

To
The Director Admn.,
Central Drugs Standard Control Organisation,
Dte. General of Health Services.,
FDA Bhawan, Kotla Road,
New Delhi-110 002.

Sub.: - Updated Suo Motu Disclosure under Section 4 under RTI Act 2005 –
Request for uploading in CDSCO website - Reg.
Ref.: Dte.'s email dated 29.12.2023.

Sir,

With reference to the Directorate's email cited above, it is to inform that as per the instructions of the Directorate, this office is sending the Suo-Motu Disclosure under Section 4 of RTI Act 2005 for uploading in the Website. As this office is a subordinate office under Central Drugs Standard Control Organization and not having separate website. It is requested to kindly upload the Suo-Motu Disclosure pertaining to Central Drugs Testing Laboratory, Hyderabad in the CDSCO Website.

| Sl.No. | Suo Motu Disclosure | Annexure |
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Yours sincerely,

(Dr. A. Visala)
DDC (I) CDSCO (HQ) &
Additional Charge
CDTL, Hyderabad.

I. PARTICULARS OF THE ORGANIZATION, FUNCTIONS AND DUTIES

CENTRAL DRUGS TESTING LABORATORY (CDTL), HYDERABAD

Accredited By: NABL (ISO/IEC-17025:2017 in Chemical Testing)

The CDTL, Hyderabad 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:

The Director,

Central Drugs Testing Laboratory

CDSCO Bhavan, S.R. Nagar,

Hyderabad- 500 038, Telangana.

Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health & Family Welfare,

Government of India

Tel. :040-23811327, 040-23811328, email: cdtlhyd@cdsco.nic.in

Details of Officials from RTI Queries:

a) First Appellate Authority :

Dr. A. Visala,

Deputy Drugs Controller (I), CDSCO (HQ) & Additional Charge, CDTL,

Tel. No. 040-23811328

b) Central Public Information Officer (CPIO):

Dr. A. Raghuram Reddy,

Government Analyst & Junior Scientific Officer, CDTL, Hyderabad

Tel. No. 040-23811327

1. Introduction/Background:

Central Drugs Testing Laboratory is a National Statutory Laboratory of Government of India for quality control of Drugs, Pharmaceuticals, Cosmetics and Medical Devices established under Drugs and Cosmetics Act, 1940 and Rules 1945 thereunder. This is a subordinate Office of the Central Drugs Standard Control Organisation (CDSCO), Directorate

General of Health Services (DGHS), Ministry of Health and Family Welfare, Government of India, functioning under the administrative control of Drug Controller General of India, New Delhi. This Laboratory is accredited with National Accreditation Board for Testing and Calibration Laboratories (NABL) in accordance with ISO/IEC 17025 on 30.06.2016 in the field of Chemical Testing (Drugs, Pharmaceuticals and Cosmetics). As validity of certification is 2 years, Laboratory got its accreditation renewed in 2018, 2020, 2021, 2023 with validity upto 29.06.2025 for 124 test parameters (30 scope moieties).

2. 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 state of art facilities and sophisticated equipment with clean and green eco-friendly environment.

3. 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.

4. Quality Policy

- CDTL, Hyderabad is committed to serve the nation for quality and excellence in testing of drugs, cosmetics and medical devices as per Schedule L1 of Drugs & Cosmetics Act 1940 and Rules 1945, Medical devices rules 2017, ISO/IEC 17025:2017 and NABL guidelines to attain highest proficiency in testing, continual improvement, transparency, good documentation practices and controlled environmental conditions.

- CDTL, Hyderabad is committed to perform quality testing of samples using calibrated equipment, documented procedures with good professional practices and compliance to applicable regulations to ensure the quality of operations in its testing.
- CDTL, Hyderabad is committed to promote efficiency with qualified and adequately trained personnel competent enough to perform work meeting the laboratory targets.
- CDTL, Hyderabad is committed to ensure customer satisfaction by maintaining impartiality, integrity, confidentiality in its operations and continuously improving its quality management system.

5. Major functions of the Laboratory:

- a) Analysis of Drugs & Pharmaceutical formulations received as Statutory Drugs Samples (Form-18 as per Drugs and Cosmetics Act and Rules), import / reimport samples, Survey Samples and custom samples from offices of CDSCO including Zonal, Sub-zonal and port offices.
- b) Imparting Training to Drug Analyst deputed by the Central, State and other Government Laboratories.
- c) To advice the CDSCO in respect of quality and toxicity of drugs awaiting for License
- d) To undertake analytical research on standardization and methodology of Drugs
- e) Quick Analysis of Drugs & Pharmaceuticals formulations received as National Survey Samples from CDSCO or other offices under Ministry of Health & Family Welfare.

6. Quality Objectives:

- a) To make all the laboratory staff aware to the requirements of good laboratory practices (GLP) as mentioned in Schedule L1 of Drugs & Cosmetics Act, 1940 and rules 1945 and as per the ISO/IEC 17025:2017 standards of NABL, Quality Council of India by conducting regular training and interactions.
- b) To implement effective quality system in the laboratory as per sugamlabs.
- c) To operate in such an environment so that the test result obtained is very close to the true result.
- d) To provide test results at the earliest and to the best satisfaction.
- e) To update technical knowledge / skill of scientific / technical staff by in- house and outside training.
- f) Regular participation in Proficiency Testing and Inter laboratory Comparison Programs.
- g) To provide proper & safe working environment to adopt Good Laboratory Practices.

7. Divisions of the Laboratory:

- a) Administrative Division
- b) Sample Receipt Division
- c) Quality Assurance & Training Division
- d) Purchase and Stores Division
- e) Reference Standard Division
- f) Testing Division (Chemicals, Biologicals, Cosmetics & Medical Devices)

8. TARGETS AND ACHIEVEMENTS

a) TARGETS:

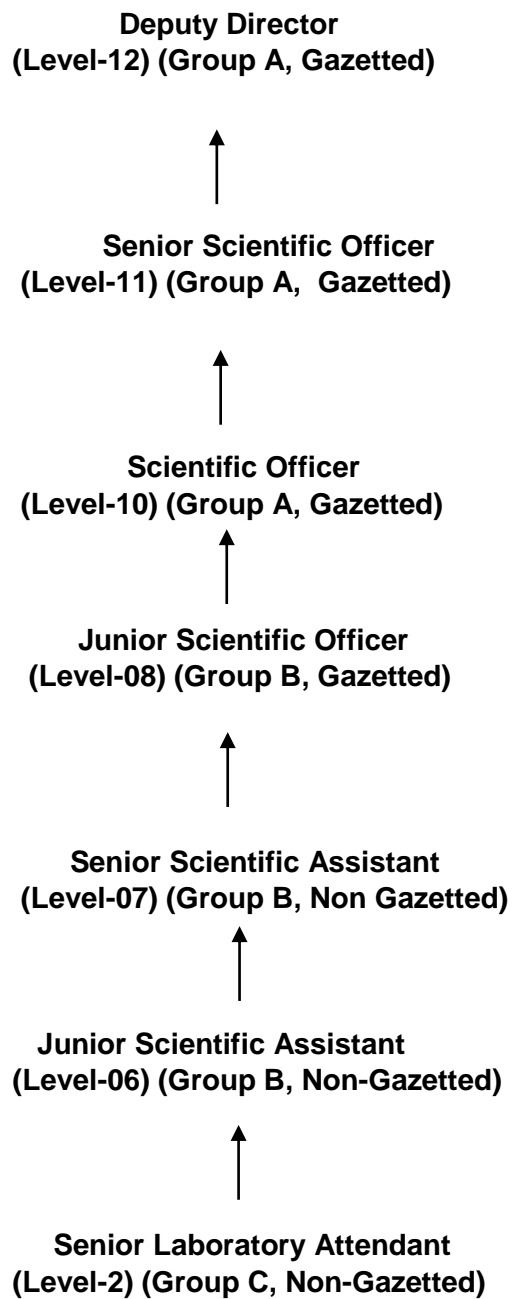
This laboratory received the samples from different Zones, sub zones, port offices of CDSCO. The details of the sample status for the four and current financial years i.e., 2019-20, 2020-21, 2021-22, 2022-23 & 2023-24 are given below.

| Sl. No. | Financial year | Annual Target for testing of Drugs / Cosmetics | Number of Samples Received | Number of Samples Tested | Number of Samples declared as NSQ/Spurious/Adulterated |
|----------------|-----------------------|---|-----------------------------------|---------------------------------|---|
| 1. | 2023-24 | 3000 | 1457 | 1378 | 25 |
| 2. | 2022-23 | 3000 | 3611 | 3611 | 23 |
| 3. | 2021-22 | 3000 | 3321 | 3321 | 11 |
| 4. | 2020-21 | 3000 | 2306 | 2306 | 08 |
| 5. | 2019-20 | 3000 | 3214 | 3214 | 10 |

b. ACHIEVEMENTS:

- i. This Laboratory has tested more than 5000 samples received as part of National wide Survey in the year 2015 conducted by NIB, Ministry of Health & Family Welfare, and Government of India and successfully achieved the task in a time bound manner.
- ii. This Laboratory is accredited with National Accreditation Board for Testing and Calibration Laboratories (NABL), Quality Council of India (QCI) in accordance with ISO/IEC 17025 on 30.06.2016 in the field of Chemical Testing (Drugs, Pharmaceuticals and Cosmetics). As validity of certification is 2 years, Laboratory got its accreditation renewed in 2018, 2020, 2021 & 2023 with validity upto 29.06.2025 for 124 test parameters (30 scope moieties).

III. ORGANOGRAM :



III. POWERS AND DUTIES OF ITS OFFICERS AND EMPLOYEES

i) Director:

- Provide an environment in which quality work can be produced
- He/She is also empowered to take decision on purchase of equipment's and contingent grant for the amount of Rs 5 Lakhs or below.
- He/She reports directly to the Drug Controller General of India under the Central Drug Standardization Organization.
- Carry out the policy and procedures enlisted for smooth running of the laboratory.
- Provide direction and training for all technical and managerial staffs involved in the receipt, handling, storage, preparation and analysis of the samples as well as the preparation, review submittal and archiving of analytical data and test reports.
- Guide, supervise and co-ordinate the activities of the different divisions of the Laboratory to achieve the quality work according to Schedule L1 of Drugs and Cosmetics Act, 1940 and rules 1945 & International GLP.
- Review of Pharmacopoeial monographs and where necessary seek amendments.
- Ensure that the Laboratory acquires and maintains the NABL certification for Quality testing.
- Supervises the Inter Laboratory testing and Proficiency testing of reference samples.

ii) Junior Scientific Officer:

- Assist Director in day-to-day technical activities of the Laboratory.
- Supervise and provide technical guidance to all analysts in analysis of drugs and cosmetic samples.
- Release of final test reports of samples analyzed.
- Approve all Laboratory records.
- Authorize and release certain quality related documents as per NABL requirements.
- Any other work assigned by Director.

iii) Junior Scientific Assistant:

- Analysis and testing of different pharmacopoeial and non-pharmacopoeial API's and formulations.
- Operating different sophisticated instruments.
- Preparation, maintenance and standardization of reference.
- Carrying out calibration test of the instruments.
- Assists in preparation of SOP's and maintenance of calibration records, maintenance of Logbooks of various equipments.
- Verify all Laboratory records.
- Assists in calling of tenders, purchase of chemicals, glassware, equipment accessories and miscellaneous items.
- Maintenance of stores ledgers correspondence pertaining to purchase of stores.
- Indents of store, issue of stores to divisions.
- Any other work assigned by Director.

iv) Bench Chemist:

- Analysis and testing of different pharmacopoeial and non-pharmacopoeial API's and formulations.
- Operating different sophisticated instruments.
- Preparation and standardization of volumetric solutions.
- Preparation and maintenance of in-house working standards.
- Carrying out calibration test of the instruments.
- Assists in preparation of SOP's and maintenance of calibration records, maintenance of Logbooks of various equipments.

v) Laboratory Assistant:

- Prepare reagents and solutions for use in testing.
- Help analysts in testing of samples.
- Help analysts in miscellaneous work of the division.
- Maintenance of Log books of the division.
- Independent analysis of the samples when and where required depending on sample load.

vi) Accounts Officer:

- Maintenance of cash books, contingent book, bill register, token register, service postage stamp.
- Prepare salary bills, contingent bills, Correspondence pertaining to budget expenditure and other accounts work.

vi) Librarian:

- Maintain the library and, under immediate supervision, performs clerical and other library work as required

vii) Admin Consultant:

- Assist Director in all ministerial work, appointments, establishment works, correspondences, noting, drafting.
- Deal with various Govt. circulars, administrative work.

viii) Data Entry Operator:

- Taking up notes, dictations, and proceedings of conference and meetings and to transcribe the same.
- General typing work, electronic data transformation, computerized typing of reports and correspondences.
- Drafting, filing, noting and performing the duties of confidential assistant.
- Maintenance of data storage system of the Laboratory for report generation.

ix) Office Assistant:

- Serving water, snacks tea etc to officers, staff and guests as per the instructions of officers and staff.
- Shifting of office equipment, chemicals, glassware, furniture and furnishing, electrical and stationary items as well as delivering of bulk papers.
- Manage incoming and outgoing files/letters/packages.
- Visiting offices to distribute/receive office documents.
- Binding/repairing of office documents.
- Organize and maintain cleanliness of work area/desk.

IV. DIRECTORY OF THE OFFICERS AND EMPLOYEES AND REMUNERATION

Incumbency positions relating to various posts / grades as on 01.01.2024

a) Regular Staff

| S. No. | Name of the Post | Group | Level | No. of Sanctioned Posts | In Position | Vacancy |
|--------------------|-----------------------------|---------------------------|-----------|-------------------------|-------------|-----------|
| 1 | Deputy Director | Group A (Gazetted) | Level -12 | 1 | Nil | 1 |
| 2 | Senior Scientific Officer | Group A (Gazetted) | Level-11 | 1 | Nil | 1 |
| 3 | Scientific Officer | Group A (Gazetted) | Level -10 | 1 | Nil | 1 |
| 4 | Junior Scientific Officer | Group B (Gazetted) | Level-8 | 2 | 1 | 1 |
| 5 | Senior Scientific Assistant | Group B (Non-Gazetted) | Level-7 | 2 | Nil | 2 |
| 6 | Junior Scientific Assistant | Group B (Non-Gazetted) | Level-6 | 2 | 1 | 1 |
| 7 | Senior Laboratory Attendant | Group C (Non-Gazetted) | Level -2 | 2 | Nil | 2 |
| Total Staff | | | | 11 | 2 | 09 |

b) Contractual Staff

| S. No. | Name of the Post | Consolidated Pay | No. of Sanctioned Posts | In Position | Vacancy |
|--------------------|---------------------|--|-------------------------|-------------|----------|
| 1. | TDA (Admin., Fin.,) | Rs.42000/- | 01 | 01 | Nil |
| 2. | Admin Consultant | Rs.36750/- | 01 | 01 | Nil |
| 3. | Accounts Officer | Rs.36750/- | 01 | 01 | Nil |
| 4. | Bench Chemist | Rs.33600/- | 22 | 22 | Nil |
| 5. | Librarian | Rs.23000/- | 01 | 01 | Nil |
| 6. | Data Entry Operator | Approx Rs. 23082/- (As per minimum wages Act) | 06 | 06 | Nil |
| 7. | Lab Assistant | Approx Rs. 21215/- (As per minimum wages Act) | 05 | 05 | Nil |
| 8. | Office Assistant | Approx Rs. 21215/- (As per minimum wages Act) | 04 | 04 | Nil |
| Total Staff | | | 41 | 41 | 0 |

**Details of the Employee and Telephone Numbers of Officers & Staff of
Central Drugs Testing Laboratory, Hyderabad for RTI act, 2005**

a) Regular Staff :

| Sl. No. | Name of the Employee | Designation | Official Phone Number | Pay Level |
|----------------|-----------------------------|---|------------------------------|------------------|
| 1. | Dr. A. Visala | Deputy Drugs Controller (I) & Additional Charge, CDTL | 040-23811328 | Level-12 |
| 2. | Dr. A. Raghuram Reddy | Junior Scientific Officer & Government Analyst | 040-23811327 | Level-8 |
| 3. | K. Nitin Kumar | Junior Scientific Assistant & Government Analyst | 040-23811327 | Level-6 |

b) Contractual Staff :

| Sl. No. | Name of the Employee | Designation | Official Phone Number | Consolidated Pay in Rs. |
|----------------|------------------------------------|--------------------|------------------------------|--------------------------------|
| 1. | Mrs. Velagandula Sahithya | Bench Chemist | 040-23811327 | 33600.00 |
| 2. | Mrs. Kongara Veera Raghava Lakshmi | Bench Chemist | 040-23811327 | 33600.00 |
| 3. | Mrs. Chilaka Sirisha Priyadarshini | Bench Chemist | 040-23811327 | 33600.00 |
| 4. | Ms. Kannali Jyoshna | Bench Chemist | 040-23811327 | 33600.00 |
| 5. | Mr. Dharmapuri Srinivas | Bench Chemist | 040-23811327 | 33600.00 |
| 6. | Mr. Santha Kumar Palanivel | Bench Chemist | 040-23811327 | 33600.00 |
| 7. | Mr. Chidurala Mani | Bench Chemist | 040-23811327 | 33600.00 |
| 8. | Ms. Chakra Srihari Rohith | Bench Chemist | 040-23811327 | 33600.00 |
| 9. | Mr. Surawar Vinayak Nandkishor | Bench Chemist | 040-23811327 | 33600.00 |
| 10. | Mr. Vavilla Sharath Babu | Bench Chemist | 040-23811327 | 33600.00 |
| 11. | Ms. Torati Satya Anjali | Bench Chemist | 040-23811327 | 33600.00 |
| 12. | Ms. Koduru Varalakshmi | Bench Chemist | 040-23811327 | 33600.00 |
| 13. | Ms. Dandu Madhavi | Bench Chemist | 040-23811327 | 33600.00 |
| 14. | Ms. P. Samyuktha Rani | Bench Chemist | 040-23811327 | 33600.00 |
| 15. | Ms. B. Basanthi Soujanya | Bench Chemist | 040-23811327 | 33600.00 |
| 16. | Ms. Bairaboyina Jyothi | Bench Chemist | 040-23811327 | 33600.00 |
| 17. | Ms. Gaddhe Lakshmi | Bench Chemist | 040-23811327 | 33600.00 |
| 18. | Mr. Venkata Siva Krishna Podisetty | Bench Chemist | 040-23811327 | 33600.00 |
| 19. | Ms. Bolla Krishna Priyanka | Bench Chemist | 040-23811327 | 33600.00 |
| 20. | Mr. R. N. Sadan Kumar | Bench Chemist | 040-23811327 | 33600.00 |

| | | | | |
|-----|--------------------------|------------------------|--------------|----------|
| 21. | Mrs. Darsanala Lavanya | Bench Chemist | 040-23811327 | 33600.00 |
| 22. | Mrs. Sunkara Rajeswari | Bench Chemist | 040-23811327 | 33600.00 |
| 23. | Mrs. Korlapati Usha Rani | Lab Assistant | 040-23811327 | 21215.00 |
| 24. | Mr. Kranthi Sagar | Lab Assistant | 040-23811327 | 21215.00 |
| 25. | Ms. Paidipala Meghana | Lab Assistant | 040-23811327 | 21215.00 |
| 26. | Ms. Kadim Sishwa Sivani | Lab Assistant | 040-23811327 | 21215.00 |
| 27. | Ms. Ashika Nitila | Lab Assistant | 040-23811327 | 21215.00 |
| 28. | Mrs. Madhavi | Admn. Consultant | 040-23811327 | 36750.00 |
| 29. | Mr. Avadhutha Kishan | TDA (ADMIN./FIN) | 040-23811327 | 42000.00 |
| 30. | Mrs. KND Lalithambika | Accounts Officer | 040-23811327 | 36750.00 |
| 31. | Mr. Murali Krishna | Librarian | 040-23811327 | 23000.00 |
| 32. | Mr. N. Sudheer Kumar | Data Entry Operator | 040-23811327 | 23082.00 |
| 33. | Ms. Kumpatla Yunanda | Data Entry Operator | 040-23811327 | 23082.00 |
| 34. | Mr. Vadeapally Karteek | Data Entry Operator | 040-23811327 | 23082.00 |
| 35. | Ms. Chevitolla Anitha | Data Entry Operator | 040-23811327 | 23082.00 |
| 36. | Mr. Gattu Srinivas | Data Entry Operator | 040-23811327 | 23082.00 |
| 37. | Ms. Prasanna | Data Entry Operator | 040-23811327 | 23082.00 |
| 38. | Mr. Aluvala Saikumar | Office Assistant | 040-23811327 | 21215.00 |
| 39. | Mr. Komaraju Prashanth | Office Assistant | 040-23811327 | 21215.00 |
| 40. | Mr. Mummadi Srihari | Office Assistant | 040-23811327 | 21215.00 |
| 41. | Mr. K. Anil | Office Assistant | 040-23811327 | 21215.00 |

IV BRIEF NOTE ON THE IMPORTANT WORK DONE ON DAY TO DAY BASIS:

a) Technical Works:

This Laboratory is receiving drugs, cosmetics and medical devices samples (Section, survey, custom and Port samples) from Offices of the CDSCO, Zonal, Subzonal and Port Offices. Testing of cough syrups received from the Manufacturer / Exporter for the purpose of Export as per directions of Drugs Controller General (India)

The samples are analysed by Physico-Chemical, Biological and Instrumental Analytical Techniques and release the test reports through online www.sugamlabs.gov.in web portal.

The Chemical /Biological Testing Division is equipped with state of art facilities and having sophisticated computerised analytical instruments like UHPLC, HPLC, GCHS, HPTLC, UV-Visible Spectrophotometer, FTIR Spectrophotometer, Auto Titrator to detect the end point to the third decimal and also digital melting/boiling point apparatus. HPLC with ELSD, PDA, RI, Fluorescence Detector, Bacterial Endotoxin Test Apparatus, Autoclaves, Incubators (Walkin), Liquid Particle Counter, Digital Polarimeter, Analytical Balance, Dissolution Auto Sampler, Total Organic Carbon Analyser, Muffle Furnace, Tablet Disintegration Apparatus, Karl Fischer Titrator, Auto Potentiometric Titrator.

The Cosmetic Testing Division is equipped with foam Height Apparatus for Shampoo, Drying Time Apparatus, Adhesion Test Apparatus for testing Nail Polish, Breaking Load Apparatus for testing Lipstick, Sieve Shaker and Brooke field Viscometer are available for testing cosmetic samples.

b) Administrative Works:

Establishment, Administration & Accounts: Typing works connected with establishment & administration, stores, purchase section, budget and accounts, maintenance of receipt and dispatch register, maintenance of leave accounts of staff members, maintenance of service books of staff members, maintenance of service stamps and maintenance of various files and other connected records.

Replying various urgent administrative and technical matters of the entire laboratory and on confidential letters received from the Dte./Ministry and other offices.

Sending yearly and half-yearly, quarterly, monthly reports of administrative and technical matters of the Laboratory.

Maintenance of cash book accounts and other connected records. Preparation of pay bills for temporary advance, LTC and other bills of contingent purchase. Appropriation of accounts along with reconciliation. Preparation of budget and final estimates along with expenditure statements.

Store Section:

Preparation of indent, procurement of chemicals, solvents, glassware, instrument/equipment, stationary and miscellaneous receipt and issue of stores including stationery Maintenance of all stock registers and other connected records, care and custody of stores along with annual physical verification of stocks as per GFR.

V. GENERAL POINTS:

- a) Procedure followed in decision-making process includes channels of supervision and accountability

Decisions are made at different levels as per hierarchy of this office and final decision making authority is Director of the Organisation

- b) Rules, regulations, instructions, manuals and records, held by it or under its control or used by its employees for discharging of functions.

Rules and Regulations framed by Govt. of India. This Laboratory follows Drugs and Cosmetics Act 1940 and Rules thereunder. As it is NABL Accredited Laboratory (ISO 17025:2017), all procedures to be followed are well documented in quality manual and quality system procedure of this Laboratory, on administrative matters, all procedures, rules and regulations are being followed as per the instructions of the Government of India issued from time to time. As it is subordinate office working under the administrative control of the Drugs Controller General (I), Central Drugs Standard Control Organisation, New Delhi, this Laboratory is following policies framed by CDSCO, Dte. G.H.S., New Delhi.

- c) Categories of documents that are held by it or under its control. Administration, Accounts and Technical and custodian of documents is with Sections in-charge of the organization.

- d) Boards, Councils, Committees and other bodies consisting of two or more persons
This Laboratory does not have any board, council or other such bodies

- e) Manner of execution of subsidy programmes, including the amounts allocated and the details of beneficiaries of such programmes. - Not Applicable

- f) Particulars of facilities available to citizens for obtaining information, including the working hours of a library. - Not Applicable



National Accreditation Board for
Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

CENTRAL DRUGS TESTING LABORATORY

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

**"General Requirements for the Competence of Testing &
Calibration Laboratories"**

for its facilities at

CDS CO BHAVAN, SR NAGAR, HYDERABAD, TELANGANA, INDIA

in the field of

TESTING

Certificate Number: TC-7495

Issue Date: 30/06/2023

Valid Until: 29/06/2025

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity : CENTRAL DRUGS TESTING LABORATORY

Signed for and on behalf of NABL



N. Venkateswaran
Chief Executive Officer