

SUO MOTU DISCLOSURE UNDER SECTION 4 OF RTI ACT 2005
(CDSCO, West Zone, Mumbai)

1. Organization and Function:-

1.1 Particulars of its Organization, Functions and Duties [Section 4(1)(b)(i)]

(i) Name and Address of the Organization:-

**CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)
(WEST ZONE) MUMBAI**

4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central,
Mumbai – 400 008

Email: wzmumbai@cdsco.nic.in

<https://cdsco.gov.in/>

<https://cdsco.gov.in/opencms/opencms/en/Home/>

**Website Designed, Developed and Maintained by CDAC as per requirements
provided by CDSCO (HQ), New Delhi.**

(ii) Head of the Organization

**Dr. Santosh V. Indraksha
Deputy Drugs Controller (India)**

(iii) Vision, Mission and Key Objectives:

Vision:

To Protect and Promote Public Health in India.

Mission:

To Safeguard and Enhance the Public Health by Assuring the Safety, Efficacy and
Quality of Drugs, Cosmetics and Medical devices.

(iv) Function and Duties:-

A) Technical:

In fulfilling its mission, the CDSCO, Zonal office, Mumbai has following functions:

1. To participate in the joint-inspection for grant/ retention of license for manufacturing of
Drugs and Cosmetics as per GSR 1337 (E) dated 27th October, 2017.
2. To participate in the joint-inspection for grant/retention of Vaccine / Sera manufacturing
units for both human as well as veterinary.

3. To participate in the joint-inspection for grant/ retention of LVP manufacturing units.
4. To participate in the joint-inspection for grant/retention of Bio-tech (r-DNA) & Bio-similar products manufacturing units i.e. recombinant (r-DNA products)
5. To participate in the joint-inspection for issuance /revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO-GMP Certification Scheme.
6. To process application for Written Confirmation (WC) for export of API to European Union as per EU Directives and their inspection, if required.
7. To participate in the joint-inspection for grant of approval for Private Testing Laboratory (PTL) for test/ analysis of Drugs & Cosmetics as per the provisions of Drugs & Cosmetics Act and Rules there under.
8. To participate in the inspection of Clinical Trial facilities and BA/BE centers as directed by the Drugs Controller General (India) from time to time. To carryout inspection for grant of license of Medical Devices (Class C & Class D) and In-vitro Diagnostic Kit (Class C & Class D) manufacturing units under Medical Devices Rules, 2017.
9. To carry out Surprise check/Raids jointly or independently on the basis of complaint received under Whistle Blower scheme and also from other sources.
10. Drawing of legal samples of Drugs from the manufacturing & sales / distribution premises including the Govt. establishment.
11. Follow up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other zonal offices, on the basis of Govt. Analyst test report.
12. To pursue the court cases pending in different courts under the zone.
13. Technical survey as and when directed by the Drugs Controller General (India) from time to time.
14. To discuss the matter with various State Drugs Controllers in the zone in connection with enforcement of the provisions of D & C Act & Rules there under from time to time.
15. To co-ordinate for answering the Parliament Questions and for obtaining the data from various State Licensing Authorities under the jurisdiction of the zone.
16. Reply of RTI applications under RTI Act, 2005.
17. To participate as observer in inspections conducted by various international regulatory agencies as and when informed by HQ.
18. To organize workshop, seminar etc. as directed by the Controlling Authority.
19. To conduct the function of Drugs Controller General (I) as and when delegated by him under rule 22 (b) & 122L and other Rules of the Drugs and Cosmetics Rules, 1945. The

following functions delegated to respective zonal officers for carrying out on his behalf:

- i. Permission for grant of license to manufacture drugs for the purpose of examination, test or analysis under the New Drugs & Clinical Trials Rules, 2019 in Form CT-11 for new drugs/investigational new drugs (Active Pharmaceutical Ingredients & formulations), Form CT-14 (Unapproved Formulations) and Form CT-15 (unapproved APIs) so as to obtain license from State Licensing Authority (SLA) of concerned State under Rules 89 of the Drugs and Cosmetics Rules, 1945 in Form-29 as per requirements.
- ii. Grant of license for import of small quantities of old drugs in Form-11 for the purpose of examination, test or analysis as provided under Rule 33 of the Drugs and Cosmetics Rules, 1945 and for import of small quantities of new drugs in Form CT-17 under the provisions of NDCT Rules, 2019
- iii. Grant of license for import of small quantities of unapproved new drugs in Form CT- 25 by Government Institutions or Autonomous Medical Institutions for treatment of patients under Rule 86 of New Drugs and Clinical Trial Rules, 2019.
- iv. No objection certificates (Dual use NOC) for grant of permissions for import of dual use items, not for medicinal use.
- v. No Objection Certificate for manufacture of Unapproved/Banned/New Drugs solely for Export purpose on Online Mode through CDSCO Zonal office w.e.f. 15/05/2024.
- vi. Any other functions as assigned by JDC (I)/DCG (I).

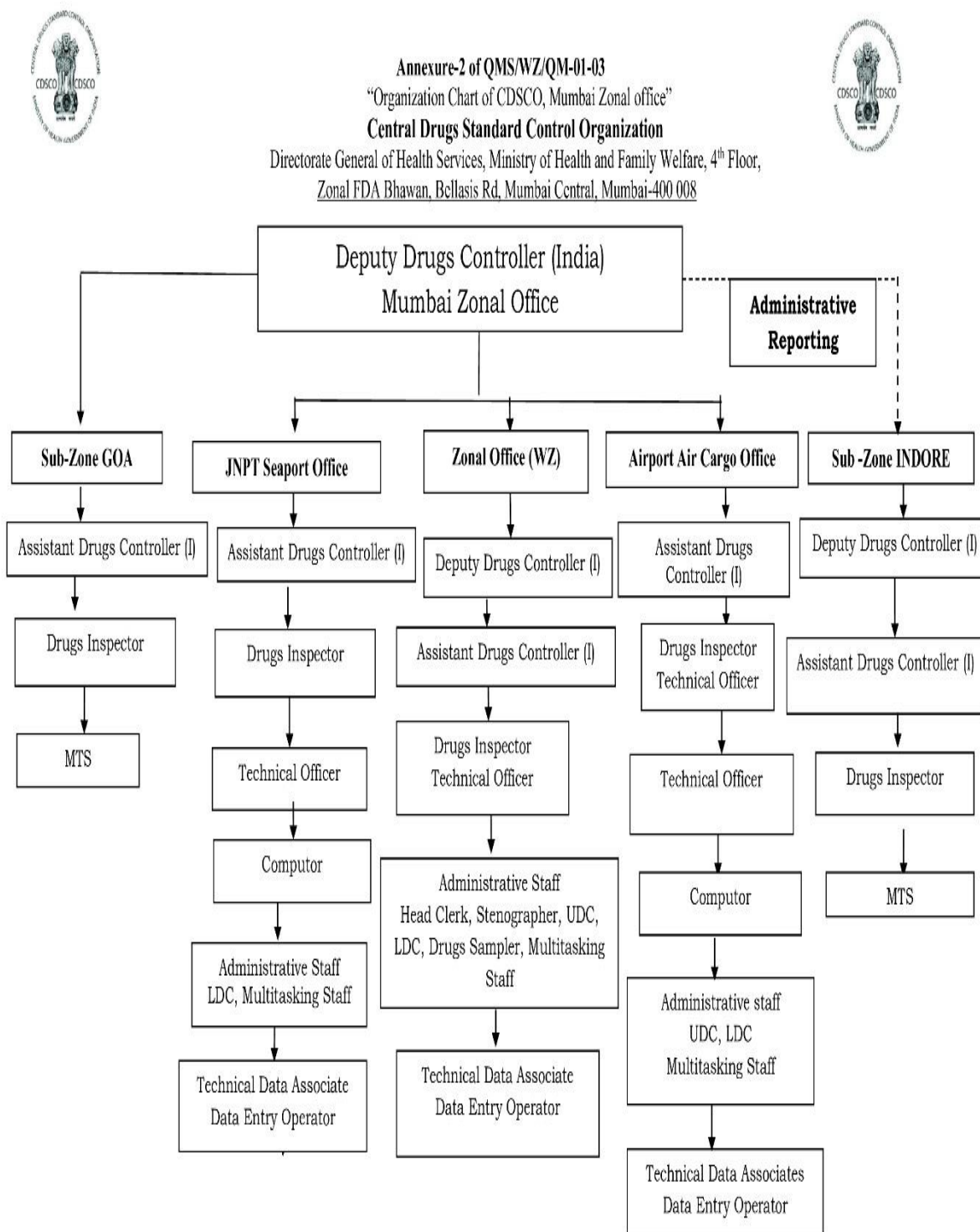
B) Administrative:

1. To Maintain the Service records/Leave records of Gazetted and Non-Gazetted Technical and Administrative Staff of CDSCO West Zone Mumbai and Sub-ordinate offices of Ahmedabad, Indore and Goa (under administrative control of CDSCO West Zone Mumbai).
2. To maintain Seniority list of Non-Gazetted employees.
3. To conduct DPC meetings for Recruitment, Promotion of posts of Gr. C employees.
4. Preparation and Grant of MACPs to eligible officials, arrears to officials.
5. To prepare Annual Budgets /preliminary and final estimate of expenditure etc.
6. To Prepare reports/replies concerning to the above administrative functions.
7. To purchase stationary and office items as per the requirements under GeM.
8. Annual Maintenance Contract (AMC) of office equipment through GeM etc.

9. To prepare Pensionary and other benefits of retired/VRS officials.
10. Processing of TA bills for reimbursement of officials of CDSCO West Zone Mumbai and sub-ordinate offices at Ahmedabad, Indore and Goa.
11. Processing of Medical bills for reimbursement of officials of CDSCO West Zone Mumbai and sub-ordinate offices at Ahmedabad, Indore and Goa
12. Processing of Professional Service bills for reimbursement of CDSCO West Zone Mumbai and sub-ordinate offices at Ahmedabad, Indore and Goa
13. Reply of RTI applications under RTI Act, 2005.
14. Any other functions assigned by JDC (I)/DCG (I) from time to time.
15. Preparing Bills for submission to PAO under Head – OE, RRT, MS, RM and online PFMS sanction for the same i.r.o officials of CDSCO West Zone Mumbai and sub-ordinate offices at Ahmedabad, Indore and Goa.
16. Giving Appropriation figures, bill numbering for all bills sub head wise – updating expenditure, budgetary Balance status.
17. Preparing monthly expenditure statement after verifying with PFMS portal for onward Transmission to HQ.
18. Preparing Budget estimates, Revised Estimates, Final estimates for onward Transmission to HQ New Delhi after compiling data of offices/ CDTL/Minilab at Ahmadabad, Indore, Goa.
19. GST TDS work- Preparing monthly Statement, create challan, preparing remittance bill to RBI, to Get done monthly e-Return filling on or before 10th of each month.
20. Verifying monthly TDS figures with PAO for Form 24G filling before 15th of each month.
21. Income Tax work of computation of IT TDS from salary after preparing salary income statement of each staff.
22. Preparing quarterly TDS statement for filling with IT NSDL-Form 24Q & form 26Q of Salaries and Non Salaries.
23. Updating, scrutinizing Investment declaration receipts in IT file
24. Getting, circulation of Form 16 of all staff and form 16A of vendors quarterly
25. Preparing data, statement asked by HQ reg. Expenditure, Budget
26. Reconciliation of monthly expenditure with PAO books of accounts

(v) Organization Chart:

ORGANIZATIONAL CHART
CDSCO (WEST ZONE) MUMBAI



Format No. QMS/WZ/QM-01-03/F02-00

vi) Any other details-the genesis, inception, formation of the department and the HoDs from time to time as well as the committees/ Commissions constituted from time to time have been dealt.

The **Central Drugs Standard Control Organization (CDSCO), West Zone, Mumbai** was started during the year July 1967 at Abubakar Mansion, Colaba, Mumbai 400001, headed by Deputy Drugs Controller (India).

The Zonal office of the CDSCO, WZ Mumbai was initially created to co-ordinate with the various State Drugs Controllers (who are the Licensing Authority) under the Act for uniform implementation and smooth enforcement of the provisions of Chapter IV of the Drugs & Cosmetics Act and Rules. The Said office was shifted to Antop Hill, CGHS Dispensary Building No. 08, Sector-1, Kane Nagar, Nr. Kane Nagar Post office, Antop Hill, Mumbai 400 0037 in the Year 1975. The West Zone office had jurisdiction over the states of Maharashtra, Gujarat, Chattisgarh, Goa, Madhya Pradesh, union Territory of Daman & Diu (Daman) and Dadra & Nagar Haveli (Silvassa). At present the West Zone office is functioning since 11th January 2010 at 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Rd., Mumbai Central, Mumbai 400 008, and has jurisdiction over the States of Maharashtra, Chattisgarh, Union Territory of Daman & Diu (Daman) and Dadra Nagar Haveli (Silvassa).

A **new Sub-Zonal office Ahmedabad** headed by an Assistant Drugs Controller (India) with the jurisdiction over the State of Gujarat had started and is functioning w.e.f. 1st April 2002. Ahmedabad Sub-zonal office was upgraded to Zonal level from 11th July 2011. Deputy Drugs Controller (India) is the head of office at CDSCO Zonal office, Ahmedabad.

The **CDSCO, Sub-Zone Indore** started its operations from the premises of Container Corporation of India Ltd., Inland Container Depot (ICD), 113-Concor Complex, Sector -3, Pithampur Industrial Area, Pithampur, Dist. Dhar, Madhya Pradesh, w.e.f. 22nd February 2010, to regulate the Export of Drugs & Cosmetics from Indore. In the Yr. 2014, CDSCO Sub-Zone Office shifted to the other premises at Quarter No. 67, 68, 69, 70, 71, 72, Type-1, Griffens Colony and now since July 2021 CDSCO Sub-Zone office is functioning from CDSCO Bhawan, GPO Square, Residency Area, A B Road, Indore (MP) – 452001 and is headed by the Dy. Drugs Controller (India) with jurisdiction over the State of Madhya Pradesh.

Central Drugs Testing Laboratory (CDTL) - Indore is engaged in the analysis of drugs and pharmaceuticals as per Drugs & Cosmetics Act and rules there under. CDTL is functioning from the same premises of CDSCO Bhawan, GPO Square, Residency Area, A B Road, Indore (MP) – 452001, from where the office of CDSCO Sub-Zone Indore is functioning.

CDSCO Sub-Zone, Goa is headed by an Assistant Drugs Controller (India) with the jurisdiction over the State of Goa had started functioning in the Yr. 2011 at 3rd Floor, Customs Building, Customs House, Marmagao, Goa 403803. Since 2017, the O/o. CDSCO, Sub-Zone/Port office, Goa was operating from the Ground Flr., Port Users Complex (Old A O Bldg.) Mormugao Harbour, Nr. to Mormugao Sub-Post office, Mormugao, Goa-403803. Since September 2023, the CDSCO, Goa Sub-Zone/Port Office is shifted and functioning at the new premises i.e. Room No. 07 & 08, First Floor, Air Cargo Terminal Building, Manohar International Airport, Dadachiwadi Road, Nagzar, Taluka Pernem, Mopa, North Goa, Goa-403512.

1.2 Power and duties of its officers and employees [Section 4(1) (b)(ii)]

- i) Powers and duties of officers (administrative, financial and judicial) &
- ii) Power and duties of other employees.

Designation	Duties
Deputy Drugs Controller (India) (DDCI)	➤ Technical head of the office of CDSCO (West Zone) Mumbai w.r.t. the activities of States under West Zone viz. Maharashtra, Chattisgarh, Goa, Daman Diu & DNH Silvassa w.r.t. Planning, co-ordination of Inspections, Investigations, Complaint investigations w.r.t. Blood Centers, Blood Products, Vaccines and LVPs, WHO GMP, Written Confirmations, Medical Devices, rDNA, Public Testing Laboratories, BA/BE, Manufacturing Licenses in Form 25/25A/28/28A/28D/28DA/28 E etc. Administrative Head for CDSCO Zonal office, Mumbai, Zonal office Ahmedabad, Sub-Zone Goa and Sub-Zone, Indore. ➤ Technical activities of Port offices viz. CDSCO JNPT Sea Port Panvel, CDSCO Air cargo Mumbai and Goa Port and co-ordination with Customs Commissioners on matters related to Port offices. ➤ Monitoring the establishment of Minilabs at Port offices. ➤ Holding additional charge of Government Medical Stores Depot (GMSD) Mumbai w.e.f. 25/06/2025. ➤ Co-ordination and co-operation with the States Drugs Controllers under West Zone (Maharashtra, Goa, Chattisgarh, U.T. of Daman Diu and Silvassa) in order to ensure uniform enforcement of Drugs & Cosmetics Act and rules there under and other related legislations for the work relating to inspections for Licensing of Blood Centres, manufacturing of Large Volume Parenterals, Biological Products including Vaccines, Medical Devices as per Medical Device Rules, 2017 and issuance of recommendation of Grant or Renewal of Certificate of Pharmaceutical Products (CoPP) as per WHO TRS guidelines by Drugs Inspectors of CDSCO and State Licensing Authorities. ➤ Co-ordination with Zonal offices, Sub-Zonal and Port offices of CDSCO for uniform implementation of Drugs & Cosmetics Act and rules there under. Co-ordination with other organizations/Associations like IDMA, IPA, Pharmexcil, Customs, DGFT, IPC, NIB, etc. ➤ Deputation of inspectors for inspection on the basis of the applications received for joint inspections, raids, investigations, seizures and drawal of samples etc. as per Drugs & Cosmetics Act and rules. ➤ Monitoring and evaluation of inspections conducted, report submitted, reviewing and forwarding to Drugs Controller General (India) and / or State Licensing Authority for necessary action as applicable. ➤ Review, monitoring, evaluation of all files, inspection reports, drafts, letters, all types of bills, budget and expenditure submitted by all levels of staff including Assistant Drugs Controllers, Drugs Inspectors, Technical Officers and Administration staff. ➤ Deputation, monitoring, evaluation and forwarding of report of joint inspections conducted by CDSCO and State Licensing Authorities under GSR 1337 (E) to concerned State Licensing Authority for necessary action (approval/compliance/rejection). ➤ Issuance of recommendations for the grant or renewal of WHO GMP COPP. ➤ Issuance of recommendations for the grant or renewal of licenses for Blood Centres.

	➤ Issuance of recommendations for the manufacture of Class C and Class D Medical Devices. ➤ Approval and signing authority for issue of Online NOCs/Licenses through SUGAM /NSWS/ONDLS/ MEDICAL DEVICE PORTALS : • Issue of NOC for import of dual use items, not for medicinal use. • Issue of NOC for Export • License for import of small quantities of drugs for examination, test or analysis in Form-11/CT-17. • License for import of drugs by Government Hospital or Autonomous Medical Institution for the treatment of patients under Form 11-A/CT-25 • Permission to manufacture Approved / Unapproved New Drugs in Form 29 / CT-11, CT-14 & CT-15 for the purpose of examination, test & analysis (Excluding for Clinical Trial Purpose, for drugs other than Biological/Medical Devices/Diagnostic Kits) in compliance to GSR 227 (E). ➤ Taking action on Not of Standard Quality drugs as per Drugs & Cosmetics Act and rules and as per CDSCO Guidance document. ➤ Deputation of Drugs Samplers at various places of suspicious nature to collect samples as surrogate patient from the sales premises by way of survey to monitor the quality of drugs and also deputation of Drugs Inspectors in case the samples are declared as NSQ by the testing laboratory. ➤ Monitoring of technical survey of drugs as and when directed by the Drugs Controller General (India). ➤ Acting as Appellate Authority for CDSCO West Zone for responding to RTI, replying Parliamentary Questions, etc. as and when required. ➤ Participation in various committees as Technical Expert, Workshops, Seminars as Speakers etc. and other related matters on behalf of DCG (I) including stakeholders meetings and resolve any issues, matters pertaining to manufacture, testing, import and export of drugs etc. ➤ Coordinating meetings with CDAC and the Maharashtra State FDA to address and resolve stakeholder issues related to CDSCO online portals. ➤ Organizing training programs for industry representatives on the use and functionality of online regulatory portals. ➤ Conducting meetings with industry associations such as IDMA, OPPI, IPA, FPME, and CHA Associations in relation to regulatory matters and ease-of-doing-business initiatives. ➤ Performing duties as Public Relations Officer by attending to visitors and industry representatives and facilitating the redressal and disposal of stakeholder grievances. ➤ Any other duties as may be assigned from time to time by the Drugs Controller General (India).
Assistant Drugs Controller (India) (ADCI)	1. Responsible for coordination and compliance with the directions of the Dy. Drugs Controller (India), CDSCO, West Zone, Mumbai for carrying out regulatory inspections (Certificate of Pharmaceutical Products, Blood Centres, Blood Products, Vaccines Sera, rDNA, Large Volume Parenterals) Inspections, Complaints, Raids/Investigations as directed by Dy. Drugs Controller (India), CDSCO, West Zone, Mumbai. 2. Monitoring of activities of Drugs Inspectors who are responsible for conduct of joint inspections, complaints investigations and sampling etc. as and when directed by the Dy. Drugs Controller (India), CDSCO, West Zone, Mumbai. 3. Coordination with Zonal Offices / State Licensing Authorities /Ports and Other Authorities as and when directed by the DDC (I) CDSCO WZ Mumbai.

	4. Processing of On-line Medical Device applications through SUGAMPORTAL as a Nodal officer / Medical Device Officer and Reviewing Officer. 5. Allotment / processing of On-line Test License applications through NSWS as Nodal Officer. 6. Acting as a Central Public Information Officer for RTI applications. 7. Responsible for co-ordinating and compliance with the directions of the Dy. Drugs Controller (India), CDSCO West Zone Mumbai for carrying out regulatory inspections (COPPs, CLAA Inspections and Complaints, Raids/Investigations) as directed by DDC (I) WZ Mumbai. 8. Deputation of Drugs Inspector for carrying out joint inspections, complaints investigations, sampling etc. in absence & as and when directed by the DDC (I) CDSCO WZ Mumbai. 9. Handling queries from the applicants as a Public Relation Officer and as a Nodal Officer for resolving grievances received from general public. 10. Acting as a Drawing and Disbursing Officer (DDO) in administration matters.
Technical Officer (TO)	1. Scrutiny of online Dual Use NOC applications on Sugam Portal as Reviewing Officer. 2. Monitoring of technical data related to all activities of office. 3. Any other duties as may be assigned from time to time by the Head of office & seniors.
Drugs Inspector/ Medical Device Officer (DI/MDO)	1. To participate in the joint inspections for issuance/revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO Certification Scheme as and when allotted by the DOC (I). 2. To participate in the joint inspections for grant/renewal of licenses with respect to the following as and when allotted by the DDC (I) : a. Blood Bank license, Vaccine/Sera manufacturing units for both human as well as Veterinary, LVP manufacturing units etc. b. For notified Medical Devices & Critical Diagnostics manufacturing units. c. For Biotech & Bio-similar products manufacturing units. d. Inspections of Clinical Trial facilities and BA/BE centers as directed by the Drugs Controller General (India) from time to time. e. Inspections for issue of Written Confirmation for export of API to EU. f. To carry out joint inspection of Drug Testing Laboratory for the purpose of grant of approval for test/analysis of Drugs & Cosmetics. 3. To carry out surprise check/raid jointly or independently on the basis of complaint received under whistle-Blower Scheme and also from other sources. 4. To follow-up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other Zonal offices. 5. Routine sampling of legal (Form 18) as well as Survey Samples for test/analysis by Central Laboratories. 6. When the samples drawn by the central Drugs Inspectors are declared spurious/adulterated/grossly sub-standard etc., the cases are investigated and prosecutions are launched in the appropriate court after obtaining necessary sanction from the Drugs Controller General (India). 7. Deputation of Drugs Samplers at various places of suspicious nature and collect samples through them as surrogate patient from the sales premises by way of survey to monitor the quality of drugs. Further surprise check/raid is to be carried out by the Drugs Inspectors in case these samples are declared as NSQ by the testing laboratory.

	8. To participate in the joint inspections with respect to grant of NOC in Form 29 as per requirements. 9. Technical Survey as and when directed by the DDC (I) from time to time. 10. To co-ordinate and assist in the training, workshops, seminars etc. as directed. 11. Any other work assigned by the DDC (I).
Technical Data Associate (TDA)	1. To assist officers in the technical related work. 2. Maintaining Documentation. 3. Prescreening and scrutiny of online Dual Use NOC through SUGAM Portal and Test License applications in Form-12, Form CT-10, Form CT-12, Form CT-13 and Form CT-16 applications on NSWS . 4. Any other work assigned by the DDC (I) / ADC (I).
Head Clerk (HC)	Supervision of administrative and accounts activities like General Administration, preparation of salary bills, personal claims of officers & staff, TA, Medical claim. Updating and maintenance of service records, leave records, Pension Cases etc.
Stenographer	Preparation of letters/replies and correspondence related to technical and administration matters. Assisting administration staff in day-to-day activities of office. Assisting Officers in their technical work. Any other work assigned by HoD and Seniors.
Upper Division Clerk (UDC)	Preparation of administrative replies, furnishing data for the RTI replies from administrative side, Validation of data in respect of officers and staff in the Personal Information system. Generating expenditure claims such as Office Expenditure, TA Claims, and Professional services through PFMS portal. Monthly Expenditure statements, preparation of revised and budget estimate for the current and ensuing year. Reconciliation of accounts with Pay and Accounts Office.
Lower Division Clerk (LDC)	Typing the official correspondence. Preparation of pay bills, income tax, e-TDS. Preparation of pension and retirement benefit papers. Purchase of stationery and other office equipment's through GeM Portal.
Multi-Tasking Staff (MTS)	To open and close the office before and after the arrival and departure of officers and staff. To assist the officers and staff in moving the files from one desk to another. To attend the Head of office and Senior officers. In addition to the auxiliary support, have to do basic clerical work, whenever there is a need.
Data Entry Operator (DEO)	Typing of letters related to technical as directed by Seniors, Sending e-mails, Scanning reports and hyperlink to respective statements, Maintaining data of inspection reports in the respective registers and computer system, Maintenance of Data Base, Any other Work assigned by the Seniors.

(iii) Rules/orders under which powers and duties are derived and exercised.

Deputy Drugs Controller (India) is working as Zonal Head & Controlling Officer under Drugs and Cosmetics Act 1940 and Rules, 1945. Drugs Inspectors derive their powers from Drugs & Cosmetics Act, 1940 (Section 21, 22 and 23) and Rules made there under (Drugs and Cosmetics Rules, 1945) and Medical Device Officer (Medical Devices Rules, 2017) and subsequent office orders issued by Directorate. Powers and duties of other posts are derived and exercised as per the practice in vogue. Copy of Drugs & Cosmetics Act and Rules under the said Act is available on CDSCO Website.

(iv) Work allocation

The information is available in the Table no.2

Procedure followed in decision making process [Section 4(1)(b)(iii)]

- a. Process of decision making Identify key decision making points.
- b. Final decision making authority.
- c. Related provisions, acts, rules etc.
- d. Time limit for taking decisions, if any.
- e. Channel of supervision and accountability.

As per Standard operating Procedure (SOP) the process of decision making based on the identified key decision making points is done at every level. SOP, guidance document and directorate order defines the hierarchy/channel of supervision of the office. The time limits for taking decisions are set by internal office orders issued from time to time. Final Decision making authority is vested with the Deputy Drugs Controller (I).

1.2 Norms for discharge of functions [Section 4(1)(b)(iv)]

- a. Nature of functions/ services offered.
- b. Norms/ standards for functions/ service delivery.
- c. Process by which these services can be accessed.
- d. Time-limit for achieving the targets.
- e. Process of redress of grievances.

The nature of functions / services offered by this office are listed under para no: 1.1.(iv).

Various Licenses/Permissions are issued through the SUGAM/NSWS/ONDLS/MD ONLINE PORTALS (www.cdsoonline.gov.in and www.cdscmdonline.gov.in).

Time limits are specified in the SOP. The grievances are redressed through Public Relation Office. Details of PRO are available on CDSCO website.

1.3 Rules, regulations, instructions manual and records for discharging functions [Section 4(1)(b)(v)]

- a. Title and nature of the record/ manual/ instruction.
- b. List of Rules, regulations, instructions manuals and records.
- c. Acts/ Rules manuals etc.
- d. Transfer policy and transfer orders.

Drugs and Cosmetics Act, 1940 and Rules made there under (Drugs and Cosmetics Rules, 1945, Medical Device Rules, 2017 and New Drugs and Clinical Trials, 2019, Cosmetics Rules 2020, Guidance document for Zonal, Sub-zonal & Port Offices and subsequent office orders issued by Directorate are followed by this office for discharging functions.

Further, Manual of Office Procedure and SUGAM online Portal User Manual in electronic format are also followed.

1.4 Transfer policy is formulated and transfer orders are issued by the Directorate. Copy of these Act, Rules, circulars, Notice is available on CDSCO website.

Categories of documents held by the authority under its control.

Categories of documents.

Custodian of documents/categories.

Documents are maintained as per the requirements of the following rules and manuals:-

Technical:

- a. Manual of Office Procedure.
- b. Drugs and Cosmetics Act, 1940.
- c. Drugs and Cosmetics Rules, 1945.
- d. CDSCO Guidance Document 2011.
- e. Medical Device Rules, 2017.
- f. New Drugs and Clinical Trials, 2019.
- g. Cosmetic Rules, 2020.
- h. Revised Schedule M, GSR 922 (E) dt. 28/12/2023.

Administrative:

Various documents and records are maintained as per the norms of Government of India

<https://dopt.gov.in/download/acts>

- (i) Boards, Councils, Committees and other Bodies constituted as part of the Public Authority [Section 4(1)(b)(viii)]
- (ii) Name of Boards, Council, and Committee etc. Composition
- (iv) Dates from which constituted (iv) Term/ Tenure.

1.5 Powers and Functions

Whether their meetings are open to the public?

Whether the minutes of the meetings are open to the public?

Information is available on CDSCO website.

1.6 Directory of officers and employees [Section 4(1) (b) (ix)]

Name and Designation of Head of Office : **Dr. Santosh V. Indraksha, Deputy Drugs Controller (India), CDSCO West Zone Mumbai.**

Telephone , Fax and email ID : **Tel: 022-23002279 / 23002215, Fax: 022-23002271, Email id : wzmumbai@cdsco.nic.in**

Sr.No.	Name of the Employee	Designation	Contact No.
1.	Dr. Santosh V. Indraksha	Dy. Drugs Controller (India)	022-23002279/23002215
2.	Milind Popatrao Patil	Asstt. Drugs Controller (India)	022-23002279/23002215
3.	Akash Rama Kondalkar	Asstt. Drugs Controller (India)	022-23002279/23002215
4.	Hemant Madhukar Patil	Drugs Inspector	022-23002279/23002215
5.	Deepak Nipunge	Drugs Inspector	022-23002279/23002215
6.	Naveen Yadav	Drugs Inspector	022-23002279/23002215
7.	A. Vijayendra Chary	Drugs Inspector	022-23002279/23002215
8.	Sangram Vurumadla	Drugs Inspector	022-23002279/23002215
9.	Ranga Harish	Drugs Inspector	022-23002279/23002215
10.	Baljeet Singh	Drugs Inspector	022-23002279/23002215
11.	Sandeep Goswami	Drugs Inspector	022-23002279/23002215
12.	M. Sundara Karthikeyan	Drugs Inspector	022-23002279/23002215
13.	V. Sooraj	Drugs Inspector	022-23002279/23002215
14.	Chinmay Kumar Hasmukhlal Patel	Drugs Inspector	022-23002279/23002215
15.	Mohan Guguloth	Drugs Inspector	022-23002279/23002215
16.	Ranjit Harishchandra Jadhav	Drugs Inspector	022-23002279/23002215
17.	Mahesh Kumar Saini	Drugs Inspector	022-23002279/23002215
18.	Suyogita M. Tajne	Drugs Inspector	022-23002279/23002215
19.	A. Santosh Kumar	Drugs Inspector	022-23002279/23002215
20.	Ruchi R Rane	Head Clerk	022-23002279/23002215
21.	Pooja P Salunkhe	Stenographer	022-23002279/23002215
22.	M. D. Wadekar	Upper Division Clerk	022-23002279/23002215
23.	Keshav V Malve	Lower Division Clerk	022-23002279/23002215
24.	Raveena Kumari	Drugs Sampler	022-23002279/23002215
25.	Shailendra R Dhotre	MTS	022-23002279/23002215
26.	Parshuram D Kashale	MTS	022-23002279/23002215

1.7 CONTACT DETAILS OF CDSCO (WEST ZONE), MUMBAI and Sub-Zonal Offices (Indore & Goa) - Refer organization website <https://cdsco.gov.in/opencms/opencms/en/Home/>

1.8 Monthly Remuneration received by officers & employees including system of compensation [Section 4(1) (b) (x)]

O/o. THE DEPUTY DRUGS CONTROLLER (INDIA) CDSCO (WEST ZONE)		
<u>Pay Band and Pay Level of Various Posts --- CDSCO WEST ZONE</u>		
CDSCO, West Zone, Mumbai, Ahmedabad Zone, Sub- Zone-Indore, Sub-Zone-Goa		
1	Deputy Drugs Controller (India)	Level-12 (78800-209200) GP 7600/-
2	Assistant Drugs Controller (India)	Level-11 (67700-208700) GP 6600/-
3	Technical Officer	Level- 8 (47600-151100) GP 4800/-
4	Drugs Inspector	Level -8 (47600-151100) GP 4800/-
5	Head Clerk	Level-6 (35400-112400) GP 4200/-
6	Steno Grade-II	Level -5 (29200-92300) GP 2800/-
7	UDC	Level- 4 (25500-81100) GP 2400/-
8	LDC	Level-2 (19900-63200) GP 1900/-
9	Drugs Sampler	Level-2 (19900-63200) GP 1900/-
10	MTS	Level-2 (19900-63200) GP 1900/-

1.9 Name, designation and other particulars of public information officers [Section 4(1) (b) (xvi)]

Name and designation of the Public Information Officer (PIO), Assistant Public Information (s) & Appellate Authority

Address, Telephone Numbers and Email ID of each designated official.

Sr No	Designation	Technical/ Administration Matters
1	Dr. Santosh Indraksha Deputy Drugs Controller (India) & Appellate Authority Central Drugs Standard Control Organization (West Zone) 4 th Flr., Zonal FDA Bhawan, GMSD Compound, Bellasis Rd., Mumbai Central, Mumbai 400 008	Deputy Drugs Controller (India) CDSCO West Zone Mumbai Email: wzmumbai@cdsco.nic.in Tel. No: 02-23002279, 23002215
2	Shri. Akash Rama Kondalkar Asstt. Drugs Controller (India) & Central Public Information Officer (CPIO) Central Drugs Standard Control Organization (West Zone) 4 th Flr., Zonal FDA Bhawan, GMSD Compound, Bellasis Rd., Mumbai Central, Mumbai 400 008	Assistant Drugs Controller (India) CDSCO West Zone Mumbai Email: wzmumbai@cdsco.nic.in Tel. No: 022-23002279, 23002215

1.11 No. of employees against whom disciplinary action has been taken:

- (iv) Pending for Minor penalty or major penalty proceedings – Nil.
- (v) Finalized for Minor penalty or major penalty proceedings – Nil.

1.12 Programmes to advance understanding of RTI (Section 26)

(i) Educational programmes

Training programme or workshop related to RTI is being attended regularly by CPIO of this office.

(ii) Efforts to encourage public authority to participate in these programmes

The department encourages public authority by granting necessary permissions whenever necessary to participate in the training programmes of RTI.

(iii) Training of CPIO/APIO:- Trainings are updated in IGOT Karmayogi Portal

Update & publish guidelines on RTI by the Public Authorities concerned

- A guidance document related to RTI is published on the website of CDSCO.
- Further, the guidelines issued by Central Information Commission are followed <https://cic.gov.in/rti-notifications>.

1.13 Transfer policy and transfer orders [F No. 1/6/2011- IR dt. 15.4.2013]

Transfer policy is formulated and transfer orders are issued by the Directorate for Gr. A and Gr. B (GZ & Non-GZ officials).

However, transfers of Gr. C employees is done internally within the office of CDSCO West Zone Mumbai / Navi Mumbai by the DDCL, CDSCO West Zone Mumbai.

Transfer Policy is publically available on CDSCO website.

2. Budget and Programme

Budget allocated to each agency including all plans, proposed expenditure and reports on disbursements made etc.[Section 4(1)(b)(xi)]

- (i) Total Budget for the public authority.
- (ii) Budget for each agency and plan & programmes.
- (iv) Revised budget for each agency, if any.
- (v) Report on disbursements made and place where the related reports are available.

The Budget Allocation is provided to CDSCO West Zone Mumbai by the Administration Section, CDSCO (HQ), New Delhi under different Heads of Account to meet the day-to-day expenditure of its own and its Sub-offices viz. CDSCO's Zonal office Ahmedabad, Sub-Zone Indore, Sub-Zone Goa including Central Drugs Testing Laboratory (CDTL), Indore and Mini Drugs Testing Laboratory (MDTL), Ahmedabad. The O/o. CDSCO Zonal office Ahmedabad, CDSCO Sub-Zone Goa, CDSCO Sub-Zone Indore, Central Drugs Testing Laboratory (CDTL), Indore and Mini Drugs Testing Laboratory (MDTL) at Ahmedabad are under the administrative control of CDSCO West Zone Mumbai.

SPEED POST

No. Admin-17011(11)/1/2025
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(CASH SECTION)

F.D.A. Bhawan, I.T.O., Kotla Road,
 New Delhi.

Dated: 10 February, 2026

To

Dy. Drugs Controller(I),
 CDSCO,(West Zone) Office of the Deputy Drugs Controller(I),
 4th Floor, FDA BHAWAN, GMSD Compound, Bellasis Road,
 Mumbai Central, Mumbai-400008

Subject :- Revised Estimates 2025-26 in respect of Major Head 2210-06104-Drugs Control (Minor Head) 02-CDSCO-0201- General Component and Revised Estimates 2025-26 in respect of Major Head 4210- Capital Outlay on Medical & Public Health -04200- Other Programmes (Minor Head) – 21-CDSCO-reg.

Sir/Madam.

I am directed to inform you that the Revised Estimates 2025-26 in respect of your office under each sub-head is as given below :-

(Rupees in thousands)

SL.N O.	ITEM	Current B.E. 2025-26	R.E. 2025-26
1.	Salaries (01)	47600	47600
2.	Rewards (05)	150	90
3.	Medical Treatment (06)	2000	2000
4.	Allowances (07)	45000	46961
5.	Leave Travel Concession (08)	1200	1200
6.	Training Expenses(09)	200	50
7.	Domestic Travel Expenses (11)	7900	7900
8.	Office Expenses (13)	18000	18000
9.	RRT for L&B(14)	8406	8920
10.	Rent for Others (18)	2000	2200
11	Digital Equipment (19)	700	700
12	Supplies and Material (21)	3000	3000
13	Minor Civil Work (27)	6310	6310
14	Professional Services (28)	1500	1000
15	Repair & Maintenance (29)	5000	1900
16	Total	148966	147831
	Capital Heads		
17	Machinery & Equipment(52)	3000	3040
18	Information computer Telecom. (71)	3000	3000
19	Furniture Fixture(74)	1500	1500
20	Building and Structure(72)	2642	2642
	Total	10142	10182

 faithfully,
 (Pawan Kumar)
 Deputy Director Admin.

Copy to:- Pay & Accounts Officer, Ministry of Health & FW, Mumbai.

पवन कुमार / PAWAN KUMAR
 उप निदेशक प्रशासन (आंतरिक) / Deputy Admin (Drugs)
 केन्द्रीय औषधि मानक नियंत्रण संगठन / Central Drugs Standard Control Organization
 C.D.S.C.O(HQ), डि. स्वास्थ्य और / C.D.S.C.O(HQ), Dis. Health Services
 Ministry of Health and Family Welfare, Government of India
 FDA Bhawan, I.T.O., Kotla Road, New Delhi - 110002

No.Admin.-17011(11)/1/2026
E.O: 33923
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
Central Drugs Standard Control organization

SPEED POST

F.D.A. Bhawan. I.T.O., Kotla Road,
New Delhi.

Dated:- 24 March, 2026

To

Dy. Drugs Controller(I),
CDSCO.(West Zone) Office of the Deputy Drugs Controller(I),
4th Floor, FDA BHAWAN, GMSD Compound, Bellasis Road,
Mumbai Central, Mumbai-400008

Subject :- Budget Estimates 2026-27 in respect of Major Head 2210-06104-Drugs Control (Minor Head) 02-CDSCO-0201- General Component and Budget Estimate 2026-27 i.e. Major Head 4210-Capital Outlay on Medical & Public Health-04100-Other programmes (Minor Head)-21 CDSCO - Reg.

Sir/Madam,

I am directed to inform you that the Budget Estimates 2026-27 in respect of your office under each sub-head is as given below :-

(Rupees in thousands)

SL.N O.	ITEM	B.E. 2025-26	R.E. 2025-26	B.E. 2026-27
1.	Salaries (01)	50000	47600	55000
2.	Rewards (05)	150	90	100
3.	Medical Treatment (06)	1000	2000	2500
4.	Allowances (07)	45000	46961	55000
5.	Leave Travel Concession (08)	500	1200	1000
6.	Training Expenses(09)	200	50	0
7.	Domestic Travel Expenses (11)	6000	7900	7000
8.	Office Expenses (13)	20000	18000	17000
9.	RRT for L&B(14)	4200	8920	4500
10.	Rent for Others (18)	2200	2200	3000
11.	Digital Equipment (19)	1000	700	1000
12.	Supplies and Material (21)	5000	3000	5000
13.	Minor Civil Work (27)	7000	6310	7000
14.	Professional Services (28)	1500	1000	1500
15.	Repair & Maintenance (29)	5000	1900	4500
16.	Total	148550	147831	164100
	Capital Heads			
17.	Machinery & Equipment(52)	3000	3040	4500
18.	Information computer Telecom. (71)	2000	3000	500
19.	Furniture Fixture(74)	500	1500	700
20.	Building and Structure(72)	00	2642	00
21.	Other Fixed Assets(77)	00	00	300
	Total	5500	10182	6000

Copy to:- Pay & Accounts Officer, Ministry of Health & FW, Mumbai.

(Pawan Kumar)
Deputy Director Admin.

ACCOUNTS OFFICE
MINISTRY OF HEALTH & F.W.
MEDICAL STORES DEPOT COMPOUND,
BELLASIS ROAD, NEAR CITY CENTRE,
CENTRAL MUMBAI - 400 008.

CDSCO, WEST ZONE, BHAWAN, I.T.O., KOTLA ROAD, NEW DELHI - 110 002.

Name of the Office: Dy. Drugs Controller (India),
CDSCO, WZ, Mumbai

(Rs. In Actual)

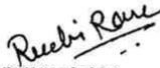
Monthly Expenditure Statement March, 2026 (Revenue Expenditure)

Function Head	Head	Budget Estimate during the Yr. 2025-26	Expenditure during the Month of March, 2026	Progressive Exp. Upto March, 2026	Balance Budget for the year 2025-26	Remark
2210-06-104-02-01	Salaries (01)	47600000	0	47426903	173097	
	Allowances (07)	46895000	0	46894346	654	
	Rewards(05)	90000	0	88077	1923	
	Leave Travel Concession (08)	1200000	197356	1187335	12665	
	Medical Treatment (06)	2000000	484133	1986432	13568	
	Training Expenses(09)	8000	0	7080	920	
	Domestic Travel Expenses(11)	8241000	930630	8236472	4528	
	Office Expenses (13)	18000000	2842660	17943948	56052	
	Rent Rates & Taxes for Land & Build. (14)	8920000	1385767	8918045	1955	
	Rent for others(18)	2200000	282885	2198143	1857	
	Prof. Services (28)	1000000	169690	999032	968	
	Material & Supplies (21)	2790000	190778	2775537	14463	
	Minor Civil Work (27)	6310000	0	4204849	2105151	LOA issued to CPWD 3 no.s - 652881+4347751+ 1299413 and Savings informed are 217654 + 953129 + 924413 (letters copy enclosed). Final certificate awaited from CPWD Horticulture.
	Digital Equipment(19)	700000	160500	635632	64368	
	Repair and Maintenance(29)	1900000	633007	1774649	125351	
Total		147854000	7277406	145276480	2577520	
Capital Expenditure						
Function Head	Head	Budget Estimate during the Yr. 2025-26	Expenditure during the Month of February, 2026	Progressive Exp. Upto February, 2026	Balance Budget for the year 2025-26	Remark
4210-04-200-21-00	Machinery & Equipment(52)	2000000	1852931	1998931	1069	
	Information, Computer Telecommunication (ICT) Equipment (71)	3000000	648800	2969414	30586	
	Furniture and Fixtures(74)	2500000	1989840	2487840	12160	
	Building and Structure(72)	2642000	0	2641530	470	LOA issued & payment made by CPWD vide Letter No.- 55(19)/2025/का.अ./द्वि-II/1471-फि Dated 23.09.2025 (Copy enclosed)
Total		10142000	4491571	10097715	44285	


(Rajendra S. Chavan)
UDC
Prepared by


(Mahadev D. Wadekar)
UDC
Prepared by


(Sampada Dhakle)
UDC
Prepared by


(Ruchi Rajendra Rane)
HEAD CLERK
Checked by

डॉ. संतोष इंद्राक्ष / Dr. Santosh Indraksha
उप औषधि नियंत्रक (भारत) / Deputy Drugs Controller (India)
भारत सरकार / Government of India
स्वास्थ्य एवं परिवार कल्याण मंत्रालय / Min. of Health & Family Welfare
स्वास्थ्य सेवा महानिदेशालय / DL General of Health Services
के.ओ.मा.नि.सं., पश्चिम घाट, मुंबई / CDSCO, West Zone Mumbai

Foreign and domestic tours (F. No. 1/8/2012- IR dt. 11.9.2012)

- i) Budget.
- ii) 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.

Foreign Tours for last 03 Years of HoD

Sr. No.	Name & Designation of the Officer	Place of Visit	Purpose of Visit	Period of Visit	Number of Members included in the Official Delegation	Total Expenditure of the Visit
1	2	3	4	5	6	7
1	Dr. Santosh Indraksha Deputy Drugs Controller (India)	Bangkok, Thailand	South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products	19-21 September, 2023	02	Sponsored by WHO
2	Dr. Santosh Indraksha Deputy Drugs Controller (India)	Geneva, Switzerland	Collaboration with WHO on regulatory systems strengthening for vaccines and medicines regulation in India	03-04 October, 2023	04	Govt. of India Fund
3	Dr. Santosh Indraksha Deputy Drugs Controller (India)	Dhaka, Bangladesh	SEARN Assembly Meeting	01-04 July 2024	02	Sponsored by WHO

Information related to procurements

- a) Notice/Tender enquires, and corrigenda if any thereon,
- b) Details of the bids awarded comprising the names of the suppliers of goods/ services being procured,
- c) The works contracts concluded – in any such combination of the above-and
- d) The rate /rates and the total amount at which such procurement or works contract is to be executed.

Nil

2.2 Manner of execution of subsidy programme

[Section 4(i)(b)(xii)]

- iii) Name of the programme of activity
- i) Objective of the programme
- ii) Procedure to avail benefits
- iii) Duration of the programme/ scheme
- iv) Physical and financial targets of the programme
- v) Nature/ scale of subsidy /amount allotted
- vi) Eligibility criteria for grant of subsidy
- vii) Details of beneficiaries of subsidy programme (number, profile etc)

Nil

2.4 Discretionary and non-discretionary grants [F. No. 1/6/2011-IR dt. 15.04.2013]

- (i) Discretionary and non-discretionary grants/ allocations to State Govt./ NGOs/other institutions
- (ii) Annual accounts of all legal entities who are provided grants by public authorities

Nil

2.5 Particulars of recipients of concessions, permits of authorizations granted by the public authority

[Section 4(1) (b) (xiii)]

- (i) Concessions, permits or authorizations granted by public authority
- (ii) For each concessions, permit or authorization granted
 - a) Eligibility criteria
 - b) Procedure for getting the concession/ grant and/ or permits of authorizations
 - c) Name and address of the recipients given concessions/ permits or authorisations
 - d) Date of award of concessions / permits of authorizations

Nil

2.6 "CAG & PAC paras [F No. 1/6/2011- IR dt. 15.4.2013]

CAG and PAC paras and the action taken reports (ATRs) after these have been laid on the table of both houses of the parliament.

Nil

3. Publicity Band Public interface

Particulars for any arrangement for consultation with or representation by the members of the public in relation to the formulation of policy or implementation thereof

[Section 4(1)(b)(vii)]

[F No 1/6/2011-IR dt. 15.04.2013]

Formulation of Policy and Implementation is carried out by Directorate

Arrangement for consultations with or representation by the members of the public

- i. Relevant Acts, Rules, Forms and other documents which are normally accessed by citizens at CDSCO website i.e., <https://www.cdsc.gov.in/> for following information.

Sr. No.	Type of Information
1.	Gazette Notifications
2.	Act & Rules
3.	Public Notices
4.	Bioequivalence and Bioavailability
5.	Blood Products
6.	Vaccines
7.	rDNA
8.	Stem Cells & Cell Based Products
9.	Global Clinical Trial
10.	Ethics Committee
11.	New Drugs
12.	Fixed Dose Combinations (FDCs)
13.	Investigational New Drugs (INDs)
14.	Subsequent New Drugs
15.	Medical Device and In-Vitro Diagnostics
16.	Cosmetics
17.	Public Relation Officer
18.	Large Volume Parenterals
19.	Blood Centers
20.	Circulars
21.	Vacancies

- ii) Arrangements for consultation with or representation by-
 - a) Formulation of Policy and Implementation is carried out by Directorate.
 - b) Day & time allotted for visitors.
 - c) Contact details of Information & Facilitation Counter (IFC) to provide publications frequently sought by RTI applicants.

Public Relation office has been established

Centralized PRO is established by Directorate to coordinate with respective Divisions, Zone, Sub-Zone. The contact details are available on CDSCO website, additionally the West Zone office has specified following:

Sr.No	Details Required	Details to be updated on CDSCO Website
1.	Name of the Zone	CDSCO Zonal Office (West Zone) Mumbai
2.	Name of PRO & Assistant Officials of PRO along with contact details.	Dr. Santosh Indraksha Deputy Drugs Controller (India), CDSCO, West Zone Mumbai Areas Covered under West Zone Divisions of Amrawati, Aurangabad, Nagpur, Nashik, Pune, Greater Mumbai and Konkan Division in Maharashtra State. States of Daman & Diu, DNH Silvassa, Chattisgarh, Goa. Execution of all activities of respective divisions and all approvals falling in either offline/online mode. ii) Port offices of CDSCO Aircargo, Airport Mumbai and JNPT Seaport Panvel. iii) CDSCO Sub-Zone/Port office, Goa <u>Names of Assistant Officials of PRO</u> Sh.Milind P Patil, Asstt. Drugs Controller (India) Sh. Akash R Kondalkar, Asstt. Drugs Controller (India) Sh. Hemant M Patil, Drugs Inspector Sh. Deepak Nipunge, Drugs Inspector Sh. A. Vijayendra Chary, Drugs Inspector Sh. Ranga Harish, Drugs Inspector Email id: wzmumbai@cdsco.nic.in Landline Nos: +91 22 23002279 / 23002215
		<u>Port offices under West Zone</u> CDSCO JNPT Seaport Panvel Sh. Rajesh Kumar Verma, ADC (I) Email: jnpt.mumbai@cdsco.nic.in Tel: 022-50500161, Fax: 022-50500169 <u>CDSCO Airport Aircargo Mumbai</u> Sh. Pravin A Jagtap, ADC (I) Email: Aircargo.mumbai@cdsco.nic.in Tel: 022-26828185, 26828067 <u>CDSCO Sub-Zone/Port office Goa</u> Sh. Kailash Chand Meena Asstt. Drugs Controller (India) Ph.No.0832-2201001 Email: goasubzone@cdsco.nic.in

Functions of PRO Office:

1. To act as single window for disposal of grievance of stakeholders on regulatory issues.
2. To provide information to the innovator regarding regulatory norms.
3. To guide, assist handhold investors in various phases of business life cycle as per existing focus on "Invest India / Make in India" without compromising quality of regulatory oversight.

Public- Private Partnerships (PPP)

- (i) Details of Special Purpose Vehicle (SPV), if any
- (ii) Detailed project reports (DPRs)
- (iii) Concession agreements.
- (iv) Operation and maintenance manuals
- (v) Other documents generated as part of the implementation of the PPP
- (vi) Information relating to fees, tolls, or the other kinds of revenues that may be collected under authorization from the government
- (vii) Information relating to outputs and outcomes
- (viii) The process of the selection of the private sector party (concessionaire etc.)
- (ix) All payment made under the PPP project

Nil

2.1 Are the details of policies / decisions, which affect public, informed to them [Section 4(1) (c)]

Publish all relevant facts while formulating important policies or announcing decisions which affect public to make the process more interactive;

- (i) Policy decisions/ legislations taken in the previous one year
- (ii) Outline the Public consultation process
- (iii) Outline the arrangement for consultation before formulation of policy

Policy decisions/ legislations is carried out by Directorate
(<https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/>)

Formulation of Policy and Implementation is also carried out by Directorate

Dissemination of information widely and in such form and manner which is easily accessible to the public. [Section 4(3)]

Use of the most effective means of communication

Internet (website): <https://www.cdsco.gov.in/> for information like below:

Sr. No.	Type of Information
1.	Gazette Notifications
2.	Public Notices
3.	Alerts
4.	Bioequivalence & Bioavailability
5.	Blood Products
6.	Vaccines
7.	Global Clinical Trial
8.	Ethics Committee
9.	New Drugs
10.	Fixed Dose Combinations (FDCs)
11.	Investigational New Drugs (INDs)
12.	Subsequent New Drugs
13.	Medical Device and In-Vitro Diagnostics
14.	Cosmetics

15.	Blood Centers
16.	Large Volume Parenterals
17.	Public Relation office
18.	Circulars
19.	Import & Registration

3.4 Form of accessibility of information manual/ handbook

[Section 4(1)(b)]

Information manual/handbook available in

- (i) Electronic format

Sr.No.	Topic	URLs
1.	e-Governance	https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf-documents/SUGAM user manual.pdf

- (ii) Printed format

Available

3.5 Whether information manual handbook available free of cost or not [Section 4(1)(b)]

List of materials available

- (i) Free of cost.

Electronic format can be accessed through website.

- (ii) At a reasonable cost of the medium.

When information required under RTI Act, fees will be charged as per Rule 4 of The Right to Information (Regulation of Fee and Cost) Rules, 2005.

4 E. Governance

4.1 Languages in which Information Manual/Handbook Available [F No. 1/6/2011-IR dt.

15.4.2013] --

English

4.2 When was the information Manual/Handbook last updated?

[F No. 1/6/2011-IR dt 15 4.2013]

Last date of Annual updation.

Updation of Manual is carried out by Directorate.

4.3 Information available in electronic form [Section 4(1)(b)(xiv)]

- (i) Details of information available in electronic form
(ii) Name/ title of the document/record/ other information (iii) Location where available

Refer Para 3.3

4.4 Particulars of facilities available to citizen for obtaining information**[Section 4(1)(b)(xv)]****(i) Name & Location of the facility**

Central Drug Standards Control Organization, West Zone, 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai – 400008.

(ii) Details of information made available

All Information available in the public domain of website (www.cdsc.gov.in) Assistance is provided to access required. Information available in the public domain through digitally, using online system.

(iii) Working hours of the facility

9.30 AM to 6.00 PM (except closed holidays)

(iv) Contact person & contact details (Phone, fax email)

All Information is available in the public domain of website (www.cdsc.gov.in) Assistance is provided to access required. Information available in the public domain through digitally using online system.

wzmumbai@cdsco.nic.in

4.5 Such other information as may be prescribed under section 4(i) (b)(xvii)**i) Grievance redressal mechanism**

Public Relation office and Grievance redressal mechanism is established at Directorate and West Zone. As and when required the Grievance will be addressed accordingly.

Functions of PRO Office:

1. To act as single window for disposal of grievance of stakeholders on regulatory issues.
2. To provide information to the innovator regarding regulatory norms.
3. To guide, assist handhold investors in various phases of business life cycle as per existing focus on "Invest India / Make in India" without compromising quality of regulatory oversight.

(ii) Details of applications received under RTI and information provided

Year	RTI applications received	RTI applications disposed
2021 - 22	18	18
2022 - 23	14	14
2023 - 24	21	21
2024 - 25	12	12
2025 - 26	78	78

(iii) List of completed Schemes/ Projects/ Programmes-

This office has not been assigned any Schemes/ Projects/ Programmes.

(iv) List of schemes/ projects/ programme underway-

This office has not been assigned any Schemes/ Projects/ Programmes.

(v) Details of all contracts entered into including name of the contractor, amount of Contract and period of completion of contract.

Sr. No.	Details of contract	Name & Address of the Contractor	Amount of contract	Period of Completion of contract
1.	Comprehensive Annual Maintenance Contract for the Split (18 Nos.) Air Conditioners Gem Contract No. -511687700384750	M/s. Trade Cool Services, B/201, Sapphire, Diamond Park, Khad Machine Road, Kausa, Mumbra, Thane 612.	@Rs. 167940/- for years which is Rs. 55980/- per yr. incl. GST.	From 30.10.2024 to 29.10.2027
2.	Annual Maintenance Service - Desktops, Laptop, Peripherals - All In One PC; hp 44 (Nos) GEMC-511687713433592	M/s. RK ENTERPRISES 503/1/B,SAI NIWAS CHS NEW MHA COMPLEX,JANKLAYAN NAGAR,MA WEST, Mumbai, MAHARASHTRA-400095, -	Rs.153956 per year incl. GST	From 06-Dec-2025 to 05-Dec-2026
3.	Monthly Basis Cab & Taxi Services - Sedan; 2500 km x 320 hours; Local GEMC-511687724589315	M/s. SAMARTH SUPPLIERS 89 CS AVENUE,ALOTE,ALOTE,ALOT Ratlam, MADHYA PRADESH-457114,	Rs. 717600 per year incl.GST	From 01-Jul-2025 to 30-Jun-2026
4.	Annual Maintenance Service - Photocopier Machine - Photocopier Machines (Monochrome , Laser , Composite Cartridge, Lower range; Canon; Neither OEM nor ASP GEMC-511687784257341	M/s. B. J. AUTOMATION 2ND FLR/OFF NO 37,BHUPAT BHAVAN,VAJU KOTAK MARG,FORT MUMBAI, Maharashtra-400001,	Rs.143781.55 per year incl. GST	From 16-Sep-2024 to 19-Sep-2026
5.	Annual Maintenance Service - Desktops, Laptop, Peripherals - Printer (Monochrome , Laser , Composite Cartridge); hp GEMC-511687796891346	M/s. B. J. AUTOMATION 2ND FLR/OFF NO 37,BHUPAT BHAVAN,VAJU KOTAK MARG,FORT MUMBAI, Maharashtra-400001.	RS. 91950 per year incl. GST	From 21-Apr-2025 to 20-Apr-2026

ii) Annual Report

Annual report of CDSCO is prepared by the Directorate by compiling the information received under monthly Key Performance Indicators (KPI) from all Zonal and Sub-Zonal offices of CDSCO. There is no separate Annual Report for West Zone office.

- iii) Frequently Asked Question (FAQs) are available on CDSCO website i.e., <https://www.cdsc.gov.in/>
- iv) Any other information such as
 - a) Citizen's Charter
 - b) Result Framework Document (RFD)
 - c) Six monthly reports on the Performance against the benchmarks set in the Citizen's Charter
- **Citizen Charter**
: https://cdsc.gov.in/opencms/export/sites/CDSCO_WEB/en/Notifications/Citizen-Charter-CDSCO.pdf

4.6 Receipt & Disposal of RTI applications & appeals [F.No 1/6/2011-IR dt.15.04.2013]

(i) Details of RTI applications received and disposed

Year	RTI applications received	RTI applications disposed
2021 - 22	18	18
2022 - 23	14	14
2023 - 24	21	21
2024 - 25	12	12
2025 - 26	78	78

(ii) Details of RTI appeals received and orders issued

Year	RTI Appeals received	RTI Appeals disposed off.
2021 - 22	02	02
2022 - 23	01	01
2023 - 24	00	00
2024 - 25	01	01
2025 - 26	07	07

4.7 Replies to questions asked in the parliament [Section 4(1)(d)(2)]

Replies to questions asked in the Parliament pertaining to this office are forwarded to Directorate for their compilation.

5. Information as may be prescribed

5.1 Such other information as may be prescribed [F.No. 1/2/2016-IR dt. 17.8.2016, F No. 1/6/2011-IR dt. 15.4.2013]

(a) Name & details of Previous FAAs

Sr.No.	Designation	Technical/ Administration Matters	Year
1.	Dr. K. Bangarurajan Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2015-2017 (Till October 2017)
2.	Sh. R. Chandrasekhar Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2017-2018 (Till Feb 2018)
3.	Dr. P.B.N. Prasad Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2018-2020 (Till June. 2020)
4.	Dr. Rubina Bose Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2020-2021 (Till June. 2021)
5.	Shri. A. Senkathir Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2021- 2023 (Till June. 2023)
6.	Dr. Jayant Kumar Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2023-2025 (Till May 2025)
7.	Dr. Santosh Indraksha Appellate Authority	Deputy Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	2025 Till date.

(b) Name & Details of Previous CPIOs

1.	Sh. Gouri Shankar Central Public Information Officer (CPIO)	Drugs Inspector Email: wzmumbai@dsco.nic.in	2015-2017
2.	Dr. Kamal K Halder Central Public Information Officer (CPIO)	Drugs Inspector (2017) Assistant Drugs Controller (India) (2018-2020) Email: wzmumbai@cdsco.nic.in	2017- 2020 (Till Aug 2020)

3.	Sh. Manish Singhal Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	September 2020- July-2023
4.	Sh. Yogesh Kashinath Shelar Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	July - 2023 to Aug. 2024
5.	Sh. Akash Rama Kondalkar Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: wzmumbai@cdsco.nic.in	Aug. 2024 to till date

(i) Details of Third Party Audit of Voluntary Disclosure

- a) Dates of audit carried out
- b) Report of the audit carried out

The checklist for the Transparency Audit was duly filled and submitted to CDSCO HQ. The Third Party Audit for all the Public Authorities under CDSCO is taken up by CDSCO HQ as communicated vide letter F.No. Z.28020/RTI/Misc-001/2023-DC dtd. 29/08/2023.

Appointment of Nodal Officers not below the rank of Joint Secretary/
Additional HoD

- (a) Date of appointment
- (b) Name & Designation of the officers
Not Applicable

(ii) Consultancy committee of key stake holders for advice on suo-motu disclosure

- (a) Dates from which constituted
- (b) Name & Designation of the officers
No such consultancy committee was constituted so far.

(iii) Committee of PIOs/FAAs with rich experience in RTI to identify frequently sought information under RTI

- (a) Dates from which constituted
- (b) Name & Designation of the Officers
No such consultancy committee was constituted so far.

6. Information Disclosed on own Initiative - Item/information disclosed, so that public have minimum resort to use of RTI Act to obtain information

Sr. No.	Type of Information	Related URLs
1.	Gazette Notifications	https://www.cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/
2.	Public Notices	https://www.cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/

3.	Bioequivalence and Bioavailability	https://www.cdsc.gov.in/opencms/opencms/en/bioequi_bioavail/
4.	Blood Products	https://www.cdsc.gov.in/opencms/opencms/en/biologicals/Blood-Products/
5.	Vaccines	https://www.cdsc.gov.in/opencms/opencms/en/biologicals/Vaccines/
6.	Global Clinical Trial	https://www.cdsc.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/
7.	Ethics Committee	https://www.cdsc.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/
8.	New Drugs	https://www.cdsc.gov.in/opencms/opencms/en/Drugs/New-Drugs/
9.	Fixed Dose Combinations (FDCs)	https://www.cdsc.gov.in/opencms/opencms/en/Drugs/FDC/
10.	Investigational New Drugs (INDs)	https://www.cdsc.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/
11.	Subsequent New Drugs	https://www.cdsc.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/
12.	Medical Device and Diagnostics	https://www.cdsc.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Invitro-Diagnostics/
13.	Cosmetics	https://www.cdsc.gov.in/opencms/opencms/en/Cosmetics/cosmetics/

6.2 Guidelines for Indian Government Websites (GIGW) is followed (released in February, 2009 and included in the Central Secretariat Manual of Office Procedures (CSMOP) by Department of Administrative Reforms and Public Grievances, Ministry of Personnel, Public Grievance and Pensions, Govt. of India)

(i) Whether STQC certification obtained and its validity.

(ii) Does the website show the certificate on the Website?

Website of CDSCO (www.cdsc.gov.in) is Designed, Developed and Maintained by CDAC as per requirement provided by CDSCO (HQ), New Delhi.

