

#### **GOVERNMENT OF INDIA**

#### MINISTRY OF HEALTH & FAMILY WELFARE

(DIRECTORATE GENERAL OF HEALTH SERVICES)

CENTRAL DRUGS STANDARD CONTROL ORGANISATION

#### REGIONAL DRUGS TESTING LABORATORY-CHANDIGARH

Accredited by: NABL (ISO/IEC-17025:2017 in Chemical & Biological Testing)

#### **RDTL PROFILE**



# REGIONALDRUGSTESTINGLABORATORY (RDTL) -**CHANDIGARH**

Sector-39C, Chandigarh-160036

#### **Location Link:**

 $\underline{https://www.google.com/maps/place/Regional+Drugs+Testing+Laboratory/@30.7}$ 405994,76.7277807,17z/data=!3m1!4b1!4m6!3m5!1s0x390fed0baaaaaaaab:0x306e d48fb58889fd!8m2!3d30.7405994!4d76.7303556!16s%2Fg%2F1tfnrctc?entry=ttu



0172-2688239



0172-2636316



rdtlchd@cdsco.nic.in

REGIONAL DRUGS TESTING LABORATORY CHANDIGARH

# HISTORY

#### **ESTABLISHEDIN -2007**

The Regional Drugs Testing Laboratory - Chandigarh (RDTL) is a National statutory laboratory in the North Zone of India. It is working under the administrative control of Drugs Controller General (I), CDSCO, Directorate General of Health Services (DGHS) in the Ministry of Health & Family Welfare, Government of India.

This laboratory is established for the testing of drugs & Cosmetics products under the control of Central Drugs Standard Control Organisation (CDSCO).

For the establishment of this laboratory, Director General of Health Services, Ministry of Health & Family Welfare, Govt. of India, Nirman Bhawan, New Delhi – 110011 in 1996 acquired a piece of land measuring 3354.328 Sq. Yd. from Estate Office, U.T., Chandigarh in 1995 at sector 39C which is about 7.00 Km from ISBT sector 17, 4 Km from sector 43 Bus stand, 13 Km from Chandigarh Railway Station and 20.5 Km from Chandigarh International Airport.

The building was constructed by CPWD Chandigarh and handed over in the year of 2007. This laboratory started its journey to fulfil its statutory duties from November-2007, since than laboratory is contentiously being flourished itself. The microbiological department was established and came into effect from June 2017. It was accredited by NABL in chemistry discipline in the year of 2016 and in microbiology discipline in the year of 2018. It is continuously discharging its duties to be a part of broad goal of CDSCO as well as Ministry of Health and Family Welfare to enhance public health by ensuring the availability of quality drugs, cosmetics and medical devices to the common people.

This laboratory receives the samples of drugs, cosmetics and medical devices in the form of Legal (Form-18), Survey and special drive from Central Officers/Drugs Inspectors of CDSCO, North Zone – Ghaziabad, Sub Zone- Baddi, Jammu, Varanasi and Assistant Drugs Controller (India) and Indira Gandhi International Airport, New Delhi. After that, the samples are being tested according to the requirement of Drugs and Cosmetics Rule 1945 and there under and the reports are being dispatched to the concerned senders of the samples.

# Review of Director

Dr. Debasis Maiti, Director In Charge

From the very beginning of its birth, this institute always thrives to discharge its duties to be a part of broad goal of CDSCO as well as Ministry of Health and Family Welfare to enhance public health, which can be ensured by making the availability of quality drugs, cosmetics and medical devices to the common people. It involves to test the samples and to submit the reports accordingly in efficient manner from its statutory periphery.

An enormous number of drugs and cosmetics are available to the common people and a number of methods and techniques are required to test the quality of these huge kinds of samples. The journey is not so smooth, but it has always accepted and overcome its challenges. This unremitting and ironic determination gifted it to be flourished, bloomed and strengthens its foundation from its root.

This institute has instilled the culture to employ the full potential and support of its employees. The employees are encouraged to work in harmonious manner for their excellent contribution with their professional approach and experiences.

## 

### Our goals for further growth and value creation:

- Delivering quality technical services by optimum utilization of its resources in a sustainable manner.
- Ensuring continuous and contemporary learning.
- Compliance norms in practice.



Continual improvement in maintaining and managing environmental aspects and



Enhancing occupational health and safety policy and management of hazards effectively.

This institute also prioritized the safety and security of its human resources, facilities and environment from the potential threats and harmful influences.

There are a number of people who are continuously thriving to flourish this institute from its germination. I would like to thank all of them for being a part of this institute and for their continuous, cordial and unconditional support over the time being.









To safeguard and enhance public health by quality and excellence in testing of drugs, cosmetics and medical devices.



To be a part of modern regulatory system in India to protect public health by ensuring provision of safe, effective and quality drugs and pharmaceuticals based on scientific excellence accountable to both the Government and the





To provide quality and effective analytical services in the area of Drugs, pharmaceuticals and cosmetics testing which can be achieved through employment of advanced testing facility with the sophisticated instruments and dedicated, committed work force by adhering to core values of transparency, accountability, efficiency, commitment, credibility and innovation.



Receipt No. 84057/2025/RDTL CHANDIGARH (Computer No. 8

To be a smart drug testing laboratory equipped with latest sophisticated equipment's and having clean and green eco-friendly environment.

# Key Objectives [

- To implement effective quality system in the laboratory.
- To ensure dependable and accurate testing facility.
- To provide test results at the earliest and to the best satisfaction.
- To update technical knowledge / skill of scientific / technical staff by inhouse and outside training.
- Regular participation in Proficiency Testing and Inter Laboratory Comparison Programs.
- To provide proper & safe working environment to adopt Good Laboratory Practices.



# **Statutory Functions and Duties of the Institute**



Analysis of Drugs and Pharmaceuticals, Cosmetics and Medical Devices in terms of schedule to the Drugs and Cosmetics Act, 1940 and rules there under so as to specify the standards of identity, purity and strength for the drugs imported, manufactured for sale, stocked or exhibited for sale or distribution in India.



Analysis of Import drugs and Cosmetics samples entering through the port offices.



Analysis of Drugs & Pharmaceutical formulations received as Survey Samples from Central Drugs Standard Control Organization and its Zonal Offices and State of Haryana, Delhi, Jammu & Kashmir and Himachal Pradesh.



Analysis of Drugs and Pharmaceutical formulations received as National Survey Samples from CDSCO under Ministry of Health and Family Welfare and various state drugs control authorities.





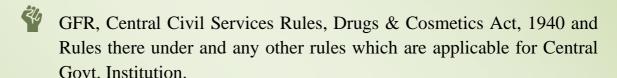
### Rules / orders under which powers and duty are derived:

Director, RDTL is exercising the powers as HOD delegated under the relevant provisions of DFP Rules, 1978 and GFRs, 2005 vide letter No. F. NO. D.21013/7/2010-DC, dated 24<sup>th</sup> May, 2010.

As per Central Civil Services Rules and Drugs & Cosmetic Act 1940 and rules there under. Also, as per ISO/IEC 17025:2017 in chemical & Biological Testing requirement for Laboratories and any other rule which are applicable for Central Govt. Institution.



### Related provisions, acts, rules etc.:





### Norms/ standards for functions/ service delivery:

As per Drugs & Cosmetics Act, 1940 and Rules there under and ISO/IEC 17025:2017 and any other rules which are applicable for Central Goyt, Institution.



### Time-limit for achieving the targets:



As per the provision of Drugs & Cosmetics Act, 1940 and Rules there under the report of the result of test and analysis in accordance with the rule (within a period of sixty days of the receipt of the sample)

#### **CHANDIGARH**



# Suo-motu disclosure U/S 4 of RTI Act 2005 [





#### **Process of Grievance Redressal:**



Already establish in CDSCO Head Quarter.



Web Notice:

https://cdsco.gov.in/opencms/opencms/en/About-us/Laboratories/

#### Details of information available in electronic form (Category of documents):



All Samples and its testing related information.



All Financial implications.



# Availability of Electronic information (Custodian of documents/categories):

Laboratory using centralised sugam software for the online receiving and online generation of reports through this software:-

https://sugamlabs.gov.in/SugamLabs/Homepage

All Financial implications: - Administration Department (Through Proper Channel).

### System of compensation to the officers and employees:



A per Central Government Rules.

#### REGIONAL DRUGS TESTING LABORATORY CHANDIGARH





### **Directory of Officers and Employees with Work Allocation**



#### Dr. Debasis Maiti,

Director In Charge

EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239

**Education:** 

M. Sc., MBA, PhD.

### Duties & Responsibilities:

- Chairman of Purchase Committee.
- Appellate Authority for RTI.
- Total Administrative Activities.
- Roles of Government Analyst and Medical Device Testing Officer.





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### **Directory of Officers and Employees with Work Allocation**



#### Sh. Hitesh Kumar Khare

Scientific Officer

EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239

#### **Education:**

M. Sc (Biochemistry), AIC (Chemistry).

- Managing testing of Samples for chemistry and instrumentation section.
- Operation and maintenance of GLC.
- Any duties assigned by Director/head of the Laboratory from time to time.
- Responsibilities of Central Public Information Officer.
- Responsibilities of DDO.
- Roles of Government Analyst and Medical Device Testing Officer.



#### REGIONAL DRUGS TESTING LABORATORY CHANDIGARH





### **Directory of Officers and Employees with Work Allocation**



#### **Dr. Susanto Chakraborty**

Research Assistant

EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239



Ph.D., M. Sc (Physics), B. Sc (Honors in Physics)

- Supervision of Bench Chemist for HPLC.
- Review of sample report.
- Operation of TOC.
- Responsibilities as a member of Purchase Committee.
- Any duties assigned by Director/Head of the Laboratory from time to time.





#### REGIONAL DRUGS TESTING LABORATORY CHANDIGARH





### **Directory of Officers and Employees with Work Allocation**



#### Sh. Chinnarao Pinisetti

Junior Scientific Assistant

EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239

Education: M. Pharm.

- Analysis of Drugs and Pharmaceutical Products.
- Operation of different sophisticated instruments in Chemical Section.
- Internal Calibration of instruments and Glassware.
- Assist in preparation of departmental SOPs and other Laboratory related works to the higher authority.
- Responsibilities of Buyer for purchasing from GEM Portal.
- Any duties assigned by Director/Head of the Laboratory from time to time.









### **Directory of Officers and Employees with Work Allocation**



### Miss Pooja Tiwari

Junior Scientific Assistant

EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239

Education:

M. Sc. In Chemistry

#### Duties & Responsibilities:

Receipt No. 84057/2025/RDTL CHANDIGARH (Computer No. 8

- Analysis of Drugs and Pharmaceutical Products.
- Operation of different sophisticated instruments in Chemical Section.
- Internal Calibration of instruments and Glassware.
- Assist in preparation of departmental SOPs and other Laboratory related works to the higher authority.
- Any other duties assigned by Director/Head of the Laboratory from time to time.
- Responsibilities as a member of Purchase Committee.





#### REGIONAL DRUGS TESTING LABORATORY CHANDIGARH



### **Directory of Officers and Employees with Work Allocation**



#### Dr. Amit Kumar

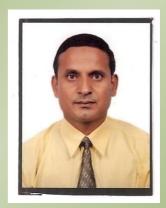
Junior Scientific Assistant EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239

Education:

M. Sc, PhD.

Duties & Responsibilities:



Official is on deputation NACWC, Cabinet Secretariat, Rashtrapati Bhavan, New Delhi, Since March 2019.



#### REGIONAL DRUGS TESTING LABORATORY CHANDIGARH



### **Directory of Officers and Employees with Work Allocation**



#### Sh. Vinod Kumar Laboratory Assistant

EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239

#### Education:

B. Sc, AIC (Chemistry).

- To ensure the Quality Assurance related work in the laboratory.
- After reviewing of Samples, sample entry in Sugam Software.
- Handling and solution of Sugam Software.
- Any duties assigned by Director/Head of the Laboratory from time to time.







### **Directory of Officers and Employees with Work Allocation**



#### Sh. Upender

**Laboratory Assistant** 

EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239

**Education:** 

M. Sc (Chemistry).

### Duties & Responsibilities:

Receipt No. 84057/2025/RDTL CHANDIGARH (Computer No. 8

- Total responsibilities of testing of cough syrup samples for export purpose from receiving of samples to release of report and data locking.
- Any duties assigned by Director/Head of the Laboratory from time to time.
- To issue & maintain records of Library books.





#### REGIONAL DRUGS TESTING LABORATORY CHANDIGARH



### **Directory of Officers and Employees with Work Allocation**



Sh. Major Singh

**Laboratory Attendant** 

EMAIL: rdtlchd@cdsco.nic.in

TEL: 0172-2688239

Education:

10+2.

Receipt No. 84057/2025/RDTL CHANDIGARH (Computer No. 8

- Archival of Control samples after testing.
- Issuing of Store items.
- Any duties assigned by Director/head of the Laboratory from time to time.









### **Employees with Gross Monthly remuneration**



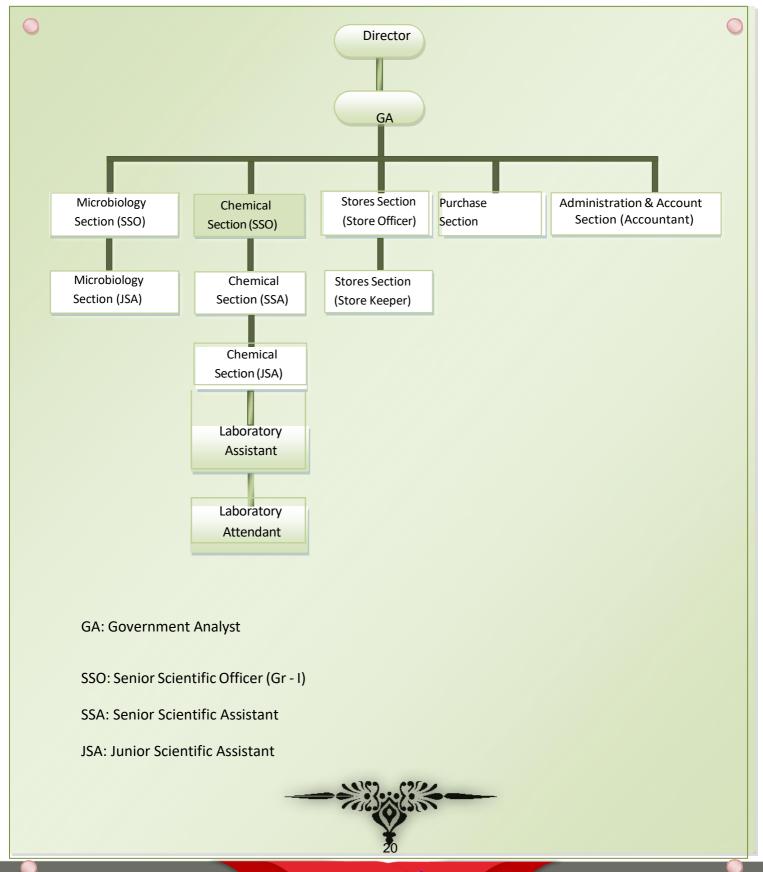


### **Total for Employees with Gross Monthly remuneration (2023-24):**

Sl. No.	Name	Designation	Mobile/ Telephone No	Email ID	Pay Level
1	Dr. Debasis Maiti	Director In Charge	0172-2688239	rdtlchd@cdsco.nic.in	10
2	Sh. Hitesh Kumar Khare	Scientific Officer	0172-2688239	rdtlchd@cdsco.nic.in	10
3	Dr. Susanto Chakraborty	Research Assistant	0172-2688239	rdtlchd@cdsco.nic.in	7
5	Sh. Chinnarao Pinisetti	Junior Scientific Assistant	0172-2688239	rdtlchd@cdsco.nic.in	6
6	Miss. Pooja Tiwari	Junior Scientific Assistant	0172-2688239	rdtlchd@cdsco.nic.in	6
7	Sh. Vinod Kumar	Laboratory Assistant	0172-2688239	rdtlchd@cdsco.nic.in	3
8	Sh. Upender	Laboratory Assistant	0172-2688239	rdtlchd@cdsco.nic.in	3
9	Sh. Major Singh	Laboratory Attendant	0172-2688239	rdtlchd@cdsco.nic.in	1

**Note:** Other than gross monthly remuneration to the employee all the employees are entitled for the LTC, CCL (only for ladies employee), tuition fees, medical reimbursements etc. as per Govt. of India Orders.

### **Organisational flow Chart of Supervision and accountability**



### **Decision Making Process**

All procedures in decision making including channels of supervision and accountability are being followed as per Govt. of India Rules/norms (Central Civil Services rules, Financial Rules, Rules of business, standing orders of Govt., manuals of Instructions) and as far as possible, decisions are taken with Ministry of Health and Family Welfare. Director has the sole responsibility to take the final decision in administrative matter with the concurrence of Director/Deputy Director Admin from CDSCO HQ, New Delhi, whereas in legal sample the G.A gives is opinion within 60 days after receiving of the samples and the final decision on such report will be taken by CDSCO, Head Quarter/SLA.



Sl. No.	Name	Designation	Time Period
1.	Dr. Surinder Singh	Director in Charge	17.05.2007 to 09.04.2008
2.	Dr. Arun Bhardwaj	Director in Charge	16.05.2008 to 02.08.2009
3.	Dr. Ram Avtar Singh	Director	03.08.2009 to 30.06.2022.
4.	Dr. Debasis Maiti	Director in Charge	01.07.2022 to till date











#### **Reception:**



Receive samples and letters



Keep initial records of the received samples



Reception.....







# **Sample Warden Section:**



Receives the samples.



Scrutinizes documents related to samples.



Issue of samples to respective sections for analysis.



Sample Section.....











## **Remnant Sample Section:**



Receive residual samples after testing the drug/ pharmaceutical/ cosmetic in the laboratory.



Storing of residual samples systematically in proper order as per sample registration number.



Storing the test reports systematically in proper order as per sample no.













# **Reference Standard Section:**



Storing primary and secondary standards in proper condition and issuing according to the requirements.



Preparation of internal working standards.



Re - standardization of the working standards.



Reference Standard Section.....









# Chemistry Laboratory:



Contains the facilities for preparation of samples for all types of experiments.



Facilities for Titrimetric Quantifications.



Facilities for Chemical Identifications.





~ Chemistry Laboratory......











# **Microbiology Laboratory:**



Controlled through HVAC system.



Separate Clean room facility for sterility test, microbial limit test and microbiological assay.



Compartmentalized media preparation, decontamination and washing facilities.



Separate facility for Liquid particle counting and Bacterial Endotoxin Test.





Microbiology Laboratory......





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## **Cosmetics Section:**

This section is well equipped with a number of instruments used in cosmetic testing as per BIS specifications. The following instruments/apparatuses are available in this section;

- Pay off Measuring Instrument.
- Drying Time Measuring Instrument.
- Automatic Scratch Tester.
- Breaking Load Test Apparatus.
- Adhesion Test Apparatus.
- Foam Height Measuring Apparatus.



~ Cosmetics Testing Laboratory......









# **Quality Assurance Section:**



Maintains records of Quality Management system.



Organizes inter laboratory comparisons and issue of documents for effective implementation of ISO/IEC17025:2017, Integrated Management System and Good Laboratory Practice.



Issue Test methods or specification in case of patent and proprietary samples.



Quality Assurance Section.....











### **Instrumentation Section:**



Separate rooms for HPLC, Polarimeter, AAS, GC, HPTLC, KF titrator, water purification system and fume hood.



Chemical storage unit is placed in fume hood area where flammable, corrosive,









~ Instrumentation Section......





# Administrative /Accounts Section:

Deals for pay and allowances of the staff, payments of the vendors and other service provider.

Preparation of budget estimate and expenditure for the financial year, correspondence with Headquarters office for various sanctions/approvals.

Looks after the recruitment rules, maintenance of Service Books, leave records and personal files, pay fixation, increments and APARs (Annual Performance Appraisal Reports) of the employees.

Purchase of chemicals, stationery, glassware and other items raised by the store section.



Admin/Accounts Section......











### **Store Section:**



Maintains stock of stationary items and chemicals, glassware and other items relating to office work and laboratory respectively.



Generate requisition for the purchase of appropriate items useful to the laboratory.



Separate storage for flammable and inflammable chemicals to prevent hazards.



Store Section.....











# **Library & Information Section:**



Equipped with reference books.



Latest journals, monthly bulletins and new arrivals (books) in the Pharma Industry are purchased to keep the staff updated with the chronicles of the Pharma Sector.



~ Library & Information Section.......











# **Conference Hall:**



Seminar Hall with sitting capacity of 70 and equipped with latest audio visual facilities.



Regular internal monthly meetings and seminars are conducted to motivate the staff and the vision is turned into action.



~ Conference Hall.....



#### REGIONAL DRUGS TESTING LABORATORY

#### CHANDIGARH



# Number of Tested Samples



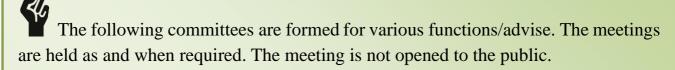
Sr. No.	Year	Total Number of Samples Tested			Total Number of Samples Failed		
		Legal	Survey	Total	Legal	Survey	Total
1	2014-15	816	922	1738	50	11	61
2	2015-16	487	5756	6243	28	167	195
3	2016-17	1352	900	2252	47	18	65
4	2017-18	2088	2641	4729	104	34	138
5	2018-19	2217	1828	4045	122	29	151
6	2019-20	2014	1352	3366	118	20	138
7	2020-21	1022	1195	2217	107	11	118
8	2021-22	1374	1685	3059	109	25	134
9	2022-23	1155	1121	2276	118	15	133
10	2023-24	1798	1214	3012	118	31	149
11	2024-2025	1134	348	1482	81	08	89





# Constituted Committees of the Laboratory (





- 1. Purchase Committee
- 2. Management Review Committee
- 3. Disposal Committee

The compositions of all the committees are having two members and one chairman and final outcome and minutes of meeting shall be discussing with the Head of the institution for further implementations/improvement.





# Transfer Policy and Transfer Orders [





There is no transfer policy for the officials and only officials temporary transfer on Deputation basis as well as the other Ministry officials can join this office through deputation as per the Recruitment Rule.

### Dr. Amit Kumar (JSA)

Official is on deputation NACWC, Cabinet Secretariat, Rashtrapati Bhavan, New Delhi, Since March 2019.



# ]] Category of Documents [[-{\$





There are following categories of document available with this laboratory

#### **Technical Documents: -**

- Quality Manual
- Master List of Record
- Master List of SOP
- Master List of STP
- Instrument Maintenance Record
- Stock register of Reference/Working Standard
- Legal Reports
- Survey Reports
- The record related to Analysis such as reports, Raw Data, Log Books, Graphs/Spectra etc, are maintained under control of laboratory

#### **Administrative Record**

- 1. Service book and personal file of permanent staff
- 2. Contingent and Salary Bill, PVR Register
- 3. Account and Administrative files
- 4. Stock Registers
- 5. Dairy Dispatch register

The custodian of technical and administrative record is under Director/Head of the institution



# 🗓 Right to Information [ 📚



List of the officers dealing with RTI matters at (RDTL), Sector-39C, Chandigarh - 160036.



### First Appelate Authority (FAA):



Dr.Debasis Maiti, Director In-Charge



Regional Drugs Testing Laboratory, CDSCO, Ministry of Health & Family Welfare, Sector-39C, Chandigarh-160036.



### **Central Public Information Officer (CPIO):**



Sh.Hitesh Kumar Khare, Senior Scientific Officer-II



Regional Drugs Testing Laboratory, CDSCO, Ministry of Health & Family Welfare, Sector-39C, Chandigarh-160036.



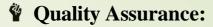
In the financial year 2024-25 the thirteen RTI has been received through RTIMIS online portal and the information has been provided within stipulated time frame.





# Quality Assurance





Quality Assurance is the sum total of organized arrangement made with objective of ensuring that medicines are of the quality required for their intended use. Quality Assurance is a team work for achieving common goal.

The Quality Assurance Section focuses on quality management & provides confidence that quality requirements are fulfilled. This section comprises of procedural activities implemented in the laboratory's quality system & ensures the operations are in accordance with the ISO/IEC 17025: 2017 Standard.

The maintenance of Quality Management System (QMS) is crucial to a laboratory for providing the correct test results. The QA Section covers important elements of Management System such as documentation, SOPs, Quality Control of Samples & Participation and conducting External Quality Assessment Schemes. Quality Assurance team takes to view the quality requirements, audits the results of control measurements and analyses quality performance in order to ensure that appropriate quality standards and procedures are implemented. This year the laboratory participated in Inter Laboratory Comparison programmes conducted by CDTL-Chennai, RDTL-Guwahati, CDL-Kolkata, IPC- Ghaziabad, CDTL-Hyderabad, CDTL-Mumbai-. This helps to review the quality levels and defines necessary improvements in the existing quality management system framework. Another activity initiated this year was revision of Quality System Procedures and Standard Operating Procedures. Also, SOPs for new instruments and processes are framed for communication in the laboratory cycle.





# Quality Assurance [ 🚼



The Quality Assurance Section shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.



#### Following activities were performed in the year 2023-24:

- The registration process of RDTL-Chandigarh in NABL Portal with respect to details such as
  information of the Laboratory Details, Discipline Details, Scope of Accreditation, Organization,
  Calibration status of each instrument, Reference Materials, Quality Control Activity etc., uploading of
  the revised Quality Manual was completed and the details submitted.
- 2. Uncertainties calculated for the drugs to be added in the scope. The drugs for which Measurement Uncertainty was calculated were metronidazole Tablets IP, Atenolol Tablets IP, Allopurinol Tablets IP, Ranitidine Tablets IP, Frusemide tablets IP, Metformin Hydrochloride Tablets IP, Pyrazinamide Tablets IP, Paracetamol Tablets IP, Paracetamol Syrup IP, Amoxicillin Capsules IP and Cetirizine Hydrochloride Tablets IP.
- 3. Uncertainties calculated for the Cosmetics to be added in the scope. The drugs for which Measurement Uncertainty was calculated were Skin Cream, Toilet Soap, Bathing Bar, Shampoo and Shaving Cream.
- 4. a. Z-Score calculated for Carbamazepine Tablets IP, Sodium Valproate Tablets IP, Allopurinol Tablets IP, Paracetamol IP, Cetirizine Tablets IP, Metformin Hydrochloride Tablets IP, Cefixime oral suspension IP, Skin cream, Shampoo, Hypodermic Syringe and communicated to the participants.
- 5. A. The Z-score obtained from CDTL –Mumbai of the average of four products is -0.8275
  - B. The Z-score obtained from IPC, Ghaziabad of the average of two products is -0.64
  - C. The Z-score obtained from CDTL Hyderabad of the average of four products is -1.25
  - D. The Z-score obtained from CDTL Kolkata of the average of Twenty-eight product is -0.110







# 🗓 Quality Assurance [ 🚼



- 6. Satisfactory Z-Score received from IPC-Ghaziabad for PT round 01 w.r.t. Assay by UV.
- 7. Out of specification & Repeat Analysis related documents were reviewed.
- 8. Log books /Raw data books issued as per requirements.
- 9. Compiling of Monthly Progress Report of RDTL-Chandigarh.
- 10. Preparation of MRM Minutes & review meetings.
- 11. RDTL-Chandigarh successfully faced the NABL Reaccreditation Audit on 18<sup>th</sup>,19<sup>th</sup> May and 29th May 2023. All the parameters that may be evaluated were reviewed by the auditor so that the laboratory achieves the overall goal of continual improvement. Four minor and two major NCs were observed for which corrective actions were taken.
- 12. Calibration of all Digital Hygrometer and Analytical Balance done.
  - Calibration of scale done through NABL accredited calibration agency.
  - Order placed to NABL accredited agency for calibration of Thermometer
  - Enquiry floated for calibration of instrument like Temperature & Pressure Indicators, Vernier caliper, Stop Watch, Balances, Micropipette, Hygrometer, Weight Box, K-type Thermometer etc. through NABL accredited agency.
  - Order placed for calibration of Vernier Caliper, Test Sieves and Weight box.
  - Calibration of BOD Incubator, Vacuum Oven, Oven, Water Bath, Balances, Autoclave, Heating Block, Refrigerator done by NABL accredited agency.
  - Order placed through NABL accredited agency for calibration of Temperature and –
     Pressure Indicators, Analytical Balance and Micropipette.



Receipt No. 84057/2025/RDTL CHANDIGARH (Computer No.





# 🛚 Quality Assurance 🛛



#### Feedback received & sent to stakeholders / vendors:

- a. Feedback sent to Indian calibration laboratory Panchkula as requested by them.
- b. Feedback sent to IPC-Ghaziabad as requested by them.
- c. Feedback sent to Fare Labs Pvt. Ltd., Gurgaon as requested by them.

# Satisfactory Feedback received from following customers for the services rendered by RDTL-Chandigarh:

- a) Drug Inspector-CDSCO, Baddi.
- b) Asstt. Drugs Controller (I)- CDSCO sub zone, Jammu.
- c) Medical Device Officer DGHS, Ministry of Health & Family Welfare S.R. Nagar, Hyderabad.
- d) Drug Inspector-CDSCO, Baddi.

#### **Proficiency Testing and ILC:**

- Proficiency Testing plan as per Form-163 updated& subsequently uploaded on NABL portal as advised.
- Participated in Proficiency testing for the year 2023-24.
- Sample received from Proficiency Testing Provider IPC-Ghaziabad for Proficiency Testing (Assay by UV). The results were communicated to IPC.
- Participated in proficiency testing for cosmetics & essential oil for Saureus, Pseudomonas aeruginosa & Candida albicans was received from Fare Labs Pvt. Ltd., Gurgaon.
- Participated in proficiency testing for Skin Cream for Thermal Stability, pH, Total Fatty Substance, Total Residue, Heavy Metals, Foam Height and Non-volatile alcohol soluble matter conducted by Fare Labs Pvt. Ltd., Gurgaon.





- 13. NABL accreditation in accordance with the standard ISO/IEC 17025:2017 was granted by Quality Council of India for Chemical, Biological & Cosmetics & Essential oils discipline with validity from 31/05/2023 to 30/05/2025. The scope for which laboratory had applied was approved by the NABL authorities.
- 14. External training of Ms. Pooja Tiwari for the laboratory System and internal Audit as per ISO/IEC 17025:2017 conducted by Training and Capacity building (TCB) cell, Quality Council of India on 01.09.2022 to 02.09.2022.
- 15. Prepared 4-year Internal Audit Plan and Yearly schedule of Internal Audit for 2023-24.
- 16. Calibration calendar prepared for Analytical Balance, pH Meter, Environment Monitoring, Monitoring of Refrigerator and Laboratory Freezer Temperatures, Environment Monitoring, Validation and Calibration in Microbiology schedules for the year 2023-24.
- 16. Expansion of scope was proposed by Quality Manager & Technical Manager. Various tests such as Disintegration test, Assay (by UV), Assay (by HPLC), Uniformity of weight, Identification tests (by IR) were added in the existing drugs under scope. Also, it was proposed MLT, Assay, Sterility and BET and Skin Cream for pH Total Fatty Substance, Foam Height and Total Fatty Matter in the scope. Accordingly, preparations for the same initiated.
- 17. Internal Audit was conducted on 9<sup>th</sup>,10<sup>th</sup> and 11<sup>th</sup> November 2022. All sections in the laboratory were covered in the audit as per the notification issued.
- 18. History Log of Instruments under scope were reviewed.
- 19.. Job description issued to newly recruited analysts.
- 20. Monthly Review meetings are done every month to discuss technical & administrative matters. All section In- charges & Division head discuss laboratory activities with the Director Incharge.



Receipt No. 84057/2025/RDTL CHANDIGARH (Computer No.



# Activities for the year 2024-25



### > Swachhta Pakhwada



### > Vigilance Awareness Week (Oath taken by all the staff)



#### REGIONAL DRUGS TESTING LABORATORY

#### **CHANDIGARH**





# Disbursements report of the public authority [



# **Expenditure statement in respect of Major Head 2210-06104-Drugs** Control, (Minor Head) 02-CDSCO-0201-General Component(Rs./-):

Sl. No.	Sub Head	2022-23	2023-24	2024-25
1	Salaries	8227000	4658000	4506294
2	Allowances	-	2935000	3171156
3	LTC		-	49201
4	Rewards	-	-	-
5	Medical Treatment	17200	607000	1221421
6	Travel Expenses	250000	185000	-
7	Office Expenses	6969000	5645000	5664403
8	Rates, Rents and Taxes	50000	50000	-
9	Publications	-	-	-
10	Supply and Materials	5223000	4336000	4936482
11	Advertising and Publicity	-	-	-
12	Minor Works	8490000	5988000	4893338
13	Repair & Maintenance	-	981000	5888191
15	Digital Equipment	-	115000	274795
	TOTAL	29449000	25500000	30605281



#### REGIONAL DRUGS TESTING LABORATORY

#### CHANDIGARH



# **Instrument Procurement Details (2023-24)**



New Instruments procured in the Year (2023-24)							
Sl.No.	Instrument Name	Qty.	Name of the supplier	Make	Purchase Date		
1	RTD Thermometer with data logger	1	HTA Instrumentation Ltd.	Delta Ohm	30.05.2022		
2	Digital thermocouple thermometer with sensor	1	HTA Instrumentation Ltd.	Center	30.05.2022		
3	Atomic Absorption Spectrometers	1	Lab-India	Lab-India	08.07.2022		

New Instruments procured in the Year (2024-25)						
Sl.No.	Instrument Name	Qty.	Name of the supplier	Make	Purchase Date	
1	Gas Chromatography (GC)	1	Thermo Fisher	Thermo Fisher	22.03.2025	
2	HPLC	2	Thermo Fisher	Thermo Fisher	22.03.2025	

