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

Central Drugs Testing Laboratory (CDTL), Mumbai, Maharashtra

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 (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 : Dr. Raman Mohan Singh

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, cdtlmumbai@gmail.com

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 manufactured in the country.
- 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 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 received as Survey Samples from CDSCO and its Zonal Offices.
- Analysis of Drugs & Pharmaceuticals formulations received as national Survey samples from CDSCO or other offices under Ministry of Health & Family Welfare
- Imparting training to Drugs Analysts deputed by the Government Laboratories from time to time.
- To undertake analytical research on standardization and methodology of drugs.

Information under the Right to Information Act 2005:

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

Annexure - I

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

Designation	Duties
Director	• Designated as Administrative and Technical Head of the laboratory. • 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 staff involved in the quality management. • Responsible to guide, supervise and coordinate the activities of the different sections of the laboratory to achieve quality work. • Responsible for overseeing the quality and timeliness of the testing of drug samples received in the laboratory. • Responsible for calling management reviews at regular intervals, not greater than twelve months or more frequently at his discretion . • Responsible to decide who should attend the MRM & allocate follow-up actions & timeliness to specific personnel. • Responsible for identifying the training needs of the staff after screening the personnel records of the technical staff. • Responsible to depute the scientific staff regularly to reputed institutes for upgradation of their knowledge & technical skills. • Responsible for authorizing specific personnel to perform particular type of technical / administrative work.
S.S.O - (I) (Pharmaceutical Chemistry)	• Designated as Technical Manager to ensure compliance with ISO/IEC 17025:2017 of the Laboratory and Management Representative for IMS certification • Designated as Divisional Head of Chemical Division comprising of Sample Warden & Reference Standard Section, Wet Chemistry and Instrumentation Section. • Responsible to allot the sample to different sections / divisions. • Responsible for assigning the daily routine work to scientific assistants and supportive staff. • Responsible for implementation of quality system of the laboratory by providing technical guidance 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 of chemical section. • Responsible for finalizing the specifications of advance instruments before approval of Director. • To ensure the calibration of all instrument / equipment shall be done as per prevailing Standard Operating Procedures. Follow up being the Nodal Officer for BAS technical issues. • Responsible for signing of reports of Chemical division. Being Government Analyst responsible for analysis of samples issued in Chemistry division. Appellate authority with respect to CDTL-Mumbai of RTI Matters. Member of Purchase Committee for procurement of new instruments, spares, material supply and stationary etc. • Responsible for timely submission of Drug alert DMU, KPI reports monthly, quarterly and annually with respect to sample warden section. • Any other administrative / technical work allotted by Director. To perform duties of Director and SSO-II in their absence.
SSO-II (Microbiology)	• Designated as Quality Manager to ensure compliance with ISO/IEC17025:2017 of the laboratory and safety officer for IMS certification. Designated as Head of Biological Division comprising of Quality Assurance, Microbiology, Cosmetic and Medical Device Section. • Responsible for implementing Quality Management System. Receipt, Storage, Distribution of samples to analysts in biological division. • Responsible for procuring the requirements for sample analysis after receipt of samples & scrutinizing the methods. • Responsible to provide technical training to staff to enhance their skills and knowledge related to analytical field. • Responsible for signing of reports from the biological division. Being Government Analyst responsible for analysis of samples issued in biological division.

	• 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 staff, suppliers etc. • Responsible to ensure the calibration / validation of equipment, Clean room as per prevailing S.O.P. • Responsible for timely submission of online & manually monthly, quarterly, Annual report with reference to TDS and RTI being CPIO of the laboratory. • Responsible for timely submission of Drug alert DMU, KPI reports monthly, quarterly and annually with respect to administrative matter. • To perform duties of SSO-I in her absence and of Director in absence of both. Any other administrative and technical work allotted by Director.
S.S.A.	• 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. • Testing of samples, validation of new methods, developing new methods under the guidance of OIC. • Carries out any other duty assigned by the OIC for effective implementation of GLP and any other duties delegated by Director/Officer I/C laboratories • SSA posted to Microbiology Section is responsible for maintenance of Clean Room, Microbial Culture and Supervision of Work of analysts in Microbiology Section. • 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. • Responsible for preparing working standards from A.P.I. and their standardization. • Preparing the specifications for various instruments to be procured as per requirement of laboratory. • 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 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. • 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 also maintains calibration and/or validation records. • JSA posted to Sample Warden Section is Assisting S.S.A. for receiving samples, codification, de codification , relevant entries in registers, maintenance of control samples and hard copies of reports. • Perform any other work as assigned by SSAs, Section in charge & Director from time to time
A.H.T.	• Carries out tests on 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
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. • Testing of samples and, calibration and maintenance of pH Meter, Tablet disintegration test apparatus, Centrifuges etc., preparation of standard buffers and maintaining records of solvent registers and monitoring environmental cleanliness. • SLA's who are qualified (post graduates) are entrusted to perform analysis of samples as per various methodologies. • Perform any other work as assigned by senior and higher officials from time to time
J.L.A	• Maintenance of Laboratory ware. • Assisting analysts and SLA's in simple 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. • JLA with graduation in science tests the drug samples issued by o/c. • SLA's who are qualified (post graduates) are entrusted to perform analysis of samples as per various methodologies. • Perform any other work as assigned by senior and higher officials from time to time
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. • General supervision and overall co-ordination of all administration work connected with Establishment ,Cash & Accounts, Budget, Procurement of stationary items stores, etc. • To prepare draft of replies of RTI queries & monthly, quarterly, annual reports & Parliament question. • Look after the legal matters in consultation with senior officers. • Maintain GPF account for all staff & prepare GPF bills.
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, Scooter, Festival & House Building advances, Medical reimbursement, Tuition fee, LTC, Income Tax matters. • Maintenance of store and its related register. • Preparing bills of store related purchase. • 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.

Peon	• Filing Daily work and assisting the administrative staff in day to day activities. • Xeroxing 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.
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

(iv) The norms set by the office for the discharge of its functions :

The discharge of functions is as per Central Government norms.

(v) 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.

Quality Policy :

Central Drugs Testing Laboratory–Mumbai, the statutory Laboratory under Drugs & Cosmetics Act & Rule 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.

(vi) 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.

(vii) 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.

(viii) 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 :

Not Applicable.

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

Sr. No	Name	Designation
1.	Dr. Raman Mohan Singh	Director
2.	Smt. M. M. Patel	SSO I
3.	Smt. S. U. Warde	SSO II
4.	Smt. A. S. Paranjpe	SSA
5.	Smt. S. S. Kaisare	SSA
6.	Dr M. V. Kumar	SSA
7.	Smt. S. A. Navaratne	SSA
8.	Smt. S. S. Parikh	JSA
9.	Dr. Anantha Rama G	JSA
10.	Shri. A. K. Nagarkar	JSA
11.	Shri. S. K. Singh	JSA
12.	Smt. A.V. Bandre	JSA
13.	Smt. S. G. Chittilapilly	JSA
14.	Smt. A. S. Nandi	JSA
15.	Smt. H. H Talapadtur	JSA
16.	Smt. Priyanka. R Kori	JSA
17.	Shri. A. W. Yenkar	JSA
18.	Shri. Amol Akash	JSA
19.	Shri.Ashok Kumar	JSA
20.	Smt. Bharni S E	JSA
21.	Smt. A. N. Gharat	A.H.T
22.	Shri.H.P.Magar	SLA
23.	Shri. J. S. Chaudhari	SLA
24.	Shri. Ramesh Jadhav	SLA
25.	Shri. A. M. Ningappagol	JLA
26.	Shri. V. J. Justin	JLA
27.	Shri. S. D. Yadav	JLA
28.	Shri. P. P. Thakur	JLA
29.	Shri. Bhushan Sonawane	JLA
30.	Shri. B. B. Gurav	Lab.Attendent
31.	Shri J M Ranga	Lab.Attendent
32.	Shri. P. B. Karve	Lab.Attendent
33.	Shri. G. B. Pawar	Lab.Attendent
34.	Shri. A. N. Palte	Lab.Attendent
35.	Shri. N. D. Marne	Lab.Attendent
36.	Shri. Y .K. Tarnekar	Lab.Attendent
37.	Shri. V. M. Ujagare	Lab.Attendent
38.	Smt. S. S. Chindarkar	OS
39.	Shri. S. N. Madvi	UDC
40.	Smt. S. D. Trimbake	LDC
41.	Shri. S. C . Acharekar	Peon
42.	Shri. D. W. Jadhav	Peon
43.	Shri. B B. Bidlan	Sweeper
44.	Shri. S B Bidlan	Sweeper
45.	Smt. Ritu Motwani	MTS

(x) The monthly remuneration received by each of the officers and employees, including the system of compensation as provided in its regulations are as follows :

Enclosed Annexure IV

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

Enclosed Annexure V

(xii) The manner of execution of subsidy programs, including the amounts allocated and the details of beneficiaries of such programs :

Not Applicable.

(xiii) Particulars of recipients of concessions, permits or authorizations granted by it :

Not Applicable

(xiv) Details in respect of the information, available to or held by it, reduced in an electronic form :

Not Applicable

(xv) 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

The library is not maintained for public use.

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

Mrs. S. U. Warde, SSO-II / CPIO

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