complied with IP : —Control of wavelengths (Wavelength accuracy) —Control of absorbance (Photometric accuracy) —Limit Of Stray Light —Resolution Power —Resolution (second order derivative spectrum) —CELLS Verification —I0 flatness —Calibration of Visible Wavelength —Calibration of absorbance reproducibility for visible wavelength —Photometric linearity at 430nm	Records of calibration of following parameters verified and found not complied with IP : —Control of wavelengths (Wavelength accuracy) —Control of absorbance (Photometric accuracy) —Limit Of Stray Light —Resolution Power —Resolution (second order derivative spectrum) —CELLS Verification —I0 flatness —Calibration of Visible Wavelength —Calibration of absorbance reproducibility for visible wavelength —Photometric linearity at 430nm	NA
46 FTIR						

S.No	Reference		Quality Rating			
			2	1	0	X
46.1	IP	Verify the records of calibration of following parameters: —Verification of the wave number scale —Control of resolution performance	NA	Records of calibration of following parameters verified and found complied with IP —Verification of the wave number scale —Control of resolution performance	Records of calibration of following parameters verified and found not complied with IP —Verification of the wave number scale —Control of resolution performance	NA
47 TOC Analyser+						
47.1	USP	Verify the records of calibration of following parameters: —System suitability: —Calibration (Four point calibration)	NA	Records of calibration of following parameters verified and found complied with USP : —System suitability: —Calibration (Four point calibration)	Records of calibration of following parameters verified and found not complied with USP : —System suitability: —Calibration (Four point calibration)	NA
48 Stability Studies						
48.1	Sch-M	Specify whether stability study is carried out in the QC and if so, is there separate area for Stability Chamber for stability studies. How many Stability Chambers have been provided? Specify whether shelf life of the product is fixed on the basis of stability studies.	Separate stability area with 02 or more than 02 walk-in or vertical stability chambers are provided for accelerated, real time studies under the control of QC. The additional chambers are provided for stability studies at intermediate conditions. The stability chambers are provided with all required temperature and RH monitoring and control devices and records of such monitoring is maintained centrally by software. Shelf life of the product was found assigned on the basis of accelerated as well as real-time stability data.	02 or more than 02 Vertical stability chambers with all required temperature and RH conditions are provided under the control of QC. The Chart/records of temperature and RH are maintained. Shelf life of the product was found assigned on the basis of accelerated and/or real-time stability data.	1) No stability chambers or one/both stability chambers are out of order. 2) No temperature and RH records are maintained for stability chambers. 3) Records of the stability studies was found not maintained for assigning shelf life of the product.	No stability studies are performed either in-house or by way of outsourcing to assess the shelf life of the products before marketing and the expiry date of the product is fixed arbitrarily
48.2	WHO TRS-986	Verify the qualification documents of all the stability chambers.	All the stability chambers are qualified by following written validation protocol and reports. Further the routine temperature and RH is monitored and recorded through centralized software with Alarm system in case of excursions.	NA	NA	NA
48.3	WHO TRS-986	Specify whether a written programme for ongoing stability determination is in place.	SOP for stability studies including details of accelerated, real-time, and ongoing stability study is maintained. The criteria for carrying out stability study of every product per year is included.	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
48.4	WHO TRS-986	Specify whether a complete description of stability study is available.	The complete description of stability studies describing study type, protocols, reporting formats etc. are well defined.	NA	NA	NA
48.5	WHO TRS-986	Verify the stability calendar along with stability protocol and documents. Attach the copy of stability calendar	Product specific Stability study protocol and calendar are maintained	NA	NA	NA
48.6	WHO TRS-986	Specify whether the stability protocol indicates complete set of testing parameters and methods.	The stability protocol indicates complete set of testing parameters and methods as applicable to the products. The method for testing used is stability indicating method.	NA	NA	NA
48.7	WHO TRS-986	Specify whether summary of all generated data from the study are retained.	Stability summary report with Comparative results of all stations with conclusion is preserved.	NA	NA	NA
48.8	WHO TRS-986	Specify the testing schedule for each product	0,1,2,3,6, for accelerated 0,3,6,12,18,24,36,48,60 for real time	NA	NA	NA
48.9	WHO TRS-986	Specify whether stability study is performed after any significant changes in process equipment, packaging materials etc.	stability study is performed after any significant changes in process equipment, packaging materials etc. and found defined in VMP as well in SOP for stability studies and records were maintained. Additional comparative stability study report is also maintained.	NA	NA	NA
48.10	WHO TRS-986	Specify the validation method for stability chambers	stability chambers are validated by following written protocol and reports. IQ, OQ,PQ reports are available.	NA	NA	NA
48.11	WHO TRS-986	Specify the Temperature and humidity for real times studies carried out for fixing shelf life of drug in the country.	40ºC +75% for accelerated stability study and 30ºC +70% for real time for products to be stored around 30ºC. For product to be stored in cold conditions the real time long term stability study is carried out at 2-8ºC and accelerated study is carried out at /25ºc+65% to determine shelf life of product	NA	NA	NA
49 Quality assurance:-						

			Quality Rating			
S.No	Reference		2	1	0	X
49.1	Sch-M	Mention the documents prepared and maintained by QA department	QA function is elaborate and has role in document preparation, control, monitoring, etc. pertaining to all aspects having impact on quality and compliance. The QA is invariably involved in documents like SMF, VMP, Validation , SOPs, Protocols, MFRs, BMRs, Vendor approval, Product specification, In-process controls, Self inspection, Product release , product complaints, recall, APQR, QRM, Change and Deviation control, Technology transfer, Management review, Training, etc. prepared and maintained by QA.	SMF, VMP, Validation , SOPs, Protocols, BMRs, Product specification, In-process controls, Self inspection, Product release , etc.	BMRs, SOPs Product release etc. No other documents related to in-process control, validation, product complaint and recall etc.	1) No separate QA Department.
49.2	Sch-M	Specify the responsibility of the QA Head.	The QA head is responsible for release of Finished Product after verification of all relevant documents from production, QC, and other related department. The responsibility of QA head is well defined and approved by the management.	The QA head is responsible for relapse of FP after verification of all relevant documents from production, QC, and other related department. T	No QA head is appointed.	No QA function and QA head is not independent.
49.3	Sch-M	Specify the procedure followed by QA department to ensure the implementation of all SOPs in the plant.	The document control is function of QA. Well defined procedure for training to the respective personnel for each SOP is imparted and only after assessment the personnel is authorize to work in accordance with that SOP. Self inspection and quality audits are performed for verification of compliance of SOPs, GMP, GLP etc. and records/reports are maintained.	Training of SOPs and Self inspection and quality audits are performed for verification of compliance of SOPs, GMP, GLP etc. and records/reports are not maintained	No formal training and self inspection records are not maintained.	NA
49.4	Sch-M	Verify the total list of SOPs maintained by QA and how QA ensure that no obsolete SOP is in circulation.	Total list of SOP is maintained. New version of sops are issued only after retrieval of old version of SOP. The issuance & retrieval records are maintained for each controlled copy of SOP by QA.	Index of SOPs are maintained. Current version of SOP are available at respective place. No records for issuance and retrieval of controlled copy of SOP are maintained.	Both obsolete and current version of SOP found at working place.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
49.5	WHO TRS-986	Specify whether any procedure is followed for preparation of SOPs and its circulation to all concerned. How master, controlled and uncontrolled copy of SOPs are processed.	SOP for SOP defines procedure for preparation of SOPs and its circulation to all concerned and maintenance of master, controlled and uncontrolled copy of SOPs with format of SOP, type of identification for master, controlled and obsolete version.	NA	NA	NA
49.6	WHO TRS-986	Mention the change control procedures & examine three recent change control forms.	Well defined procedure for recording of changes, evaluation, impact assessment and implementation of change controls are maintained. Change control log and detailed documents are maintained.	NA	NA	NA
49.7	WHO TRS-986	Specify the procedures followed to ensure CAPA process. Verify the SOP and three recent records in this regard.	The well defined written procedure are in place for reporting of incidences or deviations and its follow up (CAPA process). The records of outcome are maintained.	NA	NA	NA
49.8	WHO TRS-986	How deviation are controlled. Verify SOP and three recent deviations. Specify whether all deviations are reported and records maintained.	The well defined written procedure in place for handling/investigation of deviation. Records are maintained with respect to reported deviations.	NA	NA	NA
49.9	Sch-M	Is the production batch record and release test results reviewed for accuracy and completeness before a batch/lot of finished product is released?	The production batch record and test results are reviewed by QA for accuracy and completeness along with deviation monitoring,	The production batch record and test results are reviewed by QA for accuracy and completeness before product is released in the market but records are not maintained	The production batch record and test results are not reviewed by QA for accuracy and completeness before product is released in the market and record are not maintained	No QA procedure for reviewing of production batch record and test results before product is released in the market
49.10	Sch-M	Verify the checklist and SOP in this regard.	NA	SOP for product release found followed.	SOP for product release not found followed.	NA
49.11	Sch-M	Whether QA is involved in control of starting materials, intermediate products, bulk products, process controls, calibrations, validation and release of finish goods.	NA	QA is actively involved and review all in control of starting materials, intermediate products, bulk products, process controls, calibrations, validation and release of finish goods as per the written procedure and records are maintained.	SOP has provision of QA for involvement and review however for several functions records of review are not maintained.	No validation activity performed by QA

			Quality Rating			
S.No	Reference		2	1	0	X
49.12	Sch-M	Specify whether QA is responsible for review of production batch record and test results before product is released in the market	NA	QA Procedures are established for review of production batch record and test results before product is released in the market	No specific SOP was found followed in this regard.	No QA procedure for reviewing of production batch record and test results before product is released in the market
50 Annual Product Quality Review (APQR):-						
50.1	WHO TRS-986	Specify Whether Annual Product Quality review is carried out for each product	SOP and protocol for APQR are prepared, APQR of each product are reviewed as per well defend procedure, and reports are maintained	NA	NA	NA
50.2	WHO TRS-987	Specify whether following criteria are considered for review: —Starting materials and packaging materials —Critical in-process controls and finished product results; — All significant deviations or non-conformance —All changes made to the processes or analytical methods; — Results of the stability monitoring programme and any adverse trends —All quality-related returns, complaints and recalls and the investigations performed at the time —Adequacy of any other previous corrective actions on product process or equipment —The qualification status of relevant equipment and utilities e.g. HVAC, water, or compressed gases	all specified criteria are considered for review of APQR of each product: —Starting materials and packaging materials —Critical in-process controls and finished product results; — All significant deviations or non-conformance —All changes made to the processes or analytical methods; — Results of the stability monitoring programme and any adverse trends —All quality-related returns, complaints and recalls and the investigations performed at the time —Adequacy of any other previous corrective actions on product process or equipment —The qualification status of	NA	NA	NA
50.3	WHO TRS-988	Verify whether Cp and CpK values are calculated and what is the acceptance criteria fixed.	The system of measuring how close a process is running to its specification limits is based on process capabilities and process capability index. The values of Cp and CpK are maintained more than 1.	NA	NA	NA
51 Product Recalls:-						
51.1	Sch-M	Specify the product recall system.	Well defined SOP on defective product recall is maintained. Additionally mock recalls are performed every year for verification of effectiveness of recall procedure and records are maintained.	Procedure of effective product recall is defined in SOP. No mock recall are performed.	SOP on product recall is either deficient or not prepared. No effective recall system from each level of distribution.	NA

S.No	Reference		Quality Rating			
			2	1	0	X
51.2	Sch-M	Verify the procedure followed to handle the recalled products	NA	Recalled product are stored separately in a secured area.	No separate & secured area for recalled product	NA
51.3	Sch-M	Are distribution records available for a prompt recall of products from the market?	NA	Distribution records are promptly available for product recall up to each distribution level	Distribution details are not shared with QA/QC or designated person for recall of product.	NA
51.4	Sch-M	Verify the SOP for recall of products clearly defining responsibility, procedure reporting, reconciliation etc.	NA	QA head is designated for product recall, distribution details up to each level are promptly available to QA. Fax, Email and Emails are used for fast communication and recall is performed in shortest possible time. The communication on recall decision, response from each distributor, recalled qty and reconciliation are maintained.	Recall decision are communicated to each distributor to retail level with plenty of time and not recalled any quantity. The product are sold even after product recall communications.	NA
52 Complaints and Adverse Reactions:-						
52.1	Sch-M	Are complaints, whether received in oral or written form, documented in writing, and retained in a designated file?	Handling of complaint including product complaints are defined in SOP. Each compliant is logged in logbook.	SOP for product complaint handling is available.	Procedure for handling of complaint is available. Complaints are not handled as per SOP	1) No procedure for complaint handling 2) Complaints are not addressed.
52.2	WHO TRS-988	Are complaints reviewed on a timely basis by the Quality Assurance unit?	time bound review is performed by QA	NA	NA	NA
52.3	WHO TRS-988	Is CAPA process followed in response to each complaint documented?	CAPA is followed for each complaints	NA	NA	NA
52.4	WHO TRS-988	Specify whether system of route cause analysis is followed by the firm on the complaint of adverse drug reaction.	Technical and scientific evaluation is performed on complaint of adverse drug reaction to established the root cause. The reports on adverse events with comments and documents are reported to the licensing authority.	NA	NA	NA
52.5	Sch-M	Specify the review system for complaints concerning the quality of products.	The QA head is responsible for review of product complaints. The QA further investigate the complaint with the help of other section to take CAPA in time bound manner	The QA head is responsible for review of complaint. The complaint are investigated by QA team.	SOP is available however not being followed.	NA
52.6	Sch-M	How records of complaint and adverse reactions maintained.	NA	And records are maintained as per SOP.	No records of complaints are maintained. Usually nil complaint are reported.	NA
52.7	Draft Rules	Whether the firm has provided Pharmacovigilance department for analysing complaints of adverse drugs reactions resulting from the use of a drug.	The firm has well defined pharmocovigilance section to generate the data of adverse reaction and product complaints.	NA	NA	NA

			Quality Rating			
S.No	Reference		2	1	0	X
52.8	Sch-M	Are there any criteria for action to be taken on the basis of nature of complaint / adverse reaction?	NA	The criteria describing action to be taken , recall to be made w.r.t. nature of product complaint are well defined in SOP	No criteria for recall of product is defined	NA
53 Site Master File:-						
53.1	Sch-M	Whether all the relevant information has been included in the site master file.	NA	Yes with annexures as required.	Yes without annexures.	SMF is not factual.
53.2	Sch-M	Whether quality policy has been included in the site master file.	NA	Quality policy and quality system are well defined	Quality policy is defined	NA
53.3	Sch-M	Verify whether all information as per schedule M	NA	All informations provided in SMF was found complied with the Sch-M requirement.	All informations provided in SMF was found not complied with the Sch-M requirement.	NA
53.4	WHO TRS-988	Verify whether all information as per WHO TRS 986 and PIC/S document.	All informations provided in SMF was found complied with WHO TRS 986	NA	NA	NA
54 Validation						
54.1	WHO TRS-988	Specify the validation policy of the company	Validation policy is well defined and covers all aspects like system, processes and facility.	NA	NA	NA
54.2	WHO TRS-988	Whether a Validation Master Plan has been prepared.	Validation Master Plan is as per the policy.	NA	NA	NA
54.3	Sch-M	Verify resources and those responsible for its implementation.	NA	In-house QA capacity with specialized assistance from out side technical resources the validations are completed.	No in-house capacity or deficient system of validation.	NA
54.4	WHO TRS-988	Identify the systems and processes to be validated as per VMP	All critical quality attributes or critical system and process identified doing product development are validated as per latest available practices.	NA	NA	NA
54.5	WHO TRS-988	Verify whether documentation, standard operating procedures (SOPs), Work Instructions and Standards (applicable for national and international) are incorporated in VMP	Standard operating procedures (SOPs), Work Instructions and Standards are incorporated in VMP	NA	NA	NA
54.6	WHO TRS-988	Validation list for facilities/equipment, processes / procedure and products.	Yes available	NA	NA	NA
54.7	WHO TRS-988	Specify whether key approval criteria are mentioned in the VMP & how record and conclusion of such validation studies are prepared and maintained.	Key approval criteria are mentioned in the VMP & recording system with conclusion found followed.	NA	NA	NA
54.8	WHO TRS-988	Verify Protocol format for each validation activity, including re-validation and reasonable unforeseen events (power failures, system crash and recovery, filter integrity failure.	Yes worst case scenario taken into consideration as per the written protocols.	NA	NA	NA
54.9	WHO TRS-988	Whether validation calendar is specified in VMP.	Validation schedule is maintained in a calendar	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
54.10	Sch-M	Specify whether the critical processes validated Prospectively, retrospectively or concurrently.	NA	Prospective or concurrent validation	Retrospective validation.	NA
54.11	WHO TRS-988	In case electronic data processing systems are used, are these validated?	Yes the computer system validation is in place including Excel sheets. The system included both testing as well as manufacturing equipments	NA	NA	NA
54.12	WHO TRS-988	Please specify whether periodical challenge tests performed on the system to verify reliability.	Yes	NA	NA	NA
54.13	Sch-M	Are the validation studies performed according to pre-defined protocols?	The validation studies performed according to pre-defined protocols	Yes however protocols are not based on any recognized guidelines.	Yes however format is deficient	NA
54.14	Sch-M	Is a written report summarized, results and conclusions prepared and maintained?	NA	Yes however protocols are not based on any recognized guidelines.	Yes however format is deficient	NA
54.15	WHO TRS-988	Is the validity of the critical processes and procedures established based on a validation study?	The validity of the critical processes and procedures established based on a validation study	NA	No	NA
54.16	WHO TRS-988	Are criteria established to assess the changes originating a revalidation?	Revalidation policy is well defined covering changes.	NA	No	NA
54.17	WHO TRS-988	Are trend analyses performed to assess the need to re-validate in order to assure the processes and procedures continue to obtain the desired results?	Trend analysis is performed and is followed for signals and corrections.	NA	No	NA
55 Internal Quality / GMP Audit Programme						
55.1	Sch-M	Does a formal auditing function exist in the Quality Assurance department?	Yes, as per the written policy and schedule. The criteria for self audit with follow up actions are very well established.	Checklist for self audit and gap analysis is used for gap analysis. Well written criteria for follow up actions is not specified.	SOP and Checklist for self audit available however the outcomes are not effective.	NA
55.2	Sch-M	Does a written SOP specify who shall conduct audits and qualifications (education, training, and experience) for those who conduct audits?	Yes	NA	NA	NA
55.3	Sch-M	Does a written SOP specify the scope and frequency of audits and how such audits are to be documented?	Yes	NA	NA	NA
55.4	WHO TRS-988	Specify whether record is maintained for CAPA on the basis of self quality audit / inspection and whether same is reviewed by the management	CAPA record was found maintained on the basis of self quality audit / inspection and the same is reviewed by the management	NA	NA	NA

S.No	Reference		Quality Rating 2	1	0	X
56 Pharmaceutical Development						
56.1	ICH/Q-8-PICS	Whether there is Research and Development facility available.	R&D Facility for in house characterization of API, formulation etc.	NA	NA	NA
56.2	ICH/Q-8-PICS	Whether formulation development facility up to development of exhibit batches available.	Formulation development facility was found up to development of exhibit batches.	NA	NA	NA
56.3	ICH/Q-8-PICS	Whether firm hires consultants for technology transfer. If so details thereof.	The development of product and process is based on design of Experiment	NA	NA	NA
56.4	ICH/Q-8-PICS	Whether firm has adopted latest tools (quality by design) to develop new products.	The development of product and process is based on design of Experiment	NA	NA	NA
57 Quality Risk Assessment System:-						
57.1	ICH/Q-9-PICS	Whether the firm has adopted QRM principle to mitigate risk involved in pharmaceutical development, manufacturing and distribution. If yes specify which guidelines are followed in this regard.	Yes ICH guidelines	NA	NA	NA
57.2	ICH/Q-9-PICS	Whether firm has policy document on QRM. Specify document number and its effective date.	Written policy describing QRM approach at the time of implementation of any activity is specified. The RPN numbering based controls are put in SOP's and documents for monitoring and control	NA	NA	NA
57.3	ICH/Q-9-PICS	Which known principles have been adopted to analyse risks e.g. FMEA, HAZOP, HACCP, FTA etc.	FMEA, HAZOP, HACCP, FTA used and outcome is linked to monitoring and control	NA	NA	NA
57.4	ICH/Q-9-PICS	Whether risk priority number (RPN) is calculated based on severity, probability and detectability. If so, what is the criteria of acceptance.	yes	NA	NA	NA
57.5	ICH/Q-9-PICS	How many products, process etc. have been analysed for risk. Give brief.	All as per policy	NA	NA	NA
58 Data Integrity						

			Quality Rating			
S.No	Reference		2	1	0	X
58.1	Sch-M	Whether the records are completed at the time of the operation and are legible maintained with raw data if applicable.	Records in paper as well as software based system are maintained contemporaneously. Software supported audit trail as per the written policy is in place..	Records in paper as well as software based system are maintained contemporaneously. Software supported audit trail is not available.	Records in paper are maintained contemporaneously. No system for maintain Software based data.	1) Data is not recorded on a contemporary basis/Records are not made at the time of actual activity. 2) Records are completed later on arbitrarily. 3) Falsification of data is observed.
58.2	Sch-L1	Whether the firm has software based manufacturing and testing equipment	yes for both manufacturing and testing facility.	Only for testing facility.	Not even for testing.	NA
58.3	Sch-L1	Whether the individuals are provided log in IDs for access. All login and logout information should be available.	Yes	NA	NA	NA
58.4	Sch-L1	Whether rights to work, amend, modify, delete are specified in written document.	Yes	NA	NA	NA
58.5	Sch-L1	Whether right to access and modify are with two different individuals. If yes how QA is involved in modification of data.	Critical modification are verified by the QA and is a part of audit trail and batch release criteria.	NA	NA	NA
58.6	Sch-L1	Whether audit trails related to project creation (study creation), project (study) modification, deletion etc. are available.	Yes	NA	NA	NA
58.7	Sch-L1	Whether the data is backed up at regular intervals. If yes what is the written back up policy. The data backup must be server based.	Yes server based.	Yes but not server based (data in hard discs)	No data back up.	NA
58.8	Sch-L1	How Excel sheets are validated if calculation are done in Excel sheet.	Yes validated	NA	NA	NA
58.9	Sch-L1	Whether the firm has QA SOP for review of data integrity or audit trail. If yes how the modification and deletions are reviewed.	Yes, the rights are well defined and found as per written SOP	Yes however no QA SOP	NA	NA
59 Pharmaceutical Quality Management System (PQS)						
59.1	WHO TRS-986	Specify the management responsibility defined as per the quality manual	Corporate or Top management responsibilities are defined and specified in the quality manual.	NA	NA	NA
59.2	WHO TRS-986	Specify the Procedures followed for continual improvement of process performance and product quality	The management review meetings are held at regular intervals. Key performance indicators impacting quality are reviewed.	NA	NA	NA

S.No	Reference		Quality Rating			
			2	1	0	X
59.3	WHO TRS-986	Specify the performance indicators presently followed by the firm to monitor the effectiveness of PQS like product quality monitoring, CAPA, change management and management review	The effectiveness of the quality system is assesses by the top management by reviewing key performance indicators includes product quality, monitoring, CAPA, change management etc.	NA	NA	NA
59.4	WHO TRS-987	whether purchases are also included under PQS	Yes as per the written policy	NA	NA	NA
59.5	WHO TRS-986	Specify whether life cycle approach is followed	The system of monitoring and controlling quality from production development to marketing is in place.	NA	NA	NA
59.6	WHO TRS-986	Give synopsis of last to management review meeting held by the firm	The Management review and CAPA shared. Top management found providing necessary resources to meet any quality related compliance.	NA	NA	NA

REMARKS & RECOMMENDATIONS:

Quality Rating System

Rating	Meaning	Interpretation
2	Good	Item/area/system/knowledge is superior.
1	Adequate	Item/area/system/knowledge meets basic minimum requirements
0	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
X	Critical Deficiencies	Item/area/system/knowledge is missing or of such nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation or item was unable to be addressed during the audit.

Comment: -

1. **All deficiencies under critical category will be marked as "X" and one critical finding will make the manufacturing site unsuitable for acceptance till rectified irrespective of scores in other points.**
2. **Some users of the checklist find responses to some questions are difficult to quantify on a 0-2 scale and prefer to use a simple "Yes" or "No" approach. In such cases, a "Yes" should be assigned a "1" value and a "No" should be assigned as "0" value.**