

Guidance Document

(Medical Devices and Diagnostic Division)

**Title: Guidance Document on
Common Submission Format
for Registration / Re-
Registration of Notified
Diagnostics Kits in India**

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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVT. OF INDIA

Notice:

This Guidance Document is aimed only for creating public and stakeholder's awareness about In-Vitro Diagnostic Devices Regulation by CDSCO and is not meant to be used for legal purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules and respective Guidelines / Clarifications issued by CDSCO time to time for all their professional needs.

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D Rules Related to Registration of Notified Diagnostics Kits Specified under Drugs & Cosmetics Rules 52-54

A. Preface:

In India import, manufacturing, sale and distribution of Notified Diagnostics Kits are regulated under Drugs and Cosmetics Act, 1940; and Rules, 1945. At present following Notified Diagnostics Kits are regulated under the said Act & Rules.

1. In vitro Diagnostics Devices for HIV, HBV and HCV.
2. In vitro Diagnostics Devices for HIV, HBV and HCV (Bulk)
3. In vitro Blood Grouping Sera
4. In vitro Blood Grouping Sera(Bulk)

The proposed requirements for the regulatory control over notified Diagnostics Kits are being uploaded for the information of all stakeholders.

The document is intended to provide guidance for use in the registration of notified Diagnostics Kits in India.

This guidance document will be effective from **15/11/2013.**

SCOPE:

For marketing of imported notified Diagnostic Kits in India, Registration Certificate in Form-41 and Import License in Form-10 are required under Drugs and Cosmetics Rules. The Rule 24-A, 25-B, 27-A and 28-A of Drugs and Cosmetics Rules describe the information/data required for grant of registration certificate. This guidance documents has been prepared to specify the general requirements for grant of registration certificate in Form-41. This guidance will help the industry to submit the required documents in a more realistic manner, which in turn will also help reviewer of CDSCO to review such application in systematic manner. It is apparent that this structured application with comprehensive and rational contents will help the CDSCO to review and take necessary actions in a better way and would also ease the preparation of electronic submissions, which may happen in the near future at CDSCO

B. Requirements for Common Submission Format for Registration of Notified Diagnostics Kits in India

The following documents are required to be submitted in the following manner and order for the registration of the Notified Diagnostics Kits for import into India:-

Applicants are requested to submit following documents in 2 separate files as follows: -

1. **Covering Letter** – The covering letter is an important part of the application and should clearly specify the intent of the application (whether the application for the registration of the manufacturing site is being submitted for the first time, whether the application is for re-registration or is for the endorsement of additional products to an existing Registration Certificate) the list of documents that are being submitted (Index with page no's) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory along with details like Fax No., Email Id
2. An **Authorization letter** in original issued by the Director/Company Secretary/Partner of the Indian Agent firm revealing the name & designation of the person authorized to sign legal documents such as Form 40, Power of Attorney etc. on behalf of the firm should be submitted at the time of submission of the application for registration. Duly self-attested photocopies of the Authorization letter may be submitted at the time of submission of subsequent applications.
3. A duly filled **Form 40** as per the Performa prescribed in the Drugs & Cosmetics Rules, signed & stamped by the Indian Agent along with name & designation. The name and address of the Indian Agent should be as given in the Drug Sale Licence in Form 20B & 21B or its renewal in Form 21C. Form 40 Performa is enclosed at **Annexure - I**.
4. The **requisite fee** as prescribed in the Drugs & Cosmetics Act & Rules viz. 1500 USD for the registration of the manufacturing premises and 1000 USD for a single Device and an additional fee at the rate of 1000 USD for each additional device proposed to be imported may be submitted at notified branches of Bank of Baroda under the Head of Account "0210 - Medical and Public Health, 04 - Public Health, 104 - Fees and Fines" adjustable to Pay and Account Officer, DGHS, New Delhi in the form of a Treasury Challan. Performa for Treasury Challan (TR 6) is annexed at **Annexure - II**. The Receipt in original (TR 6) is required to be submitted along with the application for registration. Applicants are advised to make sure

that the TR6 Challan clearly indicates the USD equivalence of the amount paid in Indian Rupees.

In case of any direct payment of fee by the manufacturer in the country of origin, the fee shall be paid through Electronic Clearance System (ECS) from any bank in the Country of Origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the electronic code of the bank in the head of Account stated above and the original receipt of the said transfer shall be treated as an equivalent to the Bank Challan, subject to the approval by the Bank of Baroda that they have received the payment.

Applicant is required to submit separate fee for each categories like test strip, cassettes, midstream, etc. which the firm intent to import/Register.

5. **Power of Attorney** – The authorization by a manufacturer to his agent in India shall be documented by a Power of Attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate. Apostille Power of Attorney from Hague convention member countries is also acceptable. Performa for Power of Attorney is enclosed at **Annexure III.**

While submitting the Power of Attorney, the following points should be kept in mind: -

- It should be co-jointly signed and stamped by the manufacturer as well as the Indian Agent indicating the name & designation of the authorized signatories.
 - It should clearly list the names of all the proposed devices (including Model No's, if applicable) along with their specific Indication and/or intended use. Further, the names of the proposed devices should correlate with those mentioned in the Form 40 and Free Sale Certificate to be submitted.
 - The names & addresses of the manufacturer as well as the Indian Agent stated in the Power of Attorney should correlate with the Form 40.
 - It should be valid for the period of said Registration Certificate.
6. A duly attested /notarized (in India) and valid copy of **Wholesale License** for sale or distribution of drugs under Drugs and Cosmetics Rules in **Form 20B & 21B** or its renewal in **Form 21C** issued by the State Drug Licensing Authority.

Or

Duly attested /notarized (in India) and valid copy of Manufacturing License issued by the State Drug Licensing Authority in case the Indian Manufacturer is importing the kits in bulk form for further processing.

7. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **Free Sale Certificate/Certificate to Foreign Government/ Certificate of Marketability** for each kit issued by National Regulatory Authority of country of origin and any one of the countries Viz. USA, Canada, Japan, Australia and European Union clearly stating that the proposed Kits/Reagents are freely sold in the respective country and can be legally exported. It should also specify name and address of legal and actual manufacturing site along with applied product name(s) in generic and Brand name, if any.
8. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **ISO 13485 Certificate** in respect of the manufacturing site (s).
9. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **CE Full Quality Assurance Certificate** in respect of the legal and actual manufacturing site (s), if applicable.
10. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **CE Design Certificate** in respect of the proposed Kit(s), if applicable.
11. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **Declaration of Conformity** in respect of the proposed Kit(s).
12. **Performance Evaluation Report** from National Institute of Biologicals, Noida, India in respect of Proposed Kit(s) of three Consecutive batches.
13. The report of evaluation in details conducted by the National Control Authority (NCA) of Country of origin in respect of Proposed Kit(s) of three Consecutive batches. If the Evaluation report from NCA is not available then Evaluation / Batch release report from the authorized Notified body may also be accepted.
14. Product Inserts (English version or Authenticated translated copy) mentioning Specificity and Sensitivity wherever applicable and

published articles (if any) for each Diagnostic kits/ Reagents proposed to be imported.

15. Original Colored Labels and pack size in respect of the proposed products.
16. A) A duly filled **Schedule D (I)** along with the undertaking as per the Performa prescribed in the Drugs & Cosmetics Act & Rules, signed & stamped by the manufacturer indicating the name and designation of the authorized signatory is required to be submitted Performa for **Schedule D (I)** is enclosed at **Annexure IV**.
B) The requirements for **Plant / Site Master File** are enclosed at **Annexure- V**.
17. A) A duly filled **Schedule D (II) along with Annexure -B** as per the Performa prescribed in the Drugs & Cosmetics Act & Rules, signed & stamped by the manufacturer indicating the name and designation of the authorized signatory is required to be submitted as per **Annexure VI**.
B) The requirements for **Device Master File** are enclosed at **Annexure VII**.
18. Specimen batch test report for at least three consecutive batches showing specification of each testing parameters from Manufacturer.
19. The detailed test report of all the components used/packed in the finished kit.
20. Manufacturer undertaking for the product self-life , Specificity and Sensitivity of the proposed product wherever applicable
21. Soft copy of Dossier summary sheet in Word format

Note:

- Soft copy of the Plant Master File and Device Master File may also be submitted along with the application.
- All certificates submitted should be with in the validity period and should have at least six months valid period at the time of submission of application.

- All above mentioned regulatory and legal documents may be provided in a single file in the same sequence (From S.NO. 1-19) Plant Master File and Device Master File may be provided as separate files.
- In case of re-registration / Endorsement, a copy of registration certificate in form-41 should be submitted along with application.

C. Annexures

Annexure I	Format for Form 40
Annexure II	Format for TR6 Challan
Annexure III	Format for Power of Attorney
Annexure IV	Format for Schedule DI
Annexure V	Plant/Site Master File
Annexure VI	Schedule DII along with Annexure-B
Annexure VII	Device Master File
Annexure VIII	Format for Soft copy of Dossier summary sheet in Word format

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ANNEXURE – I

FORM 40

(See rule 24-A)

Application for issue of Registration Certificate for import of drugs into India under the Drugs and Cosmetics Rules 1945

I/We* _____ (Name, full address with telephone, fax and E-mail address) hereby apply for the grant of Registration Certificate for the manufacturer, M/s. _____ (full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises M/s _____ (full address with telephone, fax and E-mail address), and manufactured drugs meant for import into India.

1. Names of drugs for registration.

S. No.	Name of the Product		Specific Intended use
	Generic Name	Brand Name	

2. I/We enclose herewith the information and undertakings specified in Schedule D (I) and Schedule D(II) duly signed by the manufacturer for grant of Registration Certificate for the premises stated below.

3. A fee of _____ for registration of premises, the particulars of which are given below, of the manufacturer has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945-Central vide Challan No. _____ dated _____ (attached in original).

4. A fee of _____ for registration of the drugs for import as specified at Serial No. 2 above has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945-Central vide Challan No. _____, dated _____. (Attached in original).

5. Particulars of premises to be registered where manufacture is carried on:

Address _____
Telephone No. _____
Fax No. _____
E-mail _____

I/We* undertake to comply with all terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.

Place: _____

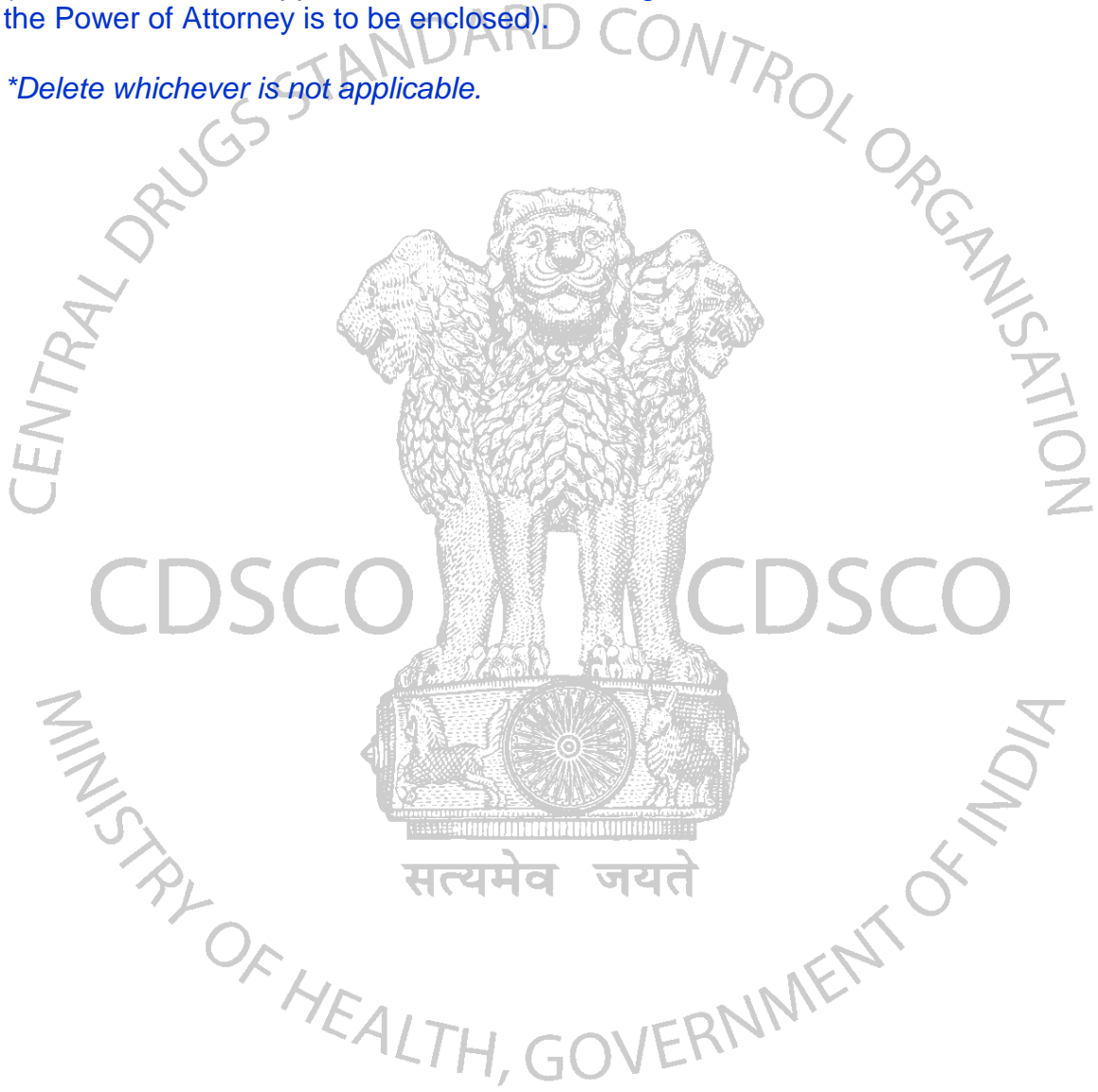
Central Drugs Standard Control Organization
Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India

Date: _____

Signature
(Name & Designation)
Seal / Stamp of manufacturer or his
Authorized Agent in India

(Note: In case the applicant is an authorized agent of the manufacturer in India, the Power of Attorney is to be enclosed).

**Delete whichever is not applicable.*



ANNEXURE – II

TR6 Challan

T.R. - 6.
 (See Rule 92)
 Challan No.

Please indicate whether	Civil
	Defence
	Railways
	Posts & Telegraphs

Challan of cash paid into Treasury/Sub-Treasury
Bank of Baroda, K.G. Marg, New Delhi

To be filled by the remitter				To be filled by the Department Officer or the Treasury			
By whom Tendered	Name (designation) and address of the person on whose behalf money is paid	Full particular of the remittance and/of authority (If any)	Amount		Head of Account	Accounts Officer by whom adjustable	Order to the Bank
			Rs.	P.			
					0210- Medical and Public Health, 04-Public Health, 104-Fee and Fines	Pay and Accounts Offices, DGHS, New Delhi	Date Correct, Receive and grant receipt (Signature and full Designation of the Officer ordering the money to be paid in).
Signature		Total					
(in words) Rupees _____ equivalent to USD (In words) _____				To be used only in the case of remittance to the Bank through Departmental officer or the Treasury Officer.			
Received payment (in words) Rupees _____							
Treasurer	Accountant	Date		Treasury Officer Agent or Manager			

ANNEXURE – III

Power of Attorney

(Power of Attorney to accompany an application for issue of Registration Certificate for import of Notified Diagnostics Kit (s) into India)

Whereas, _____ (Name of Authorized person) of M/s _____ (Name of applicant, full address with telephone, fax and E-mail address) herein after to be known as authorized agent for the M/s _____ (Name of Manufacturer) intends to apply for a Registration Certificate under the *Drugs & Cosmetics Rules 1945*, for the import, use and marketing into India, of the **Notified Diagnostics Kit (s)**, we M/s. _____ (Name and full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises M/s _____ (full address with telephone, fax and E-mail address), hereby delegate Power of Attorney that for the duration of the said registration period.

1. The said applicant shall be our Authorized agent for the Registration Certificate of Diagnostics Kits imported into India, under Rule 27-A of the *Drugs & Cosmetics Rules* and shall act in the following respects:
 - a. To act as the official representative for the product registration for and on behalf of (Manufacturer's Name) in India
 - b. To submit all necessary documents in the name of (manufacturer's name) for the registration of **Notified Diagnostics Kit (s)** manufactured by (Manufacturer's name) as defined in the schedule.
2. We shall comply with all the conditions imposed on the Registration Certificate, read with rules 74 and 78 of the *Drugs and Cosmetics rules, 1945*.
3. We declare that we are carrying on the manufacture of the **Notified Diagnostics Kits (s)** mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.
4. We shall comply with the provisions of Part IX of the *Drugs and Cosmetics Rules, 1945*.
5. Every drug manufactured by us for import under the Registration Certificate into India shall be as regard strength, quality and purity

conforms with the provisions of Chapter III of Drugs and Cosmetics Act, 1940 and Part IV of the Drugs and Cosmetics Rules 1945, and their amendments from time to time.

6. We shall from time to time report for any change or manufacturing process, or in packaging, or in labeling, or in testing, or in documentation of any of the **Notified Diagnostics Kit** (s), pertaining to the Registration Certificate, to be granted to us. Where any change in respect of any of the **Notified Diagnostics Kit** (s) under the Registration Certificate has taken place, in respect of any of the above matters, we shall inform the same to the licensing authority in writing within 30 days from the date of such changes. In such cases, where there will be any major change/modification in manufacturing or in processing or in testing, or in documentation, as the case may be, at the discretion of the licensing authority, we shall obtain necessary approval within 30 days by submitting a separate application, alongwith the registration fee as specified in clause (ii) of sub rule (3) of rule 24-A.
7. We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or “not of standard quality report” of any **Notified Diagnostics Kit** (s) pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the **Notified Diagnostics Kit** (s) is marketed/sold or distributed. The dispatch and marketing of the **Notified Diagnostics Kit** (s) in such cases shall be stopped immediately and the licensing authority shall be informed immediately. Further action in respect of stop marketing of **Notified Diagnostics Kit** (s) shall be taken as per the directions of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned **Notified Diagnostics Kit** (s) in the country of origin or in the country of marketing will be followed in India also, in consultation with the licensing authority. The licensing authority may direct any further modification to this course of action, including the withdrawal of the **Notified Diagnostics Kit** (s) from Indian market within 48 hours time period.
8. We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the rules made there under.

9. We shall allow the licensing authority and/or any person authorized by him in that behalf to enter and inspect the manufacturing premises and to examine the process/procedure and documents in respect of any **Notified Diagnostics Kits** manufactured by us for which the application for Registration Certificate has been made.

10. We shall allow the licensing authority or any person authorized by him in that behalf to take samples of the **Notified Diagnostics Kits** (s) concerned for test, analysis or examination, if considered necessary by the licensing authority.

11. We do hereby state and declare that all the photocopies in the application are true copies of the original documents.

12. We do hereby state and declare that all the documents submitted by the undersigned are true and correct.

List of Notified Diagnostics Kit (s)

S. No.	Name of the Product		Specific Intended use
	Generic Name	Brand Name	

Place:

Date:

Signature of the manufacturer
(Name & Designation)

Seal / Stamp

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Place:

Date:

Signature of the Indian Agent
(Name & Designation)

Seal / Stamp

ANNEXURE – IV

SCHEDULE D(I)

(See rule 21 (d) and rule 24 A)

Information and undertaking required to be submitted by the manufacturer or his authorized agent with the Application Form for a Registration Certificate. The format shall be properly filled in for each application in Form 40.

1. *Particulars of the manufacturer and manufacturing premises*

1.1 Name and address of the manufacturing premises (Telephone No., Fax No., E-mail address) to be registered.

1.2 Name(s) and address(es) of the Proprietor /Partners / Directors.

1.3 Name and address of the authorized Agent in India, responsible for the business of the manufacturer.

1.4 A brief profile of the manufacturer's business activity, in domestic as well as global market.

1.5 A copy of Plant Master File (duly notarized)

1.6 A copy of Plant Registration / approval Certificate issued by the Ministry of Health/National Regulatory Authority of the foreign country concerned (duly notarized)

1.7 A brief profile of the manufacturer's research activity.

2. *Particulars of the manufactured **Notified Diagnostics Kit** (s) to be registered under Registration Certificate.*

2.1 Names of **Notified Diagnostics Kit** (s) to be registered meant for import into and use in India.

2.2 A copy of the approved list showing the **Notified Diagnostics Kit** (s) mentioned in 2.1 above are permitted for manufacturing / marketing in the country of origin (duly notarized).

2.3 A copy of Good Manufacturing Practice (GMP) certificate, as per WHO-GMP guidelines, or Certificate of Pharmaceutical Products (CPP), issued by the National Regulatory Authority of the foreign country concerned, in relation to the **Notified Diagnostics Kit** (s) or formulations or special products, meant for import into India.

2.4 The domestic prices of the **Notified Diagnostics Kit** (s) to be registered in India, in the currency of the country of origin.

2.5 The name(s) of the **Notified Diagnostics Kit** (s) which are original research products of the manufacturer.

3. *Undertaking to declare that: -*

3.1. We shall comply with all the conditions imposed on the Registration Certificate, read with rules 74 and 78 of the Drugs and Cosmetics rules, 1945.

3.2 We declare that we are carrying on the manufacture of the **Notified Diagnostics Kit** (s) mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

3.3 We shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945.

3.4 Every **Notified Diagnostics Kit** (s) manufactured by us for import under the Registration Certificate into India shall be as regard strength, quality and purity conforms with the provisions of Chapter III of Drugs and Cosmetics Act, 1940 and Part IV of the Drugs and Cosmetics Rules 1945, and their amendments from time to time.

3.5 We shall from time to time report for any change or manufacturing process, or in packaging, or in labelling, or in testing, or in documentation of any of the **Notified Diagnostics Kit** (s), pertaining to the Registration Certificate, to be granted to us. Where any change in respect of any of the **Notified Diagnostics Kit** (s) under the Registration Certificate has taken place, in respect of any of the above matters, we shall inform the same to the licensing authority in writing within 30 days from the date of such changes. In such cases, where there will be any major change/modification in manufacturing or in processing or in testing, or in documentation, as the case may be, at the discretion of the licensing authority, we shall obtain necessary approval within 30 days by submitting a separate application, alongwith the registration fee as specified in clause (ii) of sub rule (3) of rule 24-A.

3.6 We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or “not of standard quality report” of any **Notified Diagnostics Kit** (s) pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the **Notified Diagnostics Kit** (s) is marketed/sold or distributed. The dispatch and marketing of the **Notified Diagnostics Kit** (s) in such cases shall be stopped immediately and the licensing authority shall be informed immediately. Further action in respect of stop marketing of **Notified Diagnostics Kit** (s) shall be taken as per the directions of

the licensing authority. In such cases, action equivalent to that taken with reference to the concerned **Notified Diagnostics Kit** (s) in the country of origin or in the country of marketing will be followed in India also, in consultation with the licensing authority. The licensing authority may direct any further modification to this course of action, including the withdrawal of the **Notified Diagnostics Kit** (s) from Indian market within 48 hours time period.

3.7 We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the rules made there under.

3.8 We shall allow the licensing authority and/or any person authorized by him in that behalf to enter and inspect the manufacturing premises and to examine the process/procedure and documents in respect of any **Notified Diagnostics Kit** (s) manufactured by us for which the application for Registration Certificate has been made.

3.9 We shall allow the licensing authority or any person authorized by him in that behalf to take samples of the **Notified Diagnostics Kit** (s) concerned for test, analysis or examination, if considered necessary by the licensing authority.

Place:
Date:

Signature of the manufacturer
(Name & Designation)
Seal / Stamp

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ANNEXURE – V

Plant / Site Master File

NOTE: The manufacturer shall submit the duly signed and notarized information pertaining to Manufacturing premises in the following format. All information/reports/data should be in English only. It is expected that the information submitted in the form of hard copy shall also be submitted in the form of soft copy. The applicant shall submit a succinct document in the Form of “Site Master File” containing specific and factual information about the production and/or control of manufacturing process carried out at actual manufacturing premises. It shall contain the following information but not limited to:

Sr. No	Requirements	Information
A	GENERAL INFORMATION	
I	Brief information on the site (including name and address), relation to other sites and, particularly, any information relevant to the understanding of the GDP (Good Documentation Practices) operations	In not more than 250 words, outline the company's activities, other sites (if any), in addition to the site that is the subject of registration.
II	Manufacturing activities as licensed by the Competent Authorities	1. Indicate whether the site has been approved by national authority, or any foreign Competent Authority (if the latter, name the authority and state if approval granted is for the manufacture of Notified Diagnostics Kit (s) of the same or different description from that in the application). 2. Quote the relevant document (licence) as issued by the Competent Authority. State the period of validity of licence/certificate document (if the validity of the document is given in the country concerned). Any conditions and/or restrictions should be stated.
III	Any other operations carried out on the site	This covers both Notified Diagnostics Kit (s) related and Non- Notified Diagnostics Kit (s) related activities.

IV	Name and exact address of the site, including telephone, fax numbers, web site URL and e-mail address	1. Name of company, site address and mailing address (if different from site address) 2. Telephone, fax nos. and email address of contact person		
V	Type of Notified Diagnostics Kit (s) handled on the site and information about specifically toxic or hazardous substances handled, mentioning the way they are handled and precautions taken	1. Quote the type of Notified Diagnostics Kit (s) handled, specifying if the Notified Diagnostics Kit (s) is handled under a contractual agreement with a contract giver. 2. Note any toxic, hazardous, highly sensitising substances handled e.g. antibiotics, hormones, cytostatics. Note whether special precautions were taken for such Notified Diagnostics Kit (s) . (List the appropriate licence numbers where applicable)		
VI	Short description of the site (size, location and immediate environment and other activities on the site)	1. Provide a map indicating the location of the site(s) and the surrounding area. Mark the site(s). 2. Other activities on the site.		
VII	Number of employees engaged in Production, Quality Control, warehousing, and distribution	Area of Operation	No of Permanent/regular employees	No of Contractual employees
		1. Production 2. Quality Control 3. Warehousing 4. Storage 5. Distribution 6. Technical & Engineering Support Services		
		Total of the above		
VIII	Use of outside scientific, analytical or other technical assistance in relation to the design, manufacture and testing	For each work process outsourced or sub-contracted (including contract delivery companies), give:- 1. Name, address, telephone no. and fax. no. of contractor 2. Brief outline of the activity being undertaken in not more than 250 words.		

IX	Short description of the quality management system of the company	(Not more than 750 words). <ol style="list-style-type: none"> 1. State the company's Quality Policy 2. Define the responsibility of the Quality Assurance function 3. Describe the elements of the QA system e.g. organisational structure, responsibilities, procedures, processes 4. Describe the audit programmes (self-inspection or audits by external organisations undertaken). 5. Describe how results are reviewed to demonstrate the adequacy of the quality system in relation to the objective i.e. quality, efficacy and safety of the product. 6. Describe vendors qualification/validation policy. When suppliers of Notified starting materials and packaging materials - actives, excipients, containers, closures and printed packaging materials are assessed, give details of how this is done 7. Record if the company has been certified to industry standards (e.g. ISO 13485:2003) 8. Describe the release for sale procedure for finished products
X	Devices registered with foreign countries	State name of the kit along with the name of the countries where the kit is approved/ registered.
B	PERSONNEL	
I	Organisation chart showing the arrangements for key personnel	Organogram listing key personnel (Quality Assurance, Production, and Quality Control) has to be constructed. Record senior managers and supervisors only.
II	Qualifications, experience and responsibilities of key personnel	<ol style="list-style-type: none"> 1. Brief details of qualifications and years of relevant experience since qualifying. 2. Job descriptions for the key personnel

III	Outline of arrangements for basic and in-service training and how records are maintained	<p>Give brief details of the training programme and include induction and continuous training, as follows:-</p> <ol style="list-style-type: none"> 1. Describe how training needs are identified and by whom. 2. Give details of training relative to GDP (Good Documentation Practices) requirements. 3. State the form of training e.g. in-house, external, and how practical experience is gained and which staff are involved. 4. Explain training evaluation procedures. 5. Explain how retraining needs are identified. 6. Give brief details of training records kept.
IV	Health requirements for personnel engaged in production	<p>Give brief details of the following:</p> <ol style="list-style-type: none"> 1. Who is responsible for checking health of employees? 2. Is there a pre-employment medical examination? 3. Are employees routinely checked from time to time depending on the nature of their work? 4. Is there a system for reporting sickness or contact with sick people before working in a Notified area? 5. Is there a system of reporting back after illness?
V	Personnel hygiene requirements, including clothing	<p>Give brief details of the following:</p> <ol style="list-style-type: none"> 1. Are there suitable washing, changing and rest areas? 2. Is the clothing suitable for the activity undertaken? Briefly describe the clothing 3. Are there clear instructions on how protective clothing should be used and when it should be changed? Is in-house or external laundry used?
C	PREMISES AND FACILITIES	
I	Layout of premises with indication of scale	<p>Layout of premises</p> <ol style="list-style-type: none"> 1. Manufacturing Plant Layout with men and material flow, Clean room classification. 2. Describe the controls available to prevent unauthorized access. 3. Provide a simple plan of each area with indication of scale. Label areas and annotate plan with names. 4. Plans should be legible

II	Nature of construction, finishes/fixtures and fittings	Nature of construction should include type of flooring, walls, roof, doors, windows etc. Details should be provided for all processing areas, packaging areas and critical storage areas.
III	Brief description of ventilation systems. More details should be given for Notified areas with potential risks of airborne contamination (including schematic drawings of the systems). Classification of the rooms used for the manufacture of sterile products should be mentioned	<p>Brief description of ventilation systems etc.</p> <p>Note 1: More details should be given for critical areas with potential risks of airborne contamination.</p> <p>Note 2: To reduce the narrative, schematic drawings should be used.</p> <p>The following data should be given:-</p> <ol style="list-style-type: none"> 1. Design criteria e.g. <ul style="list-style-type: none"> • Specification of the air supply • Temperature • Humidity • Pressure differentials and air change rate • Single pass or recirculation (%) 2. Filter design and efficiency e.g. <ul style="list-style-type: none"> • Bag 99% efficiency • HEPA 99.997% efficiency • Details of any alarms on the ventilation system should be given. 3. The limits for changing the filters should be given. 4. Give the frequency of revalidation of the system
IV	Special areas for the handling of highly toxic, hazardous and sensitizing materials	Follow the same layout as above for description of areas specially designated for the handling of highly toxic, hazardous and sensitizing materials.
V	Brief description of water systems (schematic drawings of the systems are desirable) including sanitation	<p>Brief description of water system, including sanitation should include following:</p> <ol style="list-style-type: none"> 1. The schematic drawing must go back to the city supply system 2. The capacity of the system (maximum quantity produced per hour). 3. Construction materials of the vessels and pipework 4. Specification of any filters in the system must be given 5. If water is stored and circulated, the temperature at the point of return 6. The specification of the water produced (Chemical, Conductivity and microbiological) 7. The sampling points and frequency of testing 8. The procedure and frequency of sanitation

VI	Maintenance (description of planned preventive maintenance programmes for premises and recording system)	<p>Maintenance Note: For the purpose of this guide, "maintenance" is carried out by the company and "servicing" is by an outside contractor.</p> <ol style="list-style-type: none"> 1. Describe the planned preventive maintenance programme. 2. Are there written procedures and contractual details for outside work? 4. Are there written procedures and suitable reporting forms for maintenance and servicing? Do the documents record type/frequency of service/checks, details of service, repairs and modifications? 5. Have the maintenance routines that could affect medical device quality been clearly identified? 6. Are the reports made known to the users?
D	EQUIPMENT	
I	Brief description of major production and quality control laboratories equipment (a list of the equipment is required)	<p><i>Makes and model numbers of the equipment are not required. However the following points should be addressed:</i></p> <ol style="list-style-type: none"> 1. Is the machinery constructed of appropriate material (e.g. AISI grade 316 stainless steel for product contact equipment)? 2. Have other materials been suitably validated e.g. polypropylene, chrome-plated brass, PVC, non-reactive plastic materials? 3. Is the equipment designed with ease of cleaning in mind? 4. A brief general description is required. If the equipment has additional devices, these should be recorded 5. In particular give brief information on the use of computers, microprocessors etc. in the premises.
II	Maintenance (description of planned preventive maintenance programmes and recording system).	<p>Following points should be addressed:</p> <ol style="list-style-type: none"> 1. Who is responsible for maintenance and servicing? 2. Are there written procedures and contractual details for outside work? 3. Are maintenance routines which could affect product quality clearly identified? 4. Are records kept of: <ul style="list-style-type: none"> • type and frequency of service/check • details of service repairs and modifications 5. Are reports made known to the users?

III	Qualification and calibration, including the recording system. Arrangements for computerized systems validation.	<p>Following points should be addressed:</p> <ol style="list-style-type: none"> 1. Briefly describe the company's general policy and protocols for qualification and validation (prospective and retrospective). 2. Is there regular revalidation of critical equipment? 3. An outline of process validation may be given here or cross-referenced to Production. 4. What are the arrangements for computer validation, including software validation? 5. Describe equipment calibration policy and records kept.
E	SANITATION	
I	Availability of written specifications and procedures for cleaning the manufacturing areas and equipments	<p>Cleaning procedures for the manufacturing areas and equipments should include:</p> <ol style="list-style-type: none"> 1. Are there written procedures for cleaning and specifications for cleaning agents and their concentration for the method of cleaning and the frequency? 2. Are cleaning agents changed from time to time? 3. Have the cleaning procedures been validated and what was the method of evaluating the effectiveness of cleaning? 4. Are cleaning methods monitored routinely by chemical and/or microbiological methods? 5. What are the cleaning methods (and their frequency) for the water system, air handling system and dust extraction system?
F	PRODUCTION	
I	Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters	<p>Describe the production operations using flow charts. The following points should be addressed:</p> <ol style="list-style-type: none"> 1. Describe the operations capable of being carried out at the site with the existing facilities and specify the types of diagnostics kits. 2. When only packaging is undertaken, give a brief description only, e.g. labeling, filling etc. and the nature of containers used

II	Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage.	<p>The following points should be addressed:</p> <ol style="list-style-type: none"> 1. Control of manufacturing <ul style="list-style-type: none"> • Checks on key parameters during manufacture • Records of key parameters • In-process checks • Records of in-process checks • Compliance with the Marketing Authorization 2. Packing <ul style="list-style-type: none"> • Release of bulk, semi-finished products, packing materials • Confirmation of identity and line clearance checks • Confirmation of identity and line clearance checks 3. Quarantine and release of finished products; compliance with Marketing Authorization. 4. Explain the role of the Authorized Person(s).
III	Arrangements for reprocessing or rework	What arrangements are in place for reprocessing or reworking batches of products?
IV	Arrangements for the handling of rejected materials and products	<p>The following points should be addressed:</p> <ol style="list-style-type: none"> 1. Are rejected materials and products clearly labeled? Are they stored separately in restricted area? 2. Describe arrangements for sentencing the materials and their disposal. Is destruction recorded?
V	Brief description of general policy for process validation	An outline of process validation policy only is required
G	QUALITY CONTROLS	
I	Description of the Quality Control system and of the activities of the Quality Control Department. Procedures for the release of finished products	<p>The following points should be addressed:</p> <ol style="list-style-type: none"> 1. Describe the activities of the QC system e.g. specifications, test methods, analytical testing, packaging, component testing and microbiological testing and other quality related data collection. 2. Outline the involvement in the arrangements for the preparation, revision and distribution of documents in particular those for specification test methods, batch documentation and release criteria.
H	STORAGE	
I	Policy on the storage of Diagnostics Kits.	The following points should be addressed:

		<ol style="list-style-type: none"> 1. How are the Diagnostics stored e.g. pallet racking? 2. Describe any special storage or handling conditions such as cold chain management.
E	DOCUMENTATION	
I	Arrangements for the preparation, revision and distribution of necessary documentation, including storage of master documents	<p>Arrangement for the preparation, revision and distribution of documentation should include:-</p> <ol style="list-style-type: none"> 1. Is there a description of the documentation system? 2. Who is responsible for the preparation, revision and distribution of documents? 3. Where are the master documents stored? 4. Is there a standard format and instruction of how documents are to be prepared? 5. How is the documentation controlled? 6. For how long are the documents kept? 7. Detail any arrangement for electronic or microfilmed records.
F	COMPLAINTS AND FIELD SAFETY CORRECTIVE ACTION	
I	Arrangements for the handling of complaints	<p>Following points should be included:</p> <ol style="list-style-type: none"> 1. Is there a written procedure for Diagnostics-Kit (s) complaints? 2. Who is responsible for:- <ol style="list-style-type: none"> a. Logging; b. Classifying; c. Investigating complaints. 3. Are written reports prepared? 4. Who reviews these reports? 5. For how long are complaint records kept?
II	Arrangements for the handling of field safety corrective action	<p>Following points should be included:</p> <ol style="list-style-type: none"> 1. Is there a written procedure which describes the sequence of actions to follow including:- <ol style="list-style-type: none"> a. Retrieval of distribution data; b. Notification to customers; c. Receipt/segregation/inspection of returned Diagnostics Kits d. Investigation/reporting of cause. e. Reporting corrective action. 2. Who is responsible for coordinating Diagnostics Kits field safety corrective actions? 3. Who notifies the Competent Authority of field safety corrective actions? 4. Can field safety corrective actions be effected below wholesale level?

		5. Is there written procedure for destruction of defective/unsafe kits?
G	SELF INSPECTION	
I	Short Description of the internal audit system	<p>Following points should be included:</p> <ol style="list-style-type: none"> 1. Describe how the internal audit system verifies that those activities that have a bearing on Diagnostics Kits quality comply with the planned arrangement. 2. Are there documented procedures for the internal audit system and for the follow-up actions? 3. Are the results of the internal audit documented, brought to the attention of the personnel having responsibility for the area and activities inspected? 4. <i>Does the system ensure that those responsible for the area or activity take timely corrective action on the deficiencies found?</i>
H	CONTRACT ACTIVITIES	
I	Description of the way in which the compliance of the contract acceptor is assessed	Describe briefly the details of the technical contract between the contract giver and acceptor and the way in which the QMS compliance, or compliance with other appropriate standards, is assessed. The selected standards should be assessed for the suitability of its application. The type of activities undertaken by the contract acceptor should be specified.

NOTE:

1. Any information which is not relevant may be stated as 'Not Applicable' in the relevant Sections/Columns of the above format, and reasons for non-applicability should be provided.
2. The above information should be submitted in bounded form (like spiral binding or hard binding) with page number.

ANNEXURE - VI

Schedule DII

SCHEDULE D (II)

(See rule 21 (d) and rule 24 A)

Information required to be submitted by the manufacturer or his authorised agent with the Application Form for the registration of a bulk drug/formulation/special product for its import into India. The format shall be properly filled in and the detailed information, secret in nature, may be furnished on a Computer Floppy.

1. GENERAL

- 1.1 Name of the drug/formulation/special product, a brief description and the therapeutic class to which it belongs.
- 1.2 Regulatory status of the drug. A Free Sale Certificate and/or Certificate of Pharmaceutical Products (CPP) issued by the Regulatory Authority of the country of origin. Free sale approval issued by the Regulatory Authorities of other major countries.
- 1.3 Drugs Master File (DMF) for the drug to be registered (duly notarised).
- 1.4 GMP Certificate in WHO formats or Certificate of Pharmaceutical Products (CPP) issued by National Regulatory Authority of the country of origin (duly notarized).
- 1.5 List of countries where marketing authorization or import permission for the said drug is granted with date (respective authorization shall be enclosed).
- 1.6 List of countries where marketing authorization or import permission for the said drug is cancelled/withdrawn with date.
- 1.7 List of countries where marketing authorization or import permission for the said drug is pending since (date).
- 1.8 Domestic price of the drug in the currency followed in the country of origin.
- 1.9 List of countries where the said drug is patented.

2. CHEMICAL AND PHARMACEUTICAL INFORMATION OF DRUGS.

- 2.1 Chemical name
Code name or number, if any
Non-proprietary or generic name, if any
Structure
Physico-chemical properties
- 2.2 Dosage form and its composition,
Qualitative and Quantative composition in terms of the active substance(s) and excipient(s)
List of active substance(s) separately from the constituent(s) of excipients.
- 2.3 Specifications of active and inactive ingredient(s) including pharmacopeial references.
- 2.4 Source of active ingredient(s), name and address.
- 2.5 Tests for identification of the active ingredient(s),
Method of its assays and tests for impurity profile with reference standards for the impurities (Protocol to be submitted along with reference standards for the impurities/relative substances).
- 2.6 Outline method and flow chart of manufacture of the bulk drug or finished formulation or special product.
- 2.7 Detailed test protocol for the drug with pharmacopeial reference or in house specification as approved by the registration authority, in the country of origin.
- 2.8 Stability data including accelerated stability and real time stability analysis.
- 2.9 Documentation on pack size.
- 2.10 Numerical expression on EAN bar code on the labels and cartons.
- 2.11 Safety documents on containers and closer.
- 2.12 Documentation on storage conditions.

- 2.13 Three samples of medicinal product/drug and outer packaging are to be submitted with batch certificates. An additional samples as well as reference substances with batch certificates including date of manufacture, shelf life, storage conditions of reference substance may be required both during registration procedure and during validity of registration decision.
- 2.14 Batch test reports/certificate of five consecutive production batches in details of the medicinal product are to be submitted for every site of manufacturing premises.
- 2.15 Manner of labelling as per rule 96 of the Drugs and Cosmetics Rules, 1945.
- 2.16 Package insert.
- 2.17 Details of safety handling procedure of the drug.
- 2.18 Details of PMS study report for marketing period not exceeding five years.
- 3 BIOLOGICAL AND BIOPHARMACEUTICAL INFORMATION OF DRUGS.**
- 3.1 Biological control tests applied on the starting material, if applicable.
- 3.2 Biological control tests applied on the intermediate products, if applicable.
- 3.3 Biological control tests applied on the finished medical products, if applicable.
- 3.4 Stability of the finished products in terms of biological potency of the drug, if applicable.
- 3.5 Sterility tests, if applicable, specification and protocol therein.
- 3.6 Pyrogen tests, if applicable specification and protocol therein.
- 3.7 Acute and sub-acute toxicity tests, if applicable specification and protocol therein.
- 3.8 Bio-availability studies and bio-equivalence data, if applicable.
- 3.9 Data relating to the environmental risk assessment for r-DNA products.

3.10 Other information relevant under the section.

4. PHARMACOLOGICAL AND TOXICOLOGICAL INFORMATION OF DRUGS

Executive summary of the product is to be submitted mentioning the specific and general pharmacological actions of the drug and pharmacokinetic studies on absorption, metabolism, distribution and excretion. A separate note is to be given on acute and sub-acute toxicity studies and long term toxicity studies. Specific studies on reproductive toxicity, local toxicity and carcinogenic activity of the drug is to be elaborated, as far as possible.

5. CLINICAL DOCUMENTATION

A new drug as defined under rule 122-E of the Drugs and Cosmetics Rules, 1945 is required to be permitted separately by the licensing authority under rule 122-A of the said rules prior to its registration. Such a new drug requires a brief summary on clinical documentation, along with permission under 122-A of the said rules for its Registration Certificate.

6. LABELLING AND PACKAGING INFORMATION OF DRUGS.

6.1 Labels should conform as per the specifications under the Drugs and Cosmetics Rules, 1945

6.2 Package insert should be in English and shall indicate the following

Therapeutic Indications: -Posology and method of administration.

Contra-indications:-

Special warnings and special precautions for use, if any. Interaction with other medicaments and other forms of interaction. Pregnancy and lactation, if contra-indicated. Effects of ability to drive and use machines, if contra-indicated. Undesirable effects/side effects: Antidote for overdosing.

6.3 Package insert should indicate the following pharmaceutical information:-

List of excipient

Incompatibilities

Shelf life in the medical product as packaged for sale

Shelf life after dilution or reconstitution according to direction

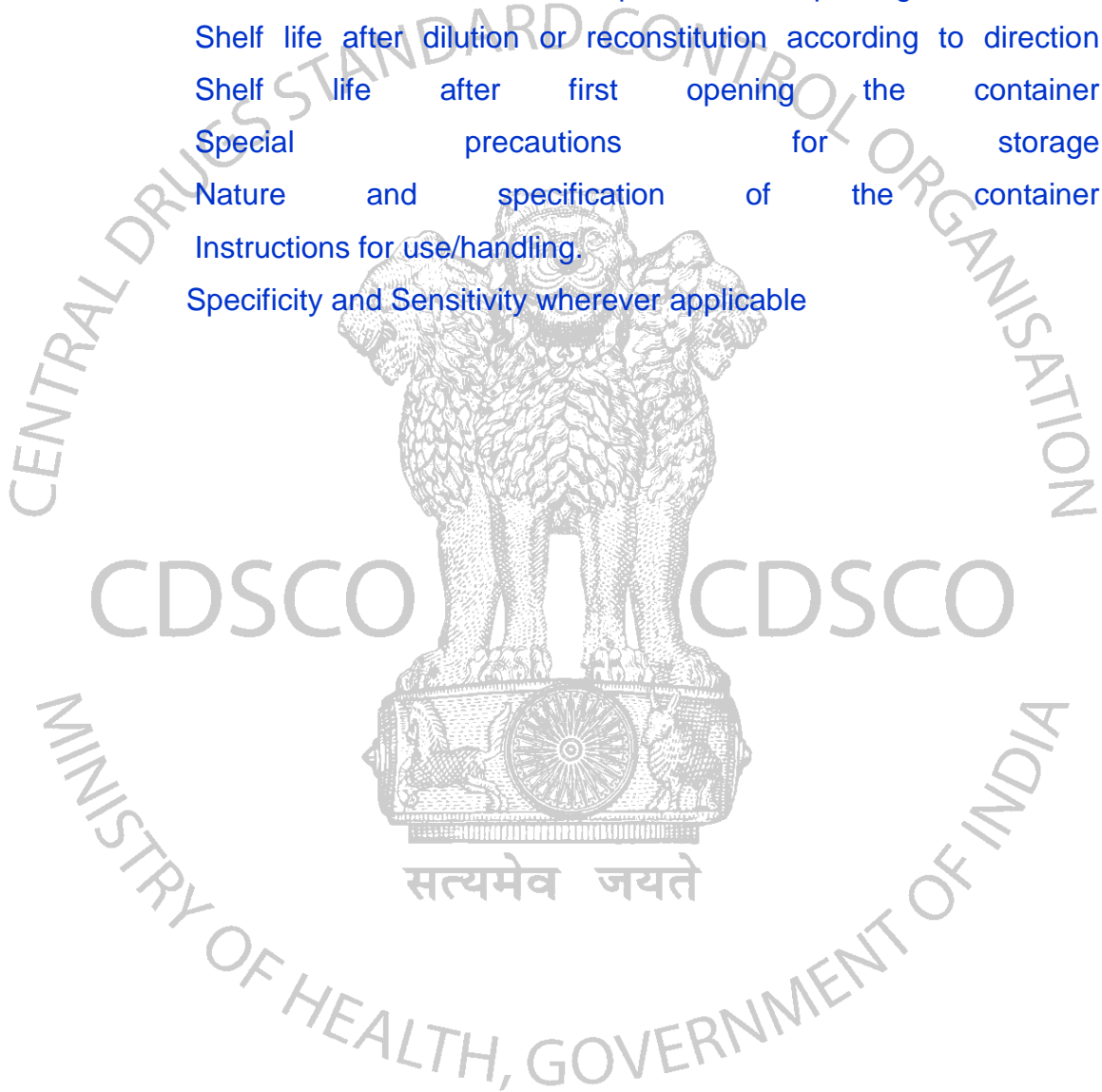
Shelf life after first opening the container

Special precautions for storage

Nature and specification of the container

Instructions for use/handling.

Specificity and Sensitivity wherever applicable



Schedule D-II ANNEXURE-B

INFORMATION TO BE SUBMITTED IN SCHEDULE D-II SPECIFIC INFORMATION REQUIRED FOR THE DIAGNOSTIC KITS

A Product dossier showing the:

1. The details of source antigen or antibody as the case may be and characterization of the same. Process control of coating of antigen or antibody on the base material like Nitrocellulose paper, strips or cards or ELISA wells etc.

Detailed composition of the kit and manufacturing flow chart process of the kit showing the specific flow diagram of individual components or source of the individual components.

2. Test protocol of the kit showing the specifications and method of testing.

In house evaluation report of sensitivity, specificity and stability studies carried out by the manufacturer.

3. The report of evaluation in details conducted by the National Control Authority of country of origin.

Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter.

4. The detailed test report of all the components used/packed in the finished kit.
5. Pack size and labeling.
6. Product inserts.

Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the kit.

Specific processing like safe handling, material control, area control, process control, stability studies, storage at quarantine stage and finished stage, packaging should be highlighted in the product dossier.

The information submitted above is true to the best of my knowledge and belief.

Place:

Date: Signature of the manufacturer
Seal / Stamp

ANNEXURE - VII

(Device Master File)

Note: The manufacturer shall submit the duly signed and notarized information pertaining to **Diagnostics Kit** (s) in the following format. All information/reports/data should be in English only. It is expected that the information submitted in the form of hard copy shall also be submitted in the form of soft copy.

The dossier shall have an index listing the details of the documents produced as requested hereunder and shall reflect the page numbers.

1.0 EXECUTIVE SUMMARY (Not more than three A4 size pages):

An executive summary shall be provided by the manufacturer and shall contain:

- 1.1 Introductory descriptive information on the **Diagnostics Kits**, the intended use and Class of Kit, novel features of the Kit (if any), Shelf Life of the Kit and a synopsis on the content of the dossier (not more than 500 words).
- 1.2 Regulatory status of the similar device in India (Approved or New Kit)
- 1.3 Domestic Price of the device in the currency followed in the Country of origin
- 1.4 Marketing History of the Kit from the date of introducing the Kit in the market
- 1.5 List of regulatory approvals or marketing clearance obtained (Submit respective copies of Approval Certificates)

GHTF and other countries	Approved Indication	Approved Shelf life	Composition and/or Material of Construction	Class of Kit	Date of First Approval
USA					
Australia					
Japan					
Canada					
European Union					
Others (Specify all countries)					

1.6 Status of pending request for market clearance

Regulatory Agency of the country	Intended use	Indication for use	Registration status and date	Reason for rejection/withdrawal, if any

1.7 Safety and performance related information on the kit:

- a. Summary of reportable events and field safety corrective action from the date of introduction

For Adverse event

Adverse Event	Frequency of Occurrence during the period (Number of Report/Total Units sold)

For Field Safety Corrective Action (FSCA)

Date of FSCA	Reason for FSCA	Countries where FSCA was conducted

- b. If the kit contains any of the following then descriptive information on the following need to be provided.

1. Animal or human fluids and/or derivatives thereof, rendered non-viable.
2. Cells, tissues and/or derivatives of microbial recombinant origin.

2.0 KIT DESCRIPTION AND PRODUCT SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

Device Master File

2.1 Device Description

The Device master file should include the following device descriptive information:

- a) The intended use of the Diagnostics kits. This may include:
- 1) what is detected
 - 2) its function (for example screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease);
 - 3) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
 - 4) whether it is automated or not;
 - 5) whether it is qualitative or quantitative;
 - 6) the type of specimen(s) required (eg. serum, plasma, whole

- blood, tissue biopsy, urine);
- 7) testing population;
 - b) the intended user (lay person or professional);
 - c) a general description of the principle of the assay method
 - d) the Class of the device and the applicable classification rule according to any one of the countries Viz. USA, Canada, Japan, Australia and European
 - e) a description of the components (e.g. reagents, assay controls and calibrators) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers) and where applicable:
 - f) a description of the specimen collection and transport materials provided with the Diagnostics kits or descriptions of specifications recommended for use;
 - g) for instruments of automated assays : a description of the appropriate assay characteristics or dedicated assays;
 - h) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;
 - i) a description of any software to be used with the Diagnostics kits;
 - j) a description or complete list of the various configurations/variants of the Diagnostics kits that will be made available;
 - k) a description of the accessories, other Diagnostics kits and other products that are not Diagnostics kits, which are intended to be used in combination with the Diagnostics kits.

Reference to the Manufacturer's Previous Device Generation(s) and/or Similar Devices or Device History

2.2 Reference to predicate and/or previous generations of the device

Where relevant to demonstrating conformity to the Essential Principles, and to the provision of general background information, the dossier should contain an overview of:

- a) the manufacturer's previous generation(s) of the device, if such exist; and/or
- b) Predicate devices available on the local and international markets.
- c) **Device History:** A summary of the product history in both the Indian market and international markets. Details should include a list of countries or regulatory jurisdictions, approximate numbers of IVDs and/or period of time supplied. The inclusion of information clearly identifying products either as new to the Indian market, or as previously Registered.

2.3 For an IVD medical device already available on the market in any jurisdiction

This information may include a summary of the number of adverse event reports related to the safety and performance of this IVD medical device in relation to the number of IVD medical devices placed on the market.

External certificates and documents which give written evidence of conformity with the Essential Principles may be annexed to the Device master file.

3. Essential Principles (EP) Checklist

The Device master file should include an EP checklist that identifies:

- a) the Essential Principles of Safety and Performance;
- b) whether each Essential Principle applies to the IVD medical device and if not, why not;
- c) the method used to demonstrate conformity with each Essential Principle that applies; and
- d) the reference to the actual technical documentation that offers evidence of conformity with each method used.

The method used to demonstrate conformity may include one or more of the following:

- a) conformity with recognized or other standards¹;
- b) conformity with a commonly accepted industry test method (reference method);
- c) conformity with appropriate in-house test methods that have been validated and verified;
- d) comparison to an IVD medical device already available on the market.

The EP checklist should include a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer and within the Device master file (when such documentation is specifically required for inclusion in the Summary Technical Documentation as outlined in this guidance).

4. Risk Analysis and Control Summary

- a) The Device master file should contain a summary of the risks identified during the risk analysis process and a description of how these risks have been controlled to an acceptable level. Preferably, this risk analysis should be based on recognised standards and be part of the manufacturer's risk management plan.
- b) The summary should address possible hazards for the IVD medical device such as the risk from false positive or false negative results, indirect risks which may result from IVD medical device-associated hazards, such as instability, which could lead to erroneous results, or from user-related hazards, such as reagents containing infectious agents.
- c) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits.

5. Design and Manufacturing Information

5.1 Device Design

The Device master file should contain information to allow a reviewer to obtain a general understanding of the design applied to the IVD medical device.

It should include a description of the critical ingredients of an assay such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the IVD medical device,

This section is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. If design takes place at multiple sites, a controlling site must be identified.

5.2 Manufacturing Processes

The Device master file should contain information to allow a reviewer to obtain a general understanding of the manufacturing processes. It is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. The information may take the form of a process flow chart showing, for example, an overview of production including the technologies used, assembly, any in-process and final product testing, and packaging of the finished IVD medical device.

5.3 Manufacturing Sites

The Device master file should identify the sites where these activities are performed (this does not include the sites of all suppliers of raw materials but only the sites that are involved in critical manufacturing activities). If QMS certificates, or the equivalent, exist for these sites, they may be annexed to the Device master file.

6. Product Validation and Verification

The information provided in the product validation and verification section of the Device master file will vary in the level of detail as determined by the class of the device

As a general rule, the Device master file should summarise the results of validation and verification studies undertaken to demonstrate conformity of the IVD medical device with the Essential Principles that apply to it. Where appropriate, such information might come from literature.

For the purpose of the Device master file document, summary and detailed information are defined as:

1. Summary Information

A summary should provide enough to assess the validity of that information by the Regulatory authorities. This summary should contain a brief description of:

- a) the study protocol,
- b) the study results,
- c) the study conclusion.

This summary may include:

- a) Where a recognized standard exists, a declaration/certificate of conformity to a recognized standard can be provided with a summary of the data if no acceptance criteria are specified in the standard;
- b) In the absence of a recognized standard, a declaration/certificate of conformity to a published standard that has not been recognized might be provided if it is supported by a rationale for its use, and summary of the data, and a conclusion, if no acceptance criteria are specified in the standard;
- c) In the absence of a recognized standard and non-recognized published standards, a professional guideline, industry method, or

in-house standard may be referred to in the summarized information. However, it should be supported by a rationale for its use, a description of the method used, a summary of the data in sufficient detail and a conclusion to allow assessment of its adequacy;

- d) A review of relevant published literature regarding the device/analyte (measurand) or substantially similar IVD medical devices.

2. Detailed Information

Detailed information should include:

- a) the complete study protocol,
- b) the method of data analysis,
- c) the complete study report,
- d) the study conclusion.

For detailed information, when a recognized standard exists that contains the protocol and the method of data analysis, this information can be substituted by a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions.

Where appropriate, actual test result summaries with their acceptance criteria should be provided and not just pass/fail statements.

7. Analytical Studies

The statements and descriptions in the following sections refer to all IVD medical devices. It must be noted however that there are applicability differences between instrumentation and reagent-based assays, and that the assays themselves may be quantitative, semi-quantitative or qualitative in nature. There may be limited applicability of some of the following subsections for qualitative or semi-quantitative assays. Where possible, comments regarding instrumentation or qualitative assays appear in the subsections.

8. Specimen type

This section should describe the different specimen types that can be used. This should include their stability and storage conditions. Stability includes storage and where applicable transport conditions. Storage includes elements such as duration, temperature limits and freeze/thaw cycles.

This section should include summary information for each matrix and anticoagulant when applicable, including a description of the measurement procedure for comparison or determination of measurement accuracy. This includes information such as specimen type tested, number of samples, sample range (using spiked samples as appropriate) or target concentrations tested, calculations and statistical methods, results and conclusions.

9. Analytical Performance Characteristics

9.1 Accuracy of measurement

This section should describe both trueness and precision studies.

Note: The general term measurement accuracy is currently used to cover both trueness and precision, whereas this term was used in the past to cover only the one component now named trueness.

While measurement **trueness**, affected by systematic error, is normally expressed in terms of bias, measurement **precision**, affected by random error, is naturally expressed in terms of standard deviation,

Accuracy is affected by a combination of systematic and random effects that contribute as individual components of the total error of measurement.

9.2 Reproducibility

This section should include reproducibility estimates and information about the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators and instruments. Such variability is also known as **“Intermediate Precision”**. Reproducibility data is obtained for instrumentation in conjunction with an appropriate assay.

Note 1: Such studies should include the use of samples that represent the full range of expected analyte (measurand) that can be measured by the test as claimed by the manufacturer.

Note 2: If a recognized standard is used, a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions.

10. Analytical sensitivity

This section should include information about the study design and results. It should provide a description of specimen type and preparation including matrix, analyte (measurand) levels, and how levels were established. The number of replicates tested at each concentration should also be provided as

well as a description of the calculation used to determine assay sensitivity. For example:

- a) Number of standard deviations above the mean value of the sample without analyte (measurand), commonly referred to as limit of blank (LoB).
- b) Lowest concentration distinguishable from zero, based on measurements of samples containing analyte (measurand), commonly referred to as limit of detection (LoD).
- c) Lowest concentration at which precision and/or trueness are within specified criteria, commonly referred to as limit of quantitation (LoQ).

Typically for a Class C and D IVD medical devices, detailed information would be provided.

11. Analytical specificity

This section should describe interference and cross reactivity studies to determine the analytical specificity, defined as the ability of a measurement procedure to detect or measure only the analyte (measurand) to be detected, in the presence of other substances/agents in the sample.

Provide information on the evaluation of potentially interfering and cross reacting substances/agents on the assay. Information should be provided on the substance/agent type and concentration tested, sample type, analyte (measurand) test concentration, and results.

Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

- a) substances used for patient treatment (e.g. therapeutic drugs, anticoagulants, etc.);
- b) substances ingested by the patient (e.g. over the counter medications, alcohol, vitamins, foods, etc.);
- c) substances added during sample preparation (e.g. preservatives, stabilizers);
- d) substances encountered in specific specimens types (e.g. haemoglobin, lipids, bilirubin, proteins);
- e) analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition (e.g. for a hepatitis A assay: test specimens negative for hepatitis A virus, but positive for hepatitis B virus).

Typically, interference studies involve adding the potential interferent to the sample and determining any bias of the test parameter relative to the control sample to which no interferent has been added.

12. Metrological traceability of calibrator and control material values

Where applicable, summarize the information about metrological traceability of values assigned to calibrators and trueness control materials. Include, for example, methods and acceptance criteria for the metrological traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation.

Precision control materials, used when establishing the reproducibility of a measurement procedure do not require the assessment of metrological traceability to a reference material or a reference method.

13. Measuring range of the assay

This section should include a summary of studies which define the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established.

This summary should include a description of specimen type, number of samples, number of replicates, and preparation including information on matrix, analyte (measurand) levels and how levels were established. If applicable, add a description of high dose hook effect and the data supporting the mitigation (e.g. dilution) steps.

14. Definition of Assay Cut-off

This section should provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including:

- a) the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included);
- b) method or mode of characterization of specimens; and
- c) statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define gray-zone/equivocal zone.

15. Stability (excluding specimen stability)

This section should describe claimed shelf life, in use stability and shipping studies.

16. Claimed Shelf life

This section should provide information on stability testing studies to support the claimed shelf life. Testing should be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies.

Such detailed information should describe:

- a) the study report (including the protocol, number of lots, acceptance criteria and testing intervals)
- b) when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies
- c) conclusions and claimed shelf life

Note: Shelf life can be derived from the lot with the longest real time stability data as long as accelerated or extrapolated data from all three lots are comparable.

17. In use stability

This section should provide information on in use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability.

In the case of automated instrumentation if calibration stability is claimed, supporting data should be included.

Such detailed information should describe:

- a) the study report (including the protocol, acceptance criteria and testing intervals)
- b) conclusions and claimed in use stability

18. Shipping stability

This section should provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions.

Shipping studies can be done under real and/or simulated conditions and should include variable shipping conditions such as extreme heat and/or cold.

Such information should describe:

- a) the study report (including the protocol, acceptance criteria)
- b) method used for simulated conditions
- c) conclusion and recommended shipping conditions

19. Clinical Evidence

The Device master file should contain the Clinical Evidence Evaluation report that demonstrates conformity of the IVD medical device to the Essential Principles that apply to it.

20. Labelling

The Device master file should typically contain a complete set of labeling associated with the IVD medical device as described in Rule 96 of Drugs and Cosmetics Rules on labelling should include the following:

- a) Labels on the IVD medical device (immediate and outer container)
- b) Instructions for use
- c) The label should bear name of the product, batch/Lot number, date of expiry or use before date, storage conditions, name and address of the actual and Legal manufacturer(if any), and Name and address of Importer, Import license number etc

21. Post Marketing Surveillance Data (Vigilance Reporting)

The dossier should contain the Post Marketing Surveillance/ Vigilance Reporting procedures and Data collected by the manufacturer encompassing the details of the complaints received and corrective and Preventive actions taken for the same.

NOTE:

1. All the test reports submitted as a part of the dossier should be signed and dated by the responsible person.
2. Batch Release Certificates and Certificate of Analysis of finished product for minimum 3 batches should be submitted.
3. All certificates submitted must be within the validity period.
4. Any information which is not relevant for the subject kits may be stated as 'Not Applicable' in the relevant Sections/Columns of the above format, and reasons for non-applicability should be provided.
5. The above information should be submitted in bounded form (like spiral binding or hard binding).

ANNEXURE - VIII

Format for Dossier summary sheet

S.No	REQUIREMENTS	INFORMATION / Comment
1.	Date of Application	
2.	Application Reference Number	
3.	Application in Form 40 duly signed and stamped by the applicant (Compare the name and address of both Legal Manufacturer and Actual Manufacturer and name of the device(s) with Schedule D(I), POA, FSC/ CFG/ Certificate of marketability)	Eg - Submitted signed by the Indian agent .Product names are correlating with POA, and Schedule D(I) and FSC.
4.	Name and Address of the Manufacturer(s) (Tel. No., Fax No. and email address)	
5.	Name and Address of Manufacturing premises (Tel. No., Fax No. and email address)	
6.	Name and Address of the Indian Agent (Tel. No., Fax No. and email address) as per Wholesale Licence / Manufacturing licence	
7.	Copy of Registration Certificate and its validity details (for endorsement application and re-registration applications)	Eg Submitted CD-04 dated 01-04-2009 valid upto 31/12/2011.
8.	Names of the Notified Diagnostic Kits to be registered.	

9.	Fees paid:	Eg - For Manufacturing Site: -----USD For Product(S): -----USD for ----- products												
10.	Bank Verification by Bank of Baroda, Mumbai under the Head of Account "0210 - Medical and Public Health, 04 -Public Health, 104 - Fees and Fines" adjustable to Pay and Account Officer, DGHS, New Delhi													
	<table border="1"> <thead> <tr> <th style="text-align: center;">Challan No.</th> <th style="text-align: center;">Fee paid in INR</th> <th style="text-align: center;">Fee paid in US Dollar</th> <th style="text-align: center;">Date of issuance</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Challan No.	Fee paid in INR	Fee paid in US Dollar	Date of issuance									
Challan No.	Fee paid in INR	Fee paid in US Dollar	Date of issuance											
	Total Amount = Rs ----- Realization of TR6 Challan: Yes / No													
11.	Duly Apostilled/attested by Indian Embassy <u>Power of Attorney</u> conjointly signed and stamped by the Indian agent and manufacturer for the products proposed for registration	Submitted / Not submitted and specify the location in the dossier (dossier No, Page No, S.No)												
12.	Duly Notarized / Attested (by gazetted officer) and valid copies of Wholesale Licence/ Manufacturing licence issued by the concerned state licensing authority for the sale / manufacture of the Diagnostic Kits in India.	Eg - Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No) , drug sale license issued by FDA, Maharashtra valid upto 31.12.2012												
13.	Duly Apostilled/notarized / Attested (by Indian Embassy) in the country of origin and valid copy.													
a.	Free Sale Certificate/ Certificate to Foreign Government/ Certificate of Marketability from the National Drug Regulatory Authority of the country of origin.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No) Mention the product name and position (page & S.No) in Form 40, POA, FSC Mention Name of the issuing authority Mention the issue date & Validity period												
b.	Free Sale Certificate/ Certificate to Foreign Government/ Certificate of Marketability from the National Drug Regulatory	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No) Mention the product name and position (page & S.No) in Form 40, POA, FSC Mention Name of the issuing authority												

	Authority of any one of the countries Viz. USA, Canada, Japan, Australia and European Union	Mention the issue date & Validity period
c.	ISO 13485 Certificate	Eg- Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No) , issued by ----- valid upto -----
d.	CE Full Quality Assurance Certificate	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No) issued by ----- valid upto -----
e.	CE Design Certificate	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No) issued by ----- valid upto -----
f.	Declaration of Conformity	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No) issued by ----- valid upto -----
14.	Schedule D (I) duly filled along with the undertaking, signed and stamped by the manufacturer -	
a.	Duly Notarized Plant Master File.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
b.	Manufacturer Business activity in Domestic as well as global market.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
c.	A brief profile of the manufacturer's research activity	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
d.	Domestic Prices of the devices in the currency followed in the country of origin.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
e.	Undertaking of Schedule D(I)	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
15.	Schedule D (II) duly filled, signed and stamped by the manufacturer - specify the location in the dossier (dossier No, Page No, S.No)	
a.	Duly Notarized Device Master File.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
b.	Class of Diagnostic Kits	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)

c.	Shelf life of product	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
d.	Whether the Notified Diagnostic Kits contain any radio active Isotopes.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
e.	list of all materials of animal or human origin used in the device. For these materials TSE/ BSE Certificate is required.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
f.	List of countries where marketing authorization or import permission is granted.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
g.	Product specifications	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
h.	Manufacturing process with Flow Chart	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
i.	Design Information (Diagnostic Kits design and validation report)	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
j.	Labels, package Insert, IFU's, Brochure or operating manual.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
k.	Documentation on packaging details	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
l.	Stability data / Self Life Report along with the Protocol	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
m.	Documentation on storage conditions	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
n.	Risk Management Report	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
o.	PMS procedures and PMS data	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
p.	Clinical Evidence report	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)

q.	Batch release Report or Certificate of Analysis	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
r.	Sale details of the proposed products during last three years (For Re registration only)	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
s.	Declaration stating that no complaint received w.r.t proposed products during last three years (For Re registration only)	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
t.	Essential Principles Checklist	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
16.	Schedule D (II) Annexure-B duly filled, signed and stamped by the manufacturer -	
a.	The details of source antigen or antibody as the case may be and characterization of the same. Process control of coating of antigen or antibody on the base material like Nitrocellulose paper, strips or cards or ELISA wells etc	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
b.	Test protocol of the kit showing the specification and method of test	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
c.	In house evaluation report of sensitivity, specificity	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
d.	The report of evaluation in details conducted by National Control Authority of country of origin	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
e.	Specimen batch test report for at least consecutive 3 batches	Submitted / Not submitted specify the location in

	showing specification of each testing parameter.	the dossier (dossier No, Page No, S.No)
f.	The detailed test report of all the components used/packed in the finished kit	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
g.	Pack size and labeling.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
h.	Product inserts.	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)
17.	Performance Evaluation Report of 3 batches of the product from NIB, Noida	Submitted / Not submitted specify the location in the dossier (dossier No, Page No, S.No)

PRODUCT SUMMARY:

Product name	Component / Composition	Intended use of kit & each component	Qualitative / Quantitative	Name of Assay technique / Principle	Storage condition of kit & each component	Shelf Life of kit & each component

APPROVAL SUMMARY:

Product name	Status In India	Status IN USA, Canada, Japan, Australia and European Union	Status In other Country

PRODUCT EVALUATION SUMMARY:

Product name	Lot number	Expiry Date	Name of Assay technique / Principle	Name & Address of Lab (India)	Report Number & Date	Specificity & Sensitivity as per insert	Specificity & Sensitivity as per Mfg COA	Specificity & Sensitivity as per Mfg COA	Specificity & Sensitivity as per Report

STABILITY DATA SUMMARY:

Product name	Lot number	Study Duration (Month)	Study Condition (C°)	Para meter tested	Initial value	End value	Proposed Storage condition of kit & each component	Proposed Shelf Life of kit & each component

D Rules Related to Registration of Notified Diagnostic Kits in India Specified under Drugs & Cosmetics Rules (For Information Only)

Rule-24-A. Form and manner of application for Registration Certificate.—

(1) An application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer himself, having a valid wholesale licence for sale or distribution of drugs under these rules, or by his authorised agent in India, either having a valid licence under the rules to manufacture for sale of a drug or having a valid wholesale licence for sale or distribution of drugs under these rules, and shall be accompanied by the fee specified in sub-rule (3) and the information's and undertakings specified in Schedules D-I and D-II duly signed by or on behalf of the manufacturer.

(2) The authorisation by a manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate.

(3) (i) A fee of one thousand and five hundred US dollars ¹ [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import into and use in India

(ii) A fee of one thousand US dollars ¹ [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional drug:
Provided that in the case of any subsequent application for registration of additional drugs by the same manufacturer, the fee to accompany shall be one thousand US dollars ¹ [or its equivalent in Indian rupees] for each drug.

(4) The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines":

Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account "0210-Medical and Public Health, 04- Public Health, 104-Fee and

Fines”, and the original receipt of the said transfer shall be treated as an equivalent to the bank challan, subject to the approval by the Bank of Baroda that they have received the payment.

(5) The applicant shall be liable for the payment of a fee of five thousand US dollars [or its equivalent in Indian rupees] for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority under Rule 22.

(6) The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.

(7) A fee of three hundred US dollars [or its equivalent in Indian rupees] shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

(8) No Registration Certificate shall be required under these Rules in respect of an inactive bulk substance to be used for a drug formulation, with or without pharmacopoeial conformity.]

Rule 25B. Registration Certificate for import of drugs manufactured by one manufacturer.—

(1) A single application may be made, and a single Registration *Drugs and Cosmetics Rules, 1945* 39

Certificate in Form 41 may be issued in respect of the import of more than one drug or class of drugs, manufactured by the same manufacturer:

Provided that the drug or classes of drugs, are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit:

Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different drugs, separate Registration Certificates shall be required in respect of the drugs manufactured by each such factory.

Rule 27-A Grant of Registration Certificate.—

(1) On receipt of an application for Registration Certificate in the Form and manner specified in Rule 24-A, the licensing authority shall, on being satisfied, that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form 41:

Provided further that if the application is complete in all respects and informations specified in Schedules D-I and D-II are in order, the licensing authority shall, within nine months from the date of receipt of an application, issue such

Registration Certificate, and in exceptional circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three months, as the licensing authority may deem fit.

- (2) If the applicant does not receive the Registration Certificate within the period as specified in the proviso to sub-rule (1), he may appeal to the Central Government and the Central Government may after such enquiry into the matter, as it considers necessary, may pass such orders in relation thereto as it thinks fit.]

Rule 28-A. Duration of Registration Certificate.— A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue:
Provided that if the application for a fresh Registration Certificate is made nine months before the expiry of the existing certificate, the current Registration Certificate shall be deemed to continue in force until orders are passed on the application.

Rule 29A. Suspension and cancellation of Registration Certificate.—If the manufacturer fails to comply with any of the conditions of the Registration Certificate, the licensing authority may after giving him an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the Registration Certificate for such period as it thinks fit either wholly or in respect of some of the substances to which it relates:

Provided that a person, who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, pass such orders in relation thereto as it thinks fit.

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