SUO MOTTO DISCLOSURE UNDER SECTION 4 OF RTI ACT, 2005

(CDSCO, SUB-ZONE JAMMU)

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

Name:-CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, SUB-ZONE, JAMMU.

Address:-O/o ADC(I), Central Drugs Standard Control Organization, Sub-Zone, Jammu, IIIM Campus Canal Road, Jammu (J&K)-180001.

0191-2584443

jammusubzone@cdsco.nic.in

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

(ii) Head of the organization

Ms. Minakshi Vashistha,

Assistant Drugs Controller (India),

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

(iii) Vision, Mission and Key objectives Vision:

Vision:

To Protect and Promote public health in India.

Mission:

To safe guard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

https://cdsco.gov.in/opencms/opencms/en/About-us/Vision/

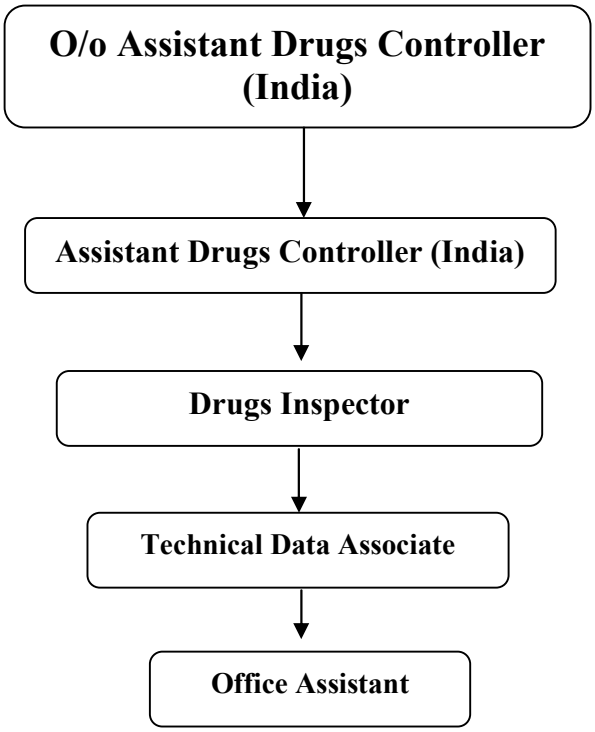
(iv) Function and duties

1. To participate in the joint inspection for issuance / revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO certification scheme after receiving the application from the manufacturing firm.
2. To participate in the joint inspection for grant/renewal of Blood Centre license.
3. To participate in the joint inspection for grant/renewal of license for Vaccine / Sera manufacturing units for both human as well as veterinary.
4. To participate in the joint inspection for grant/renewal of license for LVP manufacturing units.
5. To conduct inspection for grant of license for Class C and Class D notified Medical Devices & In vitro diagnostics.

6. To participate in the joint inspection for grant/renewal of license for Bio-Tech & Bio- similar products manufacturing units.
7. 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.
8. To carry out Surprise check/Raid jointly/independently on the basis of complaint received under Whistle Blower scheme and also from other sources.
9. To carry out joint inspection of Drug Testing Laboratory for the purpose of grant of approval for test / analysis of Drugs & Cosmetics.
10. To follow up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other zonal offices.
11. Drawing of Legal and Survey samples of drugs, cosmetics and medical devices from the manufacturing & sales / distribution premises including the Govt. establishment.
12. When the samples drawn by the Central Drugs Inspector are declared spurious / adulterated / grossly sub-standard etc., the cases are investigated and prosecution are launched in the appropriate court after obtaining necessary sanction from the Drugs Controller General (India).
13. Information regarding cancellation/suspension of manufacture licenses or withdrawal of product permission by the State Licensing Authority is circulated to other State Licensing Authorities in the zone and other zonal offices.
14. To pursue the court cases pending in different courts under the sub-zone.
15. Technical survey as and when directed by the Drugs Controller General (India) from time to time.
16. To discuss the matter with various State Drugs Controllers in the sub-zone in connection with enforcement of the provisions of D&C Act & Rules there under from time to time.
17. To co-ordinate for answering the Parliament Questions and for obtaining the data from various State Licensing Authorities under the zone.
18. Preparation of Monthly/Quarterly/Annual Reports.
19. To participate in the joint inspection with respect to grant of permission in Form CT-11/CT-14/CT-15 as per requirements.
20. To participate as observers in international regulatory agencies inspections as and when directed by Directorate.
21. To organize workshop, seminar etc. as directed.
22. To conduct the function of Drugs Controller General (I) as delegated by him under rule 22 (b) & 122L and other rules of the Drugs & Cosmetics Act. Presently (w.e.f. 20.06.2011), the following functions are delegated to respective zonal officers for carrying out on his behalf: -
    a. Grant of Permission in FormCT-11/CT-14&CT15 to manufacture drugs for the purpose of examination, test or analysis.
    b. Grant of Import Permission, Form11&CT-17 for test, analysis and examination under the Drugs and Cosmetics Rules.
23. Any other functions as assigned by DCG(I)/DDC(I).

(v) Organization Chart:

TableNo.1



(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), Sub-Zone, Jammu, was started in December 2010, in the O/o State Drugs Controller, Patoli Mangotrian, Jammu, headed by Assistant Drugs Controller (India) with having one room with staff only one ADCI and one DI. Further, In January 2012 the office was shifted in the premises of the O/o State Deputy Drugs Controller, Muthi, Jammu, J&K, with provided office space (300sq ft approx.) to CDSCO Sub Zonal office, Jammu.

Further, the office of CDSCO sub zone Jammu, shifted in the year 2015 to IIIM Campus, Canal Road, Jammu with providing two rooms- one small room and one big hall. The Sub-Zonal office of the CDSCO was created to co-coordinate 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 D&C Act and Rules. The Sub-Zone Jammu had jurisdiction over the states of UT-Jammu & Kashmir and UT-Leh Ladakh. And Sub-Zone Jammu office comes under the jurisdiction of CDSCO Baddi Zone.

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

TableNo.2

Designation	Duties
Assistant Drugs Controller	1. As a sub-zonal Department head, ensure uniform implementation of Drugs and Cosmetics Act and Rules in coordination with State Drugs Licensing Authorities of UT-Jammu & Kashmir and UT-Leh-Ladakh. 2. Monitoring the activities of Drugs Inspectors under the sub-zone and forward the recommendation letter to the concerned SLAs. 3. Issuing of Permissions for CT Applications/License for import under Form11&CT-17for test, analysis and examination. 4. Handling of General Court cases. 5. Preparation of monthly/quarterly/annual report. 6. Apart from the above mentioned technical duties, performing as a Head of Office as well as drawing and disbursing officer from the administrative and account side. Attending the meeting with stake holders and Drugs Consultative meeting at CDSCO, HQ, New Delhi. 7. First Appellate authority for RTI Questions for the O/o Deputy Drugs Controller (India),CDSCO, Zonal Office Baddi, H.P., and CPIO for RTI Question for the- O/o Assistant Drugs Controller (India), CDSCO, Sub-Zone Jammu, (J&K) 8.Handling various Administrative function related to office activities and employees and coordinate for the same to CDSCO, North Zone Ghaziabad.

	9. Shall file the reply against the writ petition filed against the Department in the jurisdiction of Jammu. 10. Organize the training and coordinate with the office staff related issues on need basis. 11. Review and verification of the inspection report submitted by Drugs Inspector and Guidance to the Drugs Inspector in technical as well as on legal matters. 12. Implementation of Act, Rules and Guidelines as mentioned. 13. Collection of information regarding manufacture, sale and distribution of spurious, not of standard quality drugs, habit forming drugs through co-ordination with State Licensing Authority, Watchers/ informers and ensuring the action against the culprits. 17 Reply/ follow up the parliament questions asked by Head Quarter, New Delhi. 18. Attend the DCC meeting and any other meeting organized by O/o Drugs Controller General (India). 21. To follow up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other zonal offices. 22. Information regarding cancellation/suspension of manufacture licenses or withdrawal of product permission by the State Licensing Authority is circulated to other State Licensing Authorities in the zone and other zonal offices. 23. Handling of various online portal Such as: E- Parichay, ONDLS, NSWS so on and delegated to concerned officers/ staff. 24. To co-ordinate with various international regulatory agencies for inspections conducted by various international regulatory agencies as and when directed. 25. Any other duties/functions as assigned by DDC(I), Joint Drugs Controller (India), Drugs Controller General of (India), from time to time.

Drugs Inspector	1. Work in accordance with the provisions of Section 21, 22 & 23 of Drugs and Cosmetic Act, 1940 and rules made there under. 2. Sampling of Drugs, Cosmetics and Medical Devices by Section and Survey. 3. Following up of NSQ reports and launching of prosecution. 4. Any other work assigned by ADC (I) from time to time
Technical Data Associate	1. To assist in evaluation of Safety, Efficacy and Quality of Drugs as per requirement of Drugs and Cosmetics Act 1940. 2. Scrutiny of Blood Center files, LVP files. 3. Timely preparation of pending list of Inspection to be carried out, Monthly, Quarterly and Annual reports. 4. Details required in respect of RTI Parliament Questions are submitted to ADC. 5. To assist CDSCO officers in the matter of monitoring documentation. 6. Files pertaining to the technical section are maintained.
Office Assistant/ Multi Task	1. To open and close the office before and after the arrival and departure of officers and staff. 2. To assist the officers and staff in moving the files from one end to other. 3. To attend the personal needs of Head of office. In addition to the auxiliary support, have to do basic clerical work also whenever there is a need. 4. Dairying and dispatching of various applications/letters, inspection reports of Blood Centre, COPP etc. Assisting to preparation of Quarterly and annual Technical reports.

(iii) Rules/orders under which powers and duty are derived and

(iv) Exercised

Drug Inspectors derive their powers from Drugs and Cosmetics Act, 1940and Rules made there under (Drugs and Cosmetics Rules, 1945, Medical Device 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.

(v) Work allocation

The information is available in the Table no.2

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

(i) Process of decision making Identify key decision making points

(ii) Final decision making authority

(iii) Related provisions, acts, rules etc.

(iv) Time limit for taking decisions ,if any

(v) 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 and guidance documents define 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 Assistant Drugs Controller (I).

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

(i) Nature of functions/services offered

(ii) Norms/standards for functions/service delivery

(iii) Process by which the services can be accessed

(iv) Time-limit for achieving the targets

(i) 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 (www.cdsconline.gov.inandwww.cdscomdonline.gov.in).Time limits are specified in the SOP. The grievances are redressed through Public Relation Office.

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

(i) Title and nature of the record/manual/instruction.

(ii) List of Rules, regulations, instructions manuals and records

(iii) Acts/Rules manuals etc.

(iv) Transfer policy and transfer orders

The 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; 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 portal User Manual in electronic format are also followed. Transfer policy is formulated and transfer orders are issued by the Directorate.

1.6 Categories of documents held by the authority under its control

(i) Categories of documents

(ii) Custodian of documents/categories

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

A) <u>Technical:</u>

a. Manual of Office Procedure
b. Drugs and Cosmetics Act,1940
c. Drugs and Cosmetics Rules,1945
d. Medical Device Rules, 2017
e. New Drugs and Clinical Trials, 2019

B) <u>Administrative:</u>

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

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

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

(i) Name of Boards, Council, Committee etc.

(ii) Composition

(iii) Dates from which constituted

(iv) Term/Tenure

(v) Powers and functions

(vi) Whether their meetings are open to the public?

(vii) Whether the minutes of the meetings are open to the public?

Boards and Committees are constituted by the Directorate.

1.8 Directory of officers and employees [Section4(1)(b)(ix)]

(i) Name and designation

(ii) Telephone, fax and emailed Email id: jammusubzone@cdsco.nic.in

LIST OF EMPLOYEES OF CDSCO, SUB-ZONE JAMMU

S. No.	NAME OF THE EMPLOYEE	DESIGNATION OF THE EMPLOYEE	LANDLINE
1	Ms Minakshi Vashistha	Assistant Drugs Controller (I)	01912584443
2	Sh. Fahim Khan	Assistant Drugs Controller (I)	01912584443
3	Smt. Sarojini Pandita	Technical Data Associate (TDA)	01912584443
4	Sh. Sushil Kumar	Office Assistant (OA)	01912584443

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

(i) List of employees with Gross monthly remuneration

(ii) System of compensation as provided in its regulations

O/o THE ASSISTANT DRUGS CONTROLLER (INDIA), CDSCO, SUB-ZONE JAMMU		
DETAILS OF POST WITH PAY BAND & PAY LEVEL		
S. No.	Name of the Post	Pay Band & Pay Level
1	Assistant Drugs Controller (India)	Pay Band:15600-39100&PayLevel-11
2	Drugs Inspector	PayBand:9300-34800&PayLevel-8
3	Technical Data Associate	Contractual Staff
4	Office Assistant(OA)	Contractual Staff

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

(i) Name and designation of the public information officer (PIO), Assistant Public Information (s) & Appellate Authority

(ii) Address, telephone numbers and email ID of each designated official.

S. No.	Name of the Officer	Telephone No	Email ID
1.	Sh Ajay Sachan Deputy Drugs Controller (India), First Appellate Authority and Deputy Drugs Controller (I), Zonal Office, Baddi	01795-246112	chandigarh@cdsco.nic.in
2.	Ms Minakshi Vashistha, CPIO and Assistant Drugs Controller (India), CDSCO, Sub-Zone, Jammu (J&K)	0191-2584443	jammusubzone@cdsco.nic.in

1.11 No. of employees against whom Disciplinary action has been proposed/taken (Section 4 (2))

No. of employees against whom disciplinary action has been

(i) Pending for Minor penalty or major penalty proceedings

(ii) 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 the 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

Yet, no physical mode organized although one Training programme organized through virtual mode " implementation & effective use of RTI-MIS Portal (e-Portal) for disposal of all RTI including Physical – RTI, through RTI-MIS Portal for all the concerned DPIO, CPIO and FAA of all the CDSCO offices"

(iv) Update & publish guidelines on RTI by the Public Authorities concerned

- **A guidance document related to RTI is published in website of CDSCO**
  https://cdsco.gov.in/opencms/opencms/en/RTI/https://cdsco.gov.in/opencms/export/system/modules/CDSCO.WEB/resources/pdf/RTI/guidance_documents1.pdf

- **Further, the guidelines issued by Central Information Commission are followed**
  https://cic.gov.in/rti-notifications

1.13 **Transfer policy and transfer orders [FNo.1/6/2011-IRdt. 15.4.2013]**

Transfer policy is formulated and transfer orders are issued by the Directorate

2. Budget and Programme

2.1 Budget allocated to each agency including all plans, proposed expenditure and reports on disbursements made etc.[Section4(1) (b)(xi)]

(i) Total Budget for the public authority

(ii) Budget for each agency and plan & programmes

(iii) Revised budget for each agency, if any

(iv) Report on disbursements made and place where the related reports are available

(v) Proposed expenditures

Budget and proposed expenditures allocation has been carried out by CDSCO, North Zone as CDSCO, Baddi has no DDO power.

2.2 Foreign and domestic tours (F.No.1/8/2012-IRdt.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.

S.No	Name of the Officer	PlacesVisited	The period of visit	Number of members in the official delegation	Expenditure on the visit
1	2	3	4	5	6
1.	Ms. Minakshi Vashistha, Assistant Drugs Controller(I)	None for last 5 years.			

(iii) 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 contracts is to be executed.

Nil

2.3 Manner of execution of subsidy programme [Section 4(i)(b)(xii)]

(i) Name of the programme of activity

(ii) Objective of the programme

(iii) Procedure to avail benefits

(iv) Duration of the programme/ scheme

(v) Physical and financial targets of the programme

(vi) Nature/ scale of subsidy /amount allotted

(vii) Eligibility criteria for grant of subsidy

(viii) Details of beneficiaries of subsidy programme (number, profile etc)

Nil

2.4 Discretionary and non-discretionary grants[F.No.1/6/2011-IRdt.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 concession, 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 para [F No. 1/6/2011- IR dt. 15.4.2013]

CAG and PAC para 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

3.1 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 its 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

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/biologicals/Blood-Products/
5.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/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/Subsequent-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/cosmetics/

ii) Arrangements for consultation with or representation by

a) Members of the public in policy formulation/ policy implementation

Policy formulation and its implementation is done by Directorate

b) Day & time allotted for visitors

c) Contact details of Information & Facilitation Counter (IFC) to provide publications frequently sought by RTI applicants:

Ms. Minakshi Vashistha, ADC(I), CPIO,O/o ADC(I), IIIM Campus, Canal road, Sub-Zone Jammu, J&K-180001, <**jammusubzone@cdsco.nic.in**>;

Public Relation office has been established

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU2Mg==

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 hand hold 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 revenue 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

3.2 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

3.3 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)

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.	Alerts	https://cdsco.gov.in/opencms/opencms/en/Notifications/Alerts/
4.	Bioequivalence and Bioavailability	https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html
5.	Blood Products	https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/
6.	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/
7	Global Clinical Trial	https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/
8	Ethics Committee	https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/

9	New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/
10	Fixed Dose Combinations (FDCs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
11	Investigational New Drugs (INDs)	https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/
12	Subsequent New Drugs	https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/
13	Medical Device and In-Vitro Diagnostics	https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/
14	Cosmetics	https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/

3.4 Form of accessibility of information manual/ handbook [Section 4(1)(b)]

Information manual/ handbook available in

(i) Electronic format

S. 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 Language in which Information Manual/Handbook Available

[F No. 1/6/2011-IR dt. 15.4.2013]

English

4.2 When was the information Manual/ Hand book 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 Para3.3

4.4 Particulars of facilities available to citizen for obtaining information [Section 4(1)(b)(xv)]

(i) Name & location of the facility

O/o Assistant Drugs Controller (India), Central Drug Standard Control Organization, Sub Zone, IIIM Campus, Canal Road, Jammu-180001.

(ii) Details of information made available

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 laptops.

(iii) Working hours of the facility

9.30AM to 6.00PM (except closed holidays)

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

O/o Assistant Drugs Controller (India), Central Drug Standard Control Organization, Sub Zone, IIIM Campus, Canal Road, Jammu-180001.

0191-2584443, jammusubzone@cdsco.nic.in

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

i) Grievance redressal mechanism

Mechanism is either by email, Telephone, direct meeting with ADC(I)

Public Relation office was established

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_fil e_division.jsp?num_id=NTU2Mg==

Functions of PRO Office:

1. To act as single window for disposal of grievance of stake holders on regulatory issues.
2. To provide information to the innovator regarding regulatory norms
3. To guide, assist hand hold 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

S. no.	Year	RTI applications received	RTI applications disposed
1	2017-18	01	01
2	2018 -19	10	10
3	2019 -20	10	10
4	2020 -21	10	10
5	2021 -22	10	10
6	2022 -23	05	05
7	2023 -24	13	13

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

This office has not entered into any contract.

(vi) Annual Report

Annual report of CDSCO is prepared by Directorate by compiling the information from the Field formations.

(vii) Frequently Asked Question (FAQs)

S. No.	Topic	URLs
1	New Drugs	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM0MA== 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/CDSCO.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/FAQ/index.html
5	Blood Centre	https://cdsco.gov.in/opencms/opencms/en/FAQ/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.pdf

viii) Any other information such as

a) Citizen's Charter

b) Result Frame work Document (RFD)

c) Six monthly reports

d) Performance against the benchmarks set in the Citizen's Charter

Nil

4.6 Receipt & Disposal of RTI applications & appeals [F.No1/6/2011-IRdt.15.04.2013

(i) Details of applications received and disposed

S. no.	**Year**	**RTI applications received**	**RTI applications disposed**
1	2017-18	01	01
2	2018 -19	10	10
3	2019 -20	10	10
4	2020 -21	10	10
5	2021 -22	10	10
6	2022 -23	05	05
7	2023 -24	13	13

(ii) Details of appeals received and orders issued

S. no.	**Year**	**RTI applications received**	**RTI applications disposed**
1	2017-18	0	0
2	2018 -19	0	0
3	2019 -20	0	0
4	2020 -21	0	0
5	2021 -22	0	0
6	2022 -23	0	0
7	2023 -24	0	0

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

Such other information as may be prescribed

[F.No.1/2/2016-IRdt.17.8.2016,FNo.1/6/2011- IR dt. 15.4.2013]

(i) Name &details of

(a) Current CPIOs& FAAs

S. No.	Name of the Officer	Telephone No	Email-ID
1	Dr. Ajay Sachan DeputyDrugsController(India), First Appellate Authority and Deputy Drugs Controller (I), Zonal Office, Baddi, H.P.	01795-247112	chandigarh@cdsco.nic.in
2	Ms. Minakshi Vashistha, CPIO and Asstt. Drugs Controller (India), CDSCO (Sub-Zone), Jammu, (J&K).	0191-2584443	jammusubzone@cdsco.nic.in

(b)Earlier CPIO & FAAs from1.1.2015

S. No.	Name of the office	CPIO	Appellate authority	Year
1	O/o Assistant Drugs Controller(I), Central Drugs Standard Control, Organization, Sub-Zone, Jammu, IIIM Campus, Canal Road, Jammu, (J&K)	Mr. B.K. Samantray (Dec. 2010 – July 2015)	Sh. A. K. Pradhan, DDC(I)	2015
				2016
		Mr. Sunil Joshi (July 2015-June 2017)		2017
		Mr. Gulshan Taneja (July- 2017- Aug. 2020)	Sh. Aseem Sahu, DDC(I), Oct. 2017	2018
				2019
		Ms. Bharti Bachloo (June 2020-24th July 2023)	Sh. Aseem Sahu, DDC(I) till April 2022	2020
				2021
			Sh. Sanjeev Kumar, DDC(I), from May 2022	2022 May 2023
			Sh.Chandrashekar Ranga, DDC(I), From June 2023	July 2023
		Ms. Minakshi Vashistha (25th July .2023-to till dated)	Chandrashekar Ranga, DDC(I),	25th July .2023 to March 2024
			Dr. Ajay Sachan, DDC(I),	April 2024 to till

(ii) Details of third party audit of voluntary disclosure

(a) Dates of audit carried out

(b) Report of the audit carried out

NIL

(iii) 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

(iv) Consultancycommitteeofkeystakeholdersforadviceonsuo-motudisclosure

(a) Dates from which constituted

(b) Name & Designation of the officers

No such consultancy committee was constituted so far.

(v) 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

6.1 Item / information disclosed so that public have minimum resort to use of RTI Act to obtain information

S. 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/biologicals/Blood-Products/
5	Vaccines	https://cdsco.gov.in/opencms/opencms/en/biologicals/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/Subsequent-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/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.cdsco.gov.in) is maintained by Directorate (FDABhawan, Kotla Road, New Delhi)