Annexure - I

Central Drugs Testing Laboratory (CDTL), Mumbai, Maharashtra

(i) Particulars of the organization, functions and duties :

Accredited By: NABL (ISO/IEC-17025:2017 in Chemical and Biological Testing) Certified For: IMS (ISO-9001:2015, ISO-14001:2015, ISO 45001:2018)

The CDTL, Mumbai is one of the National Statutory Laboratories of the Government of India, functioning under the administrative control of the Drugs Controller General of India, Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi.

Contact details:

Director of the Laboratory : C. Hariharan

Address : Zonal FDA Bhavan, Bellasis Road, Government Medical Stores Depot (GMSD) Compound, Mumbai Central, Mumbai-400 008. **Phone numbers:** 022-2300 2309, 2300 2138. **Telefax:** 022-23099240. **Email**: cdtlmumbai@cdsco.nic.in

VISION

- To be recognized globally for providing world class testing facilities for safeguarding human and animal health by establishing and reviewing quality objective at various levels of the organization.
- 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 public.

MISSION

- To provide quality and effective analytical services achieved through advanced testing in the area of drugs and pharmaceuticals by dedicated and committed work force by adhering to core values of transparency, accountability, efficiency, commitment, credibility and innovation.
- To be a smart drugs testing laboratory equipped with latest sophisticated equipments and having clean and green eco-friendly environment.

QUALITY POLICY

Central Drugs Testing Laboratory–Mumbai is committed to :

- Perform quality testing as per ISO/IEC17025:2017 and NABL guidelines to attain the highest proficiency and unbiased testing of Drugs & Cosmetics & Medical Devices in transparent, well documented and controlled environmental condition to attain proper justified quality results.
- Ensure that all laboratory personnel familiarize themselves with quality documentation while implementing policies and procedures in their work.
- Strive for continual improvement related to laboratory functions through personnel involvement at all levels.

QUALITY OBJECTIVES

- To make all the laboratory staff aware to the requirements of ISO/IEC 17025:2017 by conducting regular training and interactions.
- To implement effective quality system in the laboratory.
- To ensure dependable and accurate testing facility.
- To operate in such an environment so that the test result obtained is very close to the true result.
- To provide test results at the earliest and to the best satisfaction.
- To update technical knowledge / skill of scientific / technical staff by in- house and outside training.
- Regular participation in Proficiency Testing and Inter laboratory Comparison Programs.
- To provide proper & safe working environment to adopt Good Laboratory Practices.

The statutory and other major functions of the Laboratory include:

- Analysis of Drugs & Pharmaceuticals, Cosmetics and Medical Devices received as statutory samples.
- The Director, CDTL Mumbai Acts as "Appellate Authority" as per Drugs & Cosmetics Act, 1940 for the testing of Copper T and Tubal Rings (Intrauterine Contraceptive Devices)
- Analysis of Imported Drugs, Cosmetics and Medical Devices samples entering through the port offices.
- Analysis of Registration samples for approval of site registration as per GMP.
- Analysis of New Drugs to get license for manufacturing the same.
- Analysis of Drugs & Pharmaceutical formulations, Cosmetics & Medical Devices received from CDSCO Zonal Offices and its sub Zonal Offices or other offices under Ministry of Health and Family Welfare.
- Impart training to Drugs Analysts deputed by the Government Laboratories time to time.
- To undertake analytical research on standardization and methodology of drugs & Pharmaceutical Products.

Information under the Right to Information Act 2005:

<table>
<tr><th>Central Public Information Officer (CPIOs)</th><th>Appellate Authority</th></tr>
<tr><td>Technical matters</td><td rowspan="3">Technical and Administrative matters
Mrs. Sayali U. Warde
Senior Scientific Officer
Central Drugs Testing Laboratory, CDSCO,
ZonalFDA Bhavan, GMSD Compound,
Bellasis Road, Mumbai Central,
Mumbai - 400 008.</td></tr>
<tr><td>Mrs. Akshata S. Paranjpe
Senior Scientific Assistant
Central Drugs Testing Laboratory, CDSCO,
Zonal FDA Bhavan, GMSD Compound,
Bellasis Road,Mumbai Central,
Mumbai - 400 008.</td></tr>
<tr><td>Administrative matters</td></tr>
<tr><td>Mrs. Suranga S. Chindarkar
Office Superintendent
Central Drugs Testing Laboratory, CDSCO,
Zonal FDA Bhavan, GMSD Compound,
Bellasis Road,Mumbai Central,
Mumbai - 400 008.</td><td></td></tr>
</table>

(ii) Powers and duties of the officers and employees :

Designation	Duties
Director	• Designated as Administrative and Technical Head of CDTL-Mumbai. • Responsible for establishing the Quality policy and implementing of Quality System in the laboratory by providing technical guidance and effective administration. • Responsible to provide guidance to all technical and managerial officials involved in the quality management. • To carryout/make policy and procedures enlisted for smooth running/functioning of the Statutory & Appellate Laboratory for certain Medical Devices. • Responsible to guide, supervise and co-ordinate the activities of the different sections of the laboratory to achieve quality work. • Responsible for overseeing the quality and timeliness of the testing of drugs, cosmetics and medical devices samples received in the laboratory. • Responsible for calling management reviews at regular intervals, not greater than twelve months or more frequently at his/her discretion . • Responsible for identifying the training needs of the official after screening the personnel records of the technical officials. • Responsible to depute the scientific/technical officials regularly to the reputed institutes for upgradation oftheir knowledge & technical skills. • Responsible for authorizing specific personnel to perform particular type of technical / administrative work. • To participate in technical review of various monographs including general monograph of Indian Pharmacopeia. • To participate and provide technical guidance to BIS (Bureau of Indian Standard) for upgrading various Cosmetics and Medical Devices standards. • To sign the test report of samples (Copper T and Tubal rings - Intrauterine contraceptive devices) from the court of law. • The Director is appointing authority for the posts up to Group C level to conduct DPC for recruitment, promotion and MACP etc.
Dy. Director (Vacant)	• To help the Director in day to day administration and technical work of the Laboratory. • Supervise and provide necessary guidance to the Senior Officers in analysis of Drugs & Pharmaceuticals, Cosmetics & Medical Device samples. • Monitoring of various samples received from various part of the country. • After reviewing submitting the Appellate samples to the Director for final approval/ Signature. • To provide the necessary input to make necessary Policy for smooth functioning of the laboratory. • Review the laboratories technical and administrative record keeping practices and advise the Director for any need for improvement and corrective action on need basis. • Assist the Director in establishing the budget proposal and achieving the target of the laboratory goal. • Maintain the Laboratory as a participant for the NABL or any other certification through proficiency program. • Conduct different training programs Central & State Government trainees and analysts of the laboratory. • Provide guidance to the research pertaining to the quality control of drugs. • Help the Director for checking and finalization of monographs of International Pharmacopoeia and Indian Pharmacopoeia

SSO	• Performs the duties of Director in his/her absence. • Designated as Quality Manager to ensure compliance with ISO/IEC17025:2017 of the laboratory and M.R. for IMS certification. • As technical head responsible divisions for technical guidance to all analyst & to allot the sample to different sections. • Responsible for assigning the daily routine work to Senior Scientific Assistants and supportive staff. • Responsible for implementation of quality management system of the laboratory by providing technicalguidance and effective administration. • Responsible to provide Technical training to staff for enhancing their skills and knowledge related to analytical field. Receipt, Storage & distribution of samples to analysts. • To ensure the calibration of all instrument / equipment, clean room area shall be done as per prevailingStandard Operating Procedures. • Responsible for timely utilization of budget to meet requirement of laboratory as per GFR. As a purchase coordinator responsible for purchase of chemicals / Glassware / Instruments / Stationery as well as AMCs of instruments. As a DDO, responsible for timely clearing of all bills submitted by administration section. • Responsible for timely submission of online & manually monthly, quarterly, Annual report with reference to TDS. • Act as Appellate Authority with respect to CDTL-Mumbai for RTI matters. • Responsible for timely submission of Drug alert DMU, KPI reports monthly, quarterly and annually with respect to administrative matters and technical matters. • Responsible for signing of reports being Government Analyst • Any other administrative / technical work allotted by Director. To perform duties of Director in his/her absence. • Period i.e. review of technical competence of the analyst and provide necessary training on need basis.
SO (Vacant)	• To allot the sample to different sections / divisions. • For assigning the daily routine work to scientific assistants and supportive staff. • For implementation of quality management system of the laboratory by providing technical guidance and effective administration. • To provide Technical training to staff for enhancing their skills and knowledge related to analytical field. Receipt, Storage & distribution of samples to analysts. • To ensure the calibration of all instrument / equipment, clean room area shall be done as per prevailingStandard Operating Procedures. • For signing of reports being Government Analyst • Any other administrative / technical work allotted by Director. To perform duties of Director, Senior Scientific Officer (SSO)in his/her absence.
S.S.A.	• All Senior Scientific Assistants (SSA) notified as Government Analyst & Medical Device Testing Officer are responsible for scrutiny of legal samples/ reports and signing of Certificate of Analysis as per Drugs and Cosmetics Act 1940 and Medical Device rules thereunder. • One SSA designated as Technical Manager to ensure compliance with ISO/IEC17025:2017 of the laboratory and as CPIO for technical matters and responsible for timely submission of answer for RTI queries. Responsible for Store section activities. Responsible for Wet Chemistry section. As purchase coordinator responsible for purchase of chemicals/glassware through GeM portal. • SSA Posted to Medical Device Section is responsible for supervision of testing in that section. • SSA posted to Sample Warden Section in responsible for receiving samples, codification, decodification, relevant entries in software & proper storing of samples till they are issued to Department Heads & also of reported samples. • SSA posted to R & D Section, responsible for Testing of samples, validation of new methods, developing new methods under the guidance of Officer Incharge (O/c). As purchase coordinator responsible for purchase of instruments as well as AMCs of instruments through GeM portal. • Each SSA closely supervises the work of 9 to 10 analysts specifically assigned and checks their entries of test results and calculations in the work book and protocols of tests submitted by them.

	• Preparing the specifications for various instruments to be procured as per requirement of laboratory. • Carries out any other duty assigned by the Officer Incharge (O/c) for effective implementation of GLP and anyother duties delegated by Director/Officer I/C laboratories. • Developing new methods of analysis. • Responsible to impart training to new joinees. • Responsible for implementing Quality System in Laboratory.
J.S.A.	• Each JSA carries out tests on samples of drugs issued by the Officer Incharge (O/c) as per the instructions using various Pharmacopoeia, compendia or validated methods and enters all the test results in the work book showing relevant calculations with date, time and signature, compiles the test results in an approved format and submits to the supervisor. • JSA also maintains log books of the instruments, makes relevant entries of use of reference standards, their certificates, issue registers & is responsible for proper storage of reference and working standards. • JSA involved in maintenance of calibration and/or validation records. • One JSA responsible for preparing working standards from A.P.I. and their standardization. • Perform any other work as assigned by Senior Officials, SSAs, Section in charge & Director from time to time.
A.H.T.	• Carry out test and analysis of samples of drugs issued by the OIC as per the instructions using compendia or validated methods and enters all the test results in the work book showing relevant calculations with date, time and signature, compiles the test results in an approved format and submits to the supervisor. • Maintains log books of the instruments, makes relevant entries of use of reference standards, their certificates, issue registers & is responsible for proper storage of reference and working standards. • Perform any other work as assigned by SSAs, Section in charge & Director from time to Time. • Maintain the animal house as and when need basis.
S.L.A.	• Preparation and standardization of reagents and Media - Setting up of apparatus for tests. • Supervision of Cleaning of glass ware, other laboratory ware including thermometer and their safe keeping. • Maintaining breakage register. • Checking the work of J.L.A's and Laboratory attendants. • Testing of samples and calibration and maintenance of sophisticated instruments and maintaining records of solvent registers and monitoring environmental cleanliness. • Independent analysis of the samples as and when required depending on the sample load. • Perform any other work as assigned by senior and higher officials from time to time.
J.L.A	• Assisting Store Incharge for maintaining Store activities • Maintenance of Laboratory ware. • Assisting analysts and SLA's in sample operations like Filtration, Pellet making,evaporation, drying, setting up of apparatus. • Assisting JSA in maintaining and issuing reference standards. • General safety like shutting of fans , lights, ovens, burners at the end of work. • When required supervises the work of laboratory attendants and safaiwalas/ House Keeping officials. • Independent analysis of the samples as and when required depending on the sample load. • Perform any other work as assigned by senior and higher officials from time to time.
MTS (Lab. Attendant)	• Washing of glassware. • Dusting of laboratory. Cleaning of laboratory equipment. • Preparation of distilled water. Autoclaving, maintaining clean room area. • Assisting in setting up of instruments and in store work. • Any other work assigned by SSA / Sectional Heads & Director as and when required.

Office Superintendent	• Assist the DDO in General administrative matters relating to Establishment, processing of files, administration, appointments, Roster, Correspondence of confidential reports, pension cases etc. • Responsible as CPIO for administrative matters for RTI. • General supervision and overall co-ordination of all administration work connected with Establishment, Cash & Accounts, Budget, Procurement of stationary items stores, etc. • To prepare replies of RTI queries for administrative matters & monthly, quarterly, annual reports &Parliament question. • Look after the legal matters in consultation with senior officers. • Maintain GPF account for all official & prepare GPF bills. • As purchase coordinator responsible for purchase of stationery through GeM portal.
UDC	• Looking after the day-today work, Legal matters, Service Book, Leave records, Office orders, Pension Cases and General Establishment and Administration matters. Cash maintenance and related all records / registers along with the entries in PFMS software and monthly reconciliation with PAO. • Preparing bills of store related purchase. • Any other work assigned by O.I.C & Director as and when required.
LDC	• Preparing bills for Pay, Vehicle advances, Festival & House Building advances, Medicalreimbursement, Tuition fee, LTC, Income Tax matters. • To prepare bills in PFMS. • Maintenance of store and its related register. • Preparing bills of store related purchase. • To perform duties of Library Information Assistant in her/his absence. • Any other work assigned by O.I.C & Director as and when required.
L.I.A.	• Maintenance of protocols & Other Library related work letters purchase related work. • Maintaining records of general maintenance of building. Assisting CPIO in preparing replies of RTI queries. • To co-ordinate in the matters of purchase & prepare comparative statements. • To look after the work relating to AMC for AC, Lifts, STP, Generator, Telephone issues concerning Office Helpers, Security etc. • To prepare quarterly & annual reports on progress & activities of laboratory. • Any other work assigned by O.I.C & Director as and when required.
MTS (Peon)	• Filing of Daily work and assisting the administrative staff in day to day activities. • Photo copying of documents as per instruction Dispatching of the official documents / reports. • Any other outdoor duty and any other work assigned by O.I.C & Director as and when required.
MTS (Sweeper)	• Sweeping & cleaning of office premises; corridors & washrooms.

The procedure followed in the decision making process, including channels of supervision and accountability:
Organisation chart Enclosed Annexure - II

(iii) The norms set by the office for the discharge of its functions :
The discharge of functions is as per Central Government norms.

(iv) The rules, regulations, instructions, manuals and records, held by it or under its control or used by its employees for discharging its functions :
The working of Laboratory, administration & establishment is based on standard operating procedures, Quality Manual & Purchase Manual (GFR).

The records related to analysis such as reports, raw data, logbooks, graphs, spectra etc, are maintained under control of laboratory.

(v) A statement of the categories of documents that are held by the office or under its control :
Test reports and related document of laboratory & documents related to establishment & administration.

The laboratory maintains pharmacopeia such as Indian, British, European, US, Chinese, Japanese Pharmacopeia which are used in analysis of drugs. Also maintains Indian Standards, AOAC, ISO Standards and manufacturer's specifications required for analysis.

(vi) The particulars of any arrangement that exists for consultation with, or representation by the members of the public in relation to the formulation of its policy or implementation thereof :
Not Applicable.

(vii) A statement of the boards, councils, committees and other bodies consisting of two or more persons constituted as its part or for the purpose of its advice, and as to whether meetings of those boards, councils, committees and other bodies are open to the public.

The following committees are formed for various functions/ advice, the meetings are held as and when required. The meetings are not open to the public.

1	Cadre Review Committee	8	Purchase Committee
2	Management Review Committee	9	Committee for tobacco free workplace
3	Internal complaint to address cases of sexual harassment of women at workplace	10	Rajbhasha Committee
4	Garden (Horticulture) Committee	11	Research and Method Development Committee
5	Security Supervision Committee	12	Hygiene and Sanitary or Housekeeping Committee
6	Fire Fighting Committee	13	Disposal Committee
7	Committee for Preparation/ Up gradation reservation rosters for SC, SC, OBC, EWS & PWD	14	Reviewing Committee under Fundamental Rule (FR) 56 (J)

(viii) A directory of the officers and employees : Annexure - III

Sr. No	Name	Designation	Presently Deputed At
1	Shri. C. Hariharan	Director	
2	Smt. S. U. Warde	SSO	
3	Smt. A. S. Paranjpe	SSA	
5	Dr. M. V. Kumar	SSA	
6	Smt. S. A. Navaratne	SSA	
7	Smt. S. S. Parikh	JSA	
8	Dr. Anantha Rama G	JSA	Mini Lab., Bangalore
9	Shri. A. K. Nagarkar	JSA	Mini Lab., Sahar Airport, Mumbai
10	Shri. S. K. Singh	JSA	
11	Smt. A.V. Bandre	JSA	
12	Smt. S. G. Chittilapilly	JSA	
13	Smt. A. S. Nandi	JSA	
14	Smt. H. H Talapadtur	JSA	
15	Smt. Priyanka R. Kori	JSA	
16	Shri. A. W. Yenkar	JSA	Mini Lab., Ahmedabad
17	Shri. Amol Akash	JSA	
18	Shri. Ashok Kumar	JSA	Mini Lab., IGI Airport, New Delhi
19	Shri. J. S. Chaudhari	JSA	
20	Shri.H.P.Magar	JSA	
21	Shri. P. P. Thakur	JSA	
22	Smt. A. N. Gharat	A.H.T	Mini Lab., JNPT, Mumbai
23	Shri. Ramesh Jadhav	SLA	
24	Shri. A. M. Ningappagol	JLA	
25	Shri. V. J. Justin	JLA	
26	Shri. S. D. Yadav	JLA	
27	Shri. Bhushan Sonawane	JLA	
28	Shri. B. B. Gurav	MTS (Lab. Attendant)	
29	Shri. J M Ranga	MTS (Lab. Attendant)	
30	Shri. P. B. Karve	MTS (Lab. Attendant)	
31	Shri. G. B. Pawar	MTS (Lab. Attendant)	
32	Shri. A. N. Palte	MTS (Lab. Attendant)	
33	Shri. N. D. Marne	MTS (Lab. Attendant)	
34	Shri. Y .K. Tarnekar	MTS (Lab. Attendant)	
35	Shri. V. M. Ujagare	MTS (Lab. Attendant)	
36	Smt. S. S. Chindarkar	OS	
37	Shri. S. N. Madvi	UDC	
38	Smt. S. R. Rajangali	UDC	
39	Smt. S. D. Trimbake	LDC	
40	Shri. Manish	LDC	HQ, New Delhi
41	Smt. Neha S. Doke	LDC	
42	Shri. S. C . Acharekar	MTS (Peon)	
44	Shri. B B. Bidlan	MTS (Sweeper)	
46	Smt. Ritu Motwani	MTS	

(ix) The monthly remuneration received by each of the officers and employees, including thesystem of compensation as provided in its regulations are as follows : Enclosed Annexure IV

(x) The budget allocated to each of its agency, including the particulars of all plans, proposed expenditures and reports on disbursements made : Enclosed Annexure V

(xi) The manner of execution of subsidy programs, including the amounts allocated and the details of beneficiaries of such programs : Not Applicable.

(xii) Particulars of recipients of concessions, permits or authorizations granted by it :
Not Applicable

(xiii) Details in respect of the information, available to or held by it, reduced in an electronic form :
Not Applicable

(xiv) The particulars of facilities available to citizens for obtaining information, including the working hours of a library or reading room, if maintained for public use :

1. Information as maintained on website.
2. Through email, post or telephonically
3. The library is not maintained for public use.

(xv) The names, designations and other particulars of the Public Information Officers :

Central Public Information Officer (CPIOs)	
Technical matters	**Administrative matters**
Mrs. Akshata S. Paranjpe Senior Scientific Assistant Central Drugs Testing Laboratory, CDSCO, Zonal FDA Bhavan, GMSD Compound, Bellasis Road,Mumbai Central, Mumbai - 400 008.	Mrs. Suranga S. Chindarkar Office Superintendent Central Drugs Testing Laboratory, CDSCO, Zonal FDA Bhavan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai - 400 008.

(xvi) Such other information as may be prescribed; and thereafter update these publications every year : -

1. List of equipments available in laboratory : Annexure VI

2. List of SOPs & QSPs available : Annexure – VII

3. Achievements : Annexure - VIII
   a. Accreditation by NABL (given copy of certificate)
   b. Certificate of ISO 9001:2015, ISO 14001:2015 (given copy of certificate)
   c. ISO 45001:2018 (given copy of certificate)

4. No. of employees against whom disciplinary action has been (i) Pending for Minor penalty or major penalty proceedings - Nil

5. Foreign and domestic Tours by ministries and officials of the rank of Joint Secretary to the Government and above, as well as the heads of the Department.- (a) Places visited, (b) The period of visit, (c) The number of members in the official delegation, (d) Expenditure on the visit - Nil

6. Work Flow Sheets : Annexure - IX
   a. Chemical Division
   b. Biological Division
   c. Sample Warden Section

7. The names, designations and other particulars of the previous Public Information Officers and First Appellate Authority: During the period 2015 to 2020:

Central Public Information Officer (CPIO)	**Appellate Authority**
Mrs. Sayali U. Warde Senior Scientific Officer-II Central Drugs Testing Laboratory, CDSCO, Zonal FDA Bhavan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai - 400 008.	Mrs. Manasi M. Patel Senior Scientific Officer-I (Retd.) Central Drugs Testing Laboratory, CDSCO, ZonalFDA Bhavan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai - 400 008.