SUO MOTO DISCLOSURE UNDER SECTION 4 OF RTI ACT 2005

(CDSCO, Ahmedabad Zone)

Organization and Function

1.1 Particulars of its organization, functions and duties [Section 4(1)(b)(i)]

Name and address of the Organization

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)

AHMEDABAD ZONE

Office of Deputy Drugs Controller (I), Central Drugs Standard Control Organization, 2nd Floor, Air Cargo Complex, Old Airport Building, Bhargav Road, Near Rameshwar Char Rasta, Meghaninagar, Ahmedabad - 380016, Gujarat .

ahmedabad[at]cdsco[dot]nic[dot]in, ahd[dot]airport[at]cdsco[dot]nic[dot]in, hzr[dot]seaport[at]cdsco[dot]nic[dot]in

https://cdsco.gov.in/ (Website Designed, Developed and Maintained by CDAC as perrequirements provided by CDSCO (HQ), New Delhi)

Head of the Organization

Deputy Drugs Controller (India)

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 qualityof drugs, cosmetics and medical devices.

Function and duties

Technical:

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

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.

To participate in the joint-inspection for grant/retention of Vaccine / Sera manufacturing units for both human as well as veterinary.

To participate in the joint-inspection for grant/ retention of LVP manufacturing units.

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).

To participate in the joint-inspection for issuance /revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO-GMP Certification Scheme.

To process application for Written Confirmation (WC) for export of API to European Union as per EU Directives and their inspection, if required.

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.

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.

To carry out Surprise check/Raids jointly or independently on the basis of complaint received under Whistle Blower scheme and also from other sources.

Drawing of legal samples of Drugs from the manufacturing & sales / distribution premises including the Govt. establishment.

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.

To pursue the court cases pending in different courts under the zone.

Technical survey as and when directed by the Drugs Controller General (India) from time to time.

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.

To co-ordinate for answering the Parliament Questions and for obtaining the data from various State Licensing Authorities under the zone.

Reply of RTI applications under RTI Act, 2005.

To participate as observer in inspections conducted by various international regulatory agencies as and when informed by HQ.

To organize workshop, seminar etc. as directed by the Controlling Authority.

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: -

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 on Form-29 as per requirements.

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

No objection certificates (Dual use NOC) for grant of permissions for import of dual use items, not for medicinal use.

No objection certificates (Export NOC) for grant of permissions for export of new drug, Narcotics Drugs & unapproved drugs.

Any other functions as assigned by DCG (I)/ JDC (I)

A. Administrative:

To purchase stationeries and office items as per the requirements.

Annual Maintenance Contract (AMC) of office equipment etc.

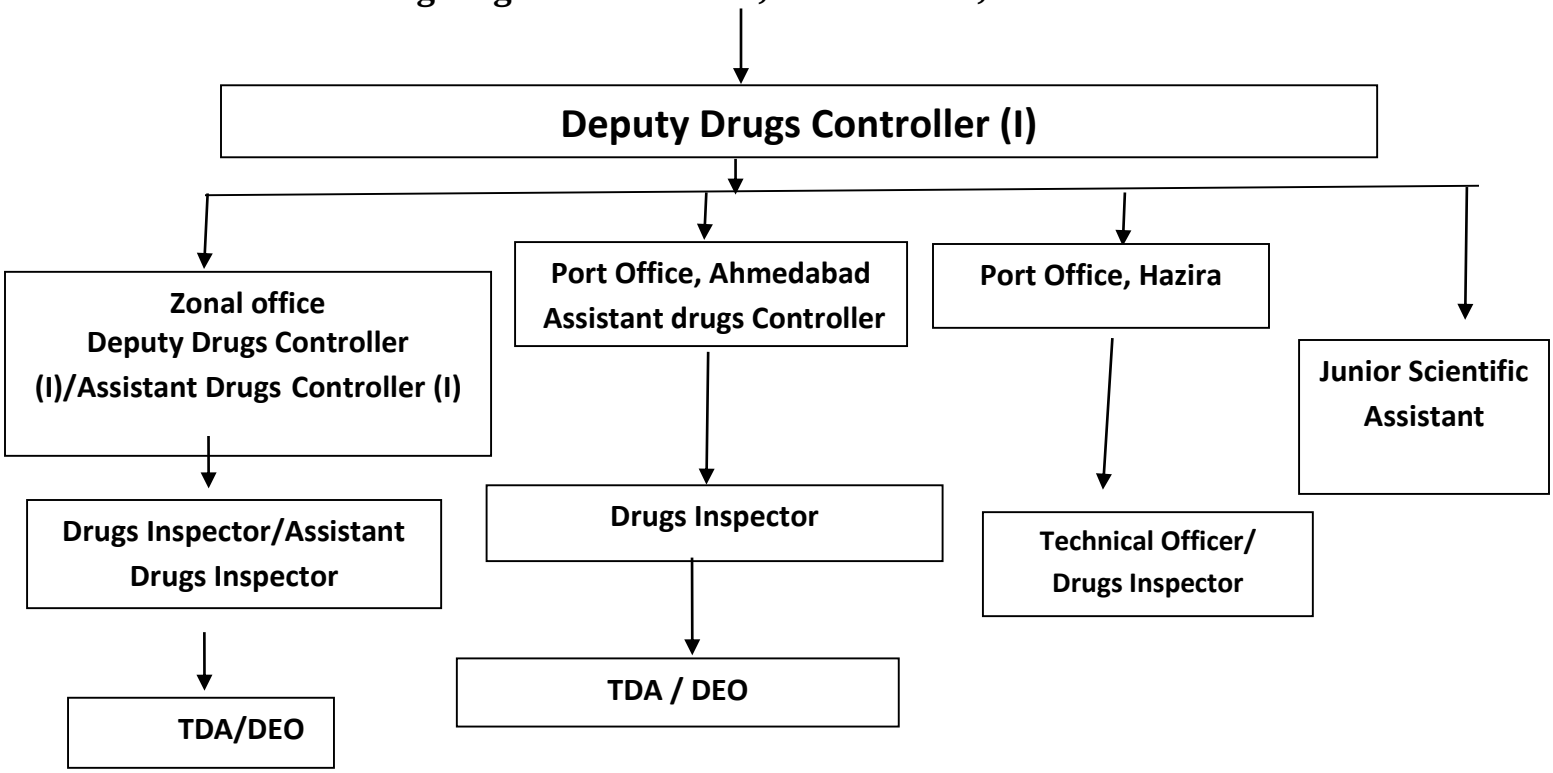
Reply of RTI applications under RTI Act, 2005.

Any other functions assigned by JDC (I)/ DCG (I) from time to time.

(v) Organization Chart:

Table No.1

Organogram of CDSCO, Zonal Office, Ahmedabad



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.

Initially the Ahmedabad Zonal office was comes under jurisdiction of Central Drugs Standard Control Organization (CDSCO), West Zone, Mumbai headed by Deputy Drugs Controller (India) situated at Abubakar Mansion, Colaba, Mumbai 400001 in the year July 1967.

A new Sub-Zonal office & Airport 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 Subzonal office was upgraded to Zonal level from 11th July 2011. Deputy Drugs Controller (India) is the head of office at CDSCO Zonal office, Ahmedabad to co-ordinate with the Gujarat 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 thereunder.

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	1. To function as licensing authority for the State of Gujarat for the activities assigned by the CDSCO, Head Quarters. 2. To function as licensing authority for the State of Gujarat for functions such as grant of NOCs for dual use, Export NOCs, permission to import/ manufacture new drugs for test & analysis purpose in Form CT-11, Form CT-14, Form CT-15, Form CT-17 etc at SUGAM and NSWS portal. 3. To function as Deputy Decision Authority for the online application pertaining to Medical Device, Written Confirmation Certificate and Registration of BA-BE Centre/CRO. 4. To coordinate with the State Licensing Authority (SLA), Gujarat for functions and information as required by the CDSCO, HQ from time to time. 5. To assign and approve job responsibilities to Assistant Drugs Controller (I), Drugs Inspector, Technical officer, Assistant Drugs Inspector or other staff as the case be. 6. To look after the administrative work of the office and to coordinate with the Deputy Drugs Controller (1) West Zone in budgetary issues. 7. To approve procedures for operation of assigned activities in respect of import, export, sampling, inspections etc. 8. To issues instructions or orders for various activities assigned to the officers and staff in respect of the inspection of BA/BE centres, Clinical Trial Sites, and ECs for verification of GCP compliance. 9. To monitor that the SOPs issued by the CDSCO HQ in respect of vaccine facilities and National Regulatory Authority assessment by WHO are complied.

	10. To issue necessary orders for joint inspection for Grant/renewal of Blood Centres, Vaccine & Bio-tech. and notified Medical Devices & Diagnostics, Certificate of Pharmaceutical Products (COPP) as per WHO-GMP Certificate Scheme, Public Testing Laboratory and to forward such inspection report to the officers of SLA. 11. To monitor import and export work of Assistant Drugs Controller (I)/Technical Officer in respect of clearance of Bill of Entry for import and shipping bills for export at port office time to time. 12. To review sampling by the officers and forward the NSQ cases to the Drugs Controller General India for sanction of prosecution by the Drugs Inspector. 13. To issue instructions to officers to participate in the inspections/investigations conducted by international regulatory body like USFDA, MHRA, ANVISA, Tanzania etc. as desired by the CDSCO HQ. 14. Acting as First Appellate Authority for RTI. 15. Parliament Questions related matters. 16. To organise in-house training or workshops for the officers and staff and to participate in various meetings in nationally or internationally as the case be. 17. To perform any other work assigned by the Drugs Controller General (India) from time to time.
Assistant Drugs Controller (India)	1. Responsible for coordination and compliance with the directions 2. of the Dy. Drugs Controller (India), CDSCO, Ahmedabad Zone for carrying out regulatory inspections (Certificate of Pharmaceutical Products, Blood Banks, Blood Products, Vaccines Sera, rDNA, Large Volume Parenteral) Inspections, Complaints, Raids/Investigations as directed by Dy. Drugs Controller (India), CDSCO, Ahmedabad Zone

	3. 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 Ahmedabad Zone. 4. Coordination with Zonal Offices / State Licensing Authorities /Ports and Other Authorities as and when directed by the DDC (I) CDSCO Ahmedabad Zone. 5. Processing of On-line Medical Device applications through SUGAM PORTAL as a Nodal officer / Medical Device Officer and Reviewing Officer. 6. Processing of On-line Test License applications through NSWS as Nodal Officer. 7. Processing of On-line Dual Use/Export NOCs applications through SUGAM as Nodal Officer. 8. Acting as a Central Public Information Officer for RTI applications. 9. Responsible for coordinating and compliance with the directions of the Dy. Drugs Controller (India), CDSCO Ahmedabad Zone for carrying out regulatory inspections (COPPs, CLAA Inspections and Complaints, Raids/Investigations) as directed by DDC (I) Ahmedabad Zone. 10. Deputation of Drugs Inspector for carrying out joint inspections, complaints investigations, sampling etc. in absence & as and when directed by the DDC (I) CDSCO Ahmedabad Zone. 11. Handling queries from the applicants as a Public Relation Officer and as a Nodal Officer for resolving grievances received from general public.
Drugs Inspector/ **Medical Device** **Officer**	1. To carry out joint inspection of Blood Centre, Vaccine & bio tech, and notified Medical Devices & Critical Diagnostics manufacturing units for grant/renewal of Licenses under CLAA Scheme. 2. To carry out joint inspection of Drug Mfg. Units for grant/issuance of Certificate of Pharmaceutical Products (COPP) as per WHO-GMP Certificate Scheme. 3. To carry out inspection of BA/BE centers, Clinical Trial Site for verification GCP compliance /grant of permission by the office of DCG(I).

	4. To carry out post-import checks as per instructed by Dy. Drugs Controller of India, CDSCO, Ahmedabad. **5.** To participate in the joint inspection for grant/renewal of license for Public Testing Laboratory. 6. Online scrutiny and processing of application for grant/addition WC certificate for applied APIs under EU norms. 7. Online scrutiny and processing of application for grant/addition Medical Devices and Diagnostic kits as per Medical Device Rules 2017. 8. Processing of application for grant additional Product in existing Certificate of Pharmaceutical Products (COPP) as per WHO-GMP Certificate Scheme. 9. To participate in the inspections/investigations conducted by the international regulatory body like, USFDA, MHRA, ANVISA, Tanzania etc. 10. Drawing of regular drugs & cosmetics samples from the manufacturing & sales/ distribution premises. 11. Processing of NSQ reports including recall of NSQ, drug procurement chain establishment, finding reason of failure & violation of drugs & cosmetics act & rules there under etc. and initiating of action (If any) like filing of court case after obtaining permission from DCG(I). 12. Preparation of reply of RTI and Parliament Questions related matters. 13. To attend various training & seminar to upgrade the knowledge. 14. To clearance of Import/Export consignment at port office Ahmadabad. 15. Any other work assigned by the DDC(I)/ADC(I) & DCG(I) time to time.

Assistant Drugs Inspector	1. To assist in evaluation of Safety, Efficacy and Quality of Drugs as per requirement of Drugs and Cosmetics Rules, 1945. 2. To assist CDSCO officers in the matter of monitoring documentation. 3. Details required in respect of RTI and Parliament Questions are submitted to DDC. 4. Scrutiny of online Dual Use NOC through SUGAM Portal & NSWS Portal i.e.Test License applications in Form-12, Form CT-10, Form CT-12, Form CT-13 and Form CT-16 applications on NSWS. 5. Data pertaining to the Risk based inspections conducted for manufacturing facilities and testing laboratories, followed by their compliance check verification and action taken by the State Licensing Authority. 6. Data pertaining to the inspections carried out for manufacturing facilities under PG Drive (Propylene Glycol drive) and their respective drug samples drawn and its test results. 7. Data with respect to legal samples of drugs & cosmetics drawn by the Drugs Inspectors and its test results. 8. Checking and monitoring and Maintenance, updation and retrieval of data pertaining to all entries of receipts/Daks and their processing. 9. Any other work assigned by the DDC (I)/ ADC(I).
Technical Data Associate	1. To assist CDSCO officers for technical matters 2. Documentation/record managemnet. 3. Prescreening and scrutiny of online Dual Use NOC through SUGAM Portal/NSWS 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).
Multi Tasking Staff	1. 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 other.

	2. To attend the personal needs of Head of office. 3. In addition to the auxiliary support, have to do basic clerical work, 4. Whenever there is a need.
Data Entry Operator	Typing of letters related to technical as directed by Seniors. Digital Signing of online applications of NOCs, Sending emails, Scanning reports and hyperlink to respective statements, Maintaining data of inspection reports in the respective registers and computer, Work assigned by 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 Ru Inspectors derive their powers from Drugs & Cosmetics Act, 1940 (Section 21, 22 and 23) and Rules made there Cosmetics Rules, 1945) and Medical Device Officer (Medical Device Rules, 2017) and subsequent office orders Directorate. Powers and duties of other posts are derived and exercised as per the practice in vogue. Copy of Dru 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)]

Process of decision making Identify key decision making points

Final decision making authority

Related provisions, acts, rules etc.

Time limit for taking a decisions, if any Channel of supervision and accountability

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

1.2 Norms for discharge of functions

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

Nature of functions/ services offered

Norms/ standards for functions/ service delivery

Process by which these services can be accessed

Time-limit for achieving the targets

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 PORTAL, NSWS

(www.cdscoonline.gov.in and **www.cdscomdonline.gov.in** & https://www.nsws.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)(

Title and nature of the record/ manual /instruction.

List of Rules, regulations, instructions manuals and records

Acts/ Rules manuals etc.

Transfer policy and transfer orders

The Drugs and Cosmetics Act, 1940 and Rules made there under (Drugs and Cosmetics Rules, 1945, Medical Dev and New Drugs and Clinical Trials, 2019, Cosmetics Rules 2020, Guidance document for Zonal, Sub-zonal & Po subsequent office orders issued by Directorate are followed by this office for discharging functions. Further, Mar Procedure and Sugam Portal and NSWS User Manual in electronic format are also followed.

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:

Manual of Office Procedure

Drugs and Cosmetics Act, 1940

Drugs and Cosmetics Rules, 1945

CDSCO Guidance Document 2011

Medical Device Rules, 2017

New Drugs and Clinical Trials, 2019

Cosmetic Rules, 2020

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/downloa

Boards, Councils, Committees and other Bodies constituted as part of the Public Authority [Section 4(1)(b)(viii)]

Name of Boards, Council, Committee etc.

Composition

Dates from which constituted (iv)Term/ Tenure

Powers and functions

Whether their meetings are open to the public?

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

Various Boards and Committees are constituted by the Directorate and information is available on CDSCO webs

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

Name and designation: **Dr. Ravi Kant Sharma**, Deputy Drugs Controller (India)

Telephone and email ID :

Tel: 079-22850706 / 22850707/ 29700619

Email id : ahmedabad@cdsco.nic.in

CONTACT DETAILS OF CDSCO Ahmedabad

Refer organization website https://cdsco.gov.in/opencms/opencms/en/Zonal-office/

1.9 Monthly Remuneration received by officers & employees including system of compensation (x)]

List of employees with Gross monthly remuneration

System of compensation as provided in its regulations

O/o. THE DEPUTY DRUGS CONTROLLER (INDIA) CDSCO (Ahmedabad)		
Salary details of various posts with Pay Band and Pay Level for CDSCO, West Zone, Mumbai, Ahmedabad Zone, Sub Zone-Indore, Sub-Zone-Goa		
1	Dy. Drugs Controller (India)	Pay Band 15600-39100 (GP-7600) & Level 12
2	Asstt. Drugs Controller (India)	Pay Band 15600-39100 (GP-6600) & Level 11
3	Drugs Inspector	Pay Band 9300-34800 (GP-4800) & Level 8
4	Asstt. Drugs Inspector	

		Pay Band 9300-34800 (GP-4200) & Level 6
5	Junior Scientific Assistant	Pay Band 9300-34800 (GP-4600) & Level 7

1.10 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	Appellate Authority	Deputy Drugs Controller (India) CDSCO Ahmedabad Zone Email: ahmedabad@cdsco.nic.in
2	Central Public Information Officer (CPIO)	Assistant Drugs Controller (India) Email: ahmedabad@cdsco.nic.in

No. of employees against whom disciplinary action has been taken: disciplinary action action taken by CDSCO (HQ)

1.12 Programmes to advance understanding of RTI (Section 26)

- Educational programmes- The department encourages public authority by granting necessary permissions whenever necessary to participate in the training programmes of RTI. However, not yet attended.

- 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.

Training of CPIO/APIO

List of Training Programmes attended by the CPIO are as follows:- Nil

Update & publish guidelines on RTI by the Public Authorities concerned

A guidance document related to RTI is published in 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).

Transfer policy is available on CDSCO website

Budget and Programme

Budget allocated to each agency including all plans, proposed expenditure and reports on disbursements made etc is maintained by the CDSCO WZ Mumbai. Please refer soumoto disclosure of the CDSCO WZ Mumbai for the same

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

2.2 Manner of execution of subsidy programme

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

Name of the programme of activity

Objective of the programme

Procedure to avail benefits

Duration of the programme/ scheme

Physical and financial targets of the programme

Nature/ scale of subsidy /amount allotted

Eligibility criteria for grant of subsidy

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]

Discretionary and non-discretionary grants/ allocations to State Govt./ NGOs/other institutions

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)]

Concessions, permits or authorizations granted by public authority

For each concessions, permit or authorization granted

Eligibility criteria Procedure for getting the concession/ grant and/ or permits of authorizations

Name and address of the recipients given concessions/ permits or authorizations

Date of award of concessions /permits of authorizations.

Nil

2.6 CAG & PAC paras [F No. 1/6/2011- IR Date. 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

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 there of

[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

Relevant Acts, Rules, Forms and other documents which are normally accessed by citizens at CDSCO website i.e., https://www.cdsco.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

Arrangements for consultation with or representation by

Members of the public in policy formulation/ policy implementation Formulation of Policy and Implementation is carried out by Directorate

Day & time allotted for visitors

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 division. The contact details are available on CDSCO website,

Functions of PRO Office:

To act as single window for disposal of grievance of stakeholders on regulatory issues.

To provide information to the innovator regarding regulatory norms.

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)

Details of Special Purpose Vehicle (SPV), if any

Detailed project reports (DPRs)

Concession agreements.

Operation and maintenance manuals

Other documents generated as part of the implementation of the PPP

Information relating to fees, tolls, or the other kinds of revenues that may be collected under authorisation from the government

Information relating to outputs and outcomes

The process of the selection of the private sector party (concessionaire etc.)

All payment made under the PPP project

Nil

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;

Policy decisions/ legislations taken in the previous one year

Outline the Public consultation process

Outline the arrangement forconsultation 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

Form of accessibility of information manual/ handbook

[Section 4(1)(b)]

Information manual/handbook available in

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) Printedformxt Available

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

List of materials available

Free of cost

Electronic format can be accessed through website.

At a reasonable cost of the medium

When information required under RTI Act, fees wi1 be charged as per Rule 4 of The Right to Information (Regulation of Fee and Cost) Rules, 2005 .

E. Governance

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

Information available in electronic form

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

Details of information available in electronic form

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)]

Name & location of the facility

Office of Deputy Drugs Controller (I), Central Drugs Standard Control Organization, 2nd Floor, Air Cargo Complex, Old Airport Building, Bhargav Road, Near Rameshwar Char Rasta, Meghaninagar, Ahmedabad - 380016, Gujarat .

Details of information made available

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

Working hours of the facility

9.30 AM to 6.00 PM [Monday to Friday except closed holidays]
10:00 AM to 5:30 PM [Monday to Saturday except closed holidays]

Contact person & contact details (Phone, fax email)

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

ahmedabad@cdsco.nic.in

Such other information as may be prescribed under section 4(i) (b)(xvii)

Grievance redressal mechanism

Public Relation office and Grievance redressed mechanism is established at Directorate level.

Functions of PRO Office:

To act as single window for disposal of grievance of stakeholders on regulatory issues.

To provide information to the innovator regarding regulatory norms.

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.

List of completed schemes/ projects/ Programmes-

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

List of schemes/ projects/ programme underway-

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

Details of all contracts entered into including name of the contractor, amount 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.	Vehicle for operational use of office through GeM (01 Vehicle)	M/s. Krish Car Rental LLP, SUR 2649 0226 05 1431 0001 G,GAMTAL, OPP. GRAM,SARDARNAGAR,SARDAR	@Rs. 40700/- p.m. incl. GST	From 16/05/2024 to 15/05/2025

	GeM Contract No: GEMC-511687771777165	NAGAR, Ahmedabad, GUJARAT-382475		
2.	Vehicle for operational use of office through GeM (01 Vehicle) GeM Contract No: GEMC-511687771777165	M/s. Krish Car Rental LLP, SUR 2649 0226 05 1431 0001 G,GAMTAL, OPP. GRAM,SARDARNAGAR,SARDAR NAGAR, Ahmedabad, GUJARAT-382475	@Rs. 40700/- p.m. incl. GST	From 16/05/2024 to 15/05/2025
3.	Comprehensive Annual Maintenance Contract for the Split (20 Nos) Air Conditioners Gem Contract No. -511687752466983	M/s. Panshul Multitrade Private Limited, F.F/4/B, Manibhadra Complex, Opposite Rajasthan Hospital, Camp Road, Ahmedabad, Gujarat-380004	@Rs. 86000/- per yr. incl. GST	Under AMC through GeM Contract No. 511687752466983 One Year from 29.07.2024 to 28.07.2025
4.	AMC for Desktop Computers, Laptops & Peripherals 70 nos	M/s. Ark Infosolution, 10, Subhash Park, Behind Chief Justice Bunglow, Bodekdev, Ahmedebad, Gujarat-380054	@Rs. 73701.37/- per year incl. GST	Under AMC through GeM Contract No. 511687740621623

	Gem Contract No. 511687740621623			One Year from 23.01.2024 to 22.01.2025
5.	AMC for Konica Minolta Photocopier Machines (03 nos) Gem Contract No. 511687740174785	M/s, Precious Business Systems, 201, Sunrise Avenue, Stadium Circle to Commerce Road, Navrangpura, Ahmedabad, Gujarat-380009	@ Rs. 40310/- per Year incl. GST	Under AMC through GeM Contract No. 511687740174785 One Year from 25.10.2023 to 24.10.2024
6.	AMC for CCTV Camera (01 No) Gem Contract No. 511687705403496	M/s, Gen X Technologies, B-15, Om Shivam Society, Jivraj Park, Ahmedabad, Gujarat-380051	@Rs. 35820/- per Year incl. GST	Under AMC through GeM Contract No. 511687705403496 One Year from 01.08.2023 to 03.08.2024
7.	AMC for EPABX System (01 No) Gem Contract No. 511687737441334	M/s. Panshul Multitrade Private Limited, F.F/4/B, Manibhadra Complex, Opposite Rajasthan Hospital, Camp Road, Ahmedabad, Gujarat-380004	@Rs. 43235.62/- per Year incl. GST	Under AMC through GeM Contract No. 511687737441334 One Year from 18.01.2024 to 18.01.2025

8.	Video Conferencing Services (WEBEX) (01 No) Gem Contract No. 511687741117395	M/s, Web Touch It Solutions, Flat No. 201, Plot No. 399, 399A & 400, Vindhya Nest Apartment, Lake View Colony, Pragati Nagar, Opposite JNTU, Hyderabad, Telangana-500090	@Rs. 24554/- per Year incl. GST	Under AMC through GeM Contract No. 5116877411173 95 One Year from 28.05.2024 to 27.05.2025

ii) Annual Report

Annual report of CDSCO is prepared by Directorate by compiling the information received under monthly KPIs from all Zonal and Sub-Zonal offices of CDSCO. There is no separate Annual Report for Ahmedabad office.

Frequently Asked Question (FAQs) are available on CDSCO website i.e., https://www.cdsco.gov.in/

Sr. No.	Topic	URLs
1.	New Drugs	https://cdsco.gov.in/opencms/opencms/s stem/modules/CDS CO.WEB/elements/download file division.1s ?num id=ND MOMA= Additional FAQs:

		https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download file division.jsp?num id=NDg1Ng= https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download file division.jsp?num id=NTU4OA-
2.	Medical Devices	https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf -documents/medical-device/Updated-FAQ-MDR 2017.pdf
3.	Phyto pharmaceuticals	https://cdsco.gov.in/opencms/opencms/system/modules/CDS CO.WEB/elements/download file division.jsp?num id=MzI0MA=—
4.	Import of small quantities of drugs for the purposes of examination testing or analysis	https://cdsco.gov.in/opencms/opencms/en/FAO/index.html
5.	Blood Bank	https://cdsco.gov.in/opencms/opencms/en/FAO/index.html
6.	Cosmetics	https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf -documents/cosmetics/FAQcos.pdf
7.	BA/BE	https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf -documents/BA BE/revidsefaqbabe df

8.	Import & Registration	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/import-registration/Import_guidance_doc.pdf

Any other information such as

Citizen's Charter

Result Framework Document (RFD)

Six monthly reports on the Performance against the benchmarks set in the Citizen's Charter

Citizen Charter
:https://cdsco.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 t.15.04.2013]

4.7 Details of applications received and **disposed**

S.No	Year	RTI applications received	RTI applications disposed
1.	2019 - 20	45	45
2.	2020 - 21	34	34
3.	2021 - 22	37	37
4.	2022 - 23	16	16
5.	2023 - 24	17	27

Details of appeals received and orders issued

S.No	Year	RTI applications received	RTI applications disposed
1.	2019 - 20	01	01
2.	2020 - 21	00	00
3.	2021 - 22	00	00
4.	2022 - 23	00	00
5.	2023 - 24	00	00

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

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

5. Information as may be prescribed

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]

Name & details of CPIOs & FAAs Since 2015

Sr. No.	Year	Name of the Officer	Designation	Telephone No	Email ID
1.	2015-2020	Mr. Arvind Kukrety	Deputy Drugs Controller (I) **First Appellate Authority**	079-22850706, 079-22850707 & 079-29700619	arvindkukrety@cdsco.nic.in
2.	2020-2023	Mr. Jayant Kumar	Deputy Drugs Controller (I) **First Appellate Authority**	079-22850706, 079-22850707 & 079-29700619	jayant@cdsco.nic.in

3.	2023	Dr. Ravi Kant Sharma	Deputy Drugs Controller (I) **First Appellate Authority**	079-22850706, 079-22850707 & 079-29700619	rk.sharma66@nic.in
4.	2018-2021	Manish Neekhra	Drugs Inspector **Central Public Information Officer**	079-22850706, 079-22850707 & 079-29700619	manish.neekhra@cdsco.nic.in
5.	2021-2022	Mr. Shashi Paul	Drugs Inspector **Central Public Information Officer**	079-22850706, 079-22850707 & 079-29700619	shashi.paul@cdsco.nic.in
6.	2022-2024	Sh. Satyanarayan Saini	Assistant Drugs Controller (I) **Central Public Information Officer**	079-22850706, 079-22850707 & 079-29700619	sainisn@cdsco.nic.in

7.	2024	Sh. Manish Singhal	Assistant Drugs Controller (I) **Central Public Information Officer**	079-22850706, 079-22850707 & 079-29700619	manishsinghal@cdsco.nic.in

Details of third party audit of voluntary disclosure

Dates of audit carried out in Year 2022

Report of the audit carried out in Year 2022

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

Date of appointment

Name & Designation of the officers

Not Applicable

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

Dates from which constituted

Name & Designation of the officers

No such consultancy committee was constituted so far.

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

Dates from which constituted

Name & Designation of the Officers

No such consultancy committee was constituted so far.

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://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/
2.	Public Notices	https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/
3.	Bioequivalence and Bioavailability	https://cdsco.gov.in/opencms/opencms/en/bioequi bioavail/ index.html
4.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/bio1ogica1s/Blood-Products/
5.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/bio1ogica1s/Vaccines/
6.	Global Clinical Trial	https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/
7.	Ethics Committee	https://cdsco.gov.in/opencms/opencms/en/Clinical- Trial/Ethics-Committee/
8.	New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/
9.	Fixed Dose Combinations (FDCs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
10.	Investigational New Drugs (INDs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/
11.	Subsequent New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequen t-New-Drugs/
12.	Medical Device and In-Vitro Diagnostics	https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/
13.	Cosmetics	https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosme tics/

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)

Whether STQC certification obtained and its validity.

Does the website show the certificate on the Website?

Website of CDSCO (www.cdsco.gov.in) is Designed, Developed and Maintained by CDAC as per request provider by CDSCO (HQ), New Delhi