**SUO MOTO DISCLOSURE UNDER SECTION 4 (1)(b) OF RTI ACT, 2005**
**(CDSCO, Sub Zone Guwahati)**

# 1. Organization and Function

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

**(i) Name and address of the Organization**

**CENTRAL DRUG STANDARD CONTROL ORGANIZATION, SUBZONE GUWAHATI**

*CDSCO Sub-Zone, Guwahati Regional Drugs Testing Laboratory campus, Six Mile, Panjabari Road, Guwahati-781022, Assam. PH: 0361-2332628*
*Email: Subzone [dot]guwahati[at]cdsco[dot]nic[dot].in*

***(ii)*** **Head of the organization**

*Shri Dinesh Kumar*
*Assistant Drugs Controller (India)*
*https://cdsco.gov.in/opencms/opencms/en/Departments/Sub-Zone/Guwahati/*

**(iii) CDSCO 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.*
*https://cdsco.gov.in/opencms/ope ncms/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, r-DNA derived products, living modified organism, Monoclonal Antibodies, Stem cell derived products and gene therapeutic products intended to be used as drugs for both human as well as veterinary use.*
4. *To participate in the joint inspection for grant/renewal of license for LVP manufacturing units.*
5. *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.*
6. *To carry out Surprise check/Raid jointly/independently on the basis of complaint received under Whistle Blower scheme and also from other sources.*
7. *To carry out joint inspection of Drug Testing Laboratory(s)/Medical Device Testing Laboratory for the purpose of grant of approval of the site for test / analysis of Drugs, Cosmetics and Medical devices.*
8. *To follow up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other zonal offices.*
9. *Drawing of Legal samples of drugs, cosmetics and Medical Devices from the*

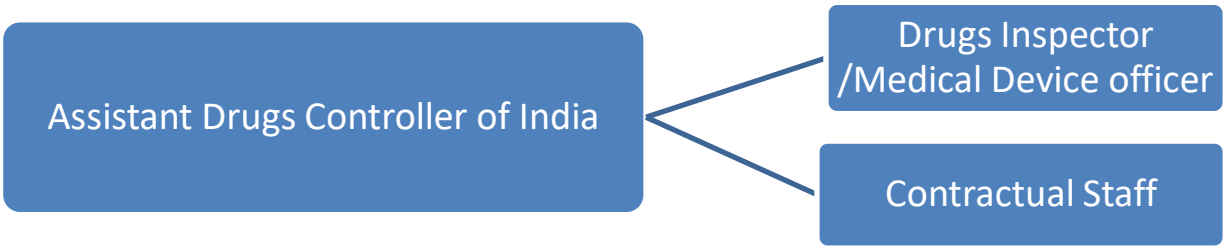
*manufacturing & sales / distribution premises including the Govt. establishment.*

10. *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).*
11. *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.*
12. *To pursue the court cases pending in different courts under the jurisdiction of this 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 zone.*
16. *To act as a Public Authority for responding RTI queries.*
17. *Preparation of Monthly/Quarterly/Annual Reports.*
18. *To participate as observers in international regulatory agencies inspections as and when directed by Directorate.*
19. *To organize workshop, seminar etc. as directed.*
20. *To conduct inspection for grant of license for Class C and Class D Medical Devices & In vitro diagnostics.*
21. *To participate in the joint inspection for grant/renewal of license for Bio-Tech & Bio-similar products manufacturing units.*
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: -*
    - *Grant of Permission in Form CT-11/CT-14, CT15 & CT 17 to manufacture drugs for the purpose of examination, test or analysis.*
    - *Permit for import to small quantities of drugs for personal use under Form 12B of the Drugs and Cosmetics Rules.*

***23.*** *Any other functions as assigned by DCG (I)from time to time*

(v) **Organization Chart:**

**Table No.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-:**

*Reply- : The Central Drugs Standard Control Organization (CDSCO), Sub Zone Guwahati, Assam was started during the year 2017 headed by Assistant Drugs Controller (India) with sanctioned 07 post of Drugs Inspectors. The Sub Zonal office of the CDSCO, Guwahati was initially 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. After the opening of a Sub Zonal office at Guwahati to cater the needs of the North Eastern States of India, the current jurisdiction of CDSCO Subzonal Zonal office at Guwahati includes the states of Assam, Meghalaya, Nagaland, Tripura, Mizoram, Arunachal Pradesh and Manipur.*

**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**

**Reply- TableNo.2**

| ***Designation*** | ***Duties*** |
|---|---|
| *Assistant Drugs Controller(India)* | 1. *Responsible for overall activities of Sub Zone Guwahati including technical and non- technical in order to meet good regulatory practices on behalf of CDSCO to achieve patient safety and also to meet quality systems of medicines.*<br>2. *Enforcement of various provisions of Drugs and Cosmetics Acts 1940 and Rules 1945 made there under, in accordance with the directive issued by* |

| | |
|---|---|
| | *Drugs Controller Genera l(India)*<br>3. *Coordination with SLAs in case of Inspection of manufacturing premises jointly with State Drug Control Authorities for drugs covered under the CLAA Scheme, i.e., blood, its components and blood products, LVP biological products like Vaccine, rDNA derived products etc for the purpose of grant /renewal of manufacturing licenses.*<br>4. *Evaluation of New manufacturing license application for Central License Approving Authority(CLAA) items i.e. blood, its components and blood products, LVP, Vaccines Medical Devices(class C and D) for grant/renewal of manufacturing license.*<br>5. *Coordination with SLAs in case Inspection of manufacturing facilities with the State Drug Control Authorities for grant of WHO GMP Certificate (Certificate of Pharmaceutical product).*<br>6. *Coordination with SLAs in case of Carrying out Investigation/Surprise check/Raid jointly/independently on the basis of complaint received under Whistle Blower scheme, in the matter of Parliament Question and RTI etc.*<br>7. *Evaluation and Authorization of export NOC, Form 11, NOC for Form 29 and authorization for Inspection of testing labs, Ethics Committee, Clinical trial sites. Grant of Permission in Form CT-11/CT-14 & CT-15 to manufacture drugs for the purpose of examination, test or analysis.*<br>8. *Permit for import to small quantities of drugs for personal use under Form 12B of the Drugs Rules, 1945 .*<br>9. *Deputation of officers for various inspection/investigation/surprise check/ raids etc.*<br>10. *Authorization for Circulation of notifications received from Headquarter, other Zonal/Sub-Zonal offices/ states/UT regarding NSQ drugs.*<br>11. *To monitor SUGAM portal, ONDLS Portal , NSWS Portal, e-office, admin activities, training program, QMS and assistance to DCG (I) office.* |
| ***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.*<br>2. *Sampling of Drugs, Cosmetics and Medical Devices*<br>3. *Following up of NSQ reports and launching of prosecution.*<br>4. *Another work assigned by ADC (I) from time to time.* |
| ***Multi Tasking Staff*** | *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 end to other. 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. Inward & Dispatch in go fall receipts and correspondences including inspection reports of Blood Centre, COPP and* |

| | |
|---|---|
| | *Medical devices to DCG(I),applicant and SLAs. Assisting in Admin related works and other official bills, records etc. Any other works assigned by DI /ADC (I) time to time.* |

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

*Reply: Drug Inspectors derive their powers from Drugs and Cosmetics Act, 1940 and Rules made there under (Drugs Rules, 1945, Medical Device Rules, 2017, NDCT Rules, 2019 and Cosmetics Rules,2020) and subsequent office orders issued by the Directorate. Powers and duties of other posts are derived and exercised as per the practice in vogue.*

**(iv) Work allocation**

Reply: The information is available in the Table no.2

**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 a decisions, if any**
**(v) Channel of supervision and accountability**

*Reply: 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 document defines the hierarchy/ channel of supervision of the office. The time limits for taking decisions are set by Office orders issued by competent authority from time to time. Final Decision making authority is vested with the Assistant Drugs Controller (I).*

***Link of Guidance document for zonal & sub Zonal offices-***
***chromeextension://efaidnbmnnnibpcajpcglclefindmkaj/https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdfdocuments/importregistration/Guidingdoentforzonalsub-zonalportoffices17.06.2011.pdf***

**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**
**(v) Process of redress of grievances**

*Reply: -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.in and www.cdscomdonline.gov.in) NSWS (CT permission) and ONDLS portals (Blood Centers) . Time limits are specified in the SOP. The grievances are redressed through Public Relation Office.*

**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**

Reply-: The Drugs and Cosmetics Act, 1940 and Rules made thereunder (Drugs 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 portal User Manual in electronic format is also followed. Transfer policy is formulated and transfer orders are issued by the Directorate.

**Categories of documents held by the authority under its control**

**(i) Categories of documents**
**(ii) Custodian of documents/categories**

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

**A) *Technical:***

**a.** Manual of Office Procedure
**b.** Drugs and Cosmetics Act,1940
**c.** Drugs Rules,1945
**d.** Medical Device Rules,2017
**e.** New Drugs and ClinicalTrials,2019
**f.** Cosmetics Rules,2020

**B) *Administrative:***

*Various documents and records are maintained as per the norms of Government of India-https://dopt.gov.in/download/acts*

**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?**

Reply - *Boards and Committees are constituted by the Directorate.*

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

(i) Name and designation
(ii) Telephone, fax and email ID

Reply: Emailid : ***Subzone [dot]guwahati[at]cdsco[dot]nic[dot].in***

| *S.NO* | *NAME OF EMPLOYEE* | *DESIGNATION* | *LANDLINENO. 0361-2332628 WITH EXTENSION NO.* |
|---|---|---|---|
| *1.* | *Sh. Dinesh Kumar* | *ADC(I)* | *311* |
| *2.* | *Sh.Baljeet Singh* | *Drugs Inspector* | *312* |
| *3.* | *Sh.Harish* | *Drugs Inspector* | *312* |
| *4.* | *Sh.Mohan Biswas* | *MTS* | *313* |

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

**(iii) List of employees with Gross monthly remuneration**
**(iv) System of compensation as provided in its regulations**

Reply:-

| *S.N.* | *DESIGNATION* | *PAY-BAND* | *PAY-LEVEL* |
|---|---|---|---|
| *1.* | *ADC(I)* | *15600-39100* | *11* |
| *2.* | *Drugs Inspector* | *9300-34800* | *8 and 9 ( After MACP)* |

**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.**

**Reply:**

| *S.NO* | *Name of the Officer* | *Telephone No* | *EmailID* |
|---|---|---|---|
| ***1.*** | ***Shri Dinesh Kumar First Appellate Authority and Assistant Drugs Controller(I), CDSCO Subzone ,Guwahati*** | ***0361-2332628 Ext: 311*** | ***Subzone[dot]guwahati[at]cdsco[dot]nic[dot].in*** |
| ***2.*** | ***Shri Baljeet Singh CPIO and Drugs Inspector, CDSCO Subzone ,Guwahati*** | ***0361-2332628 Ext.No:312*** | ***Subzone[dot]guwahati[at]cdsco[dot]nic[dot].in*** |

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

**(iii)** Pending for Minor penalty or major penalty proceedings
**(iv)** Finalized for Minor penalty or major penalty proceedings

*Reply: Nil*

**Programmes to advance understanding of RTI (Section 26)**

**(i) Educational Programmes**

Reply :- *Training programme or workshop related to RTI has not been attended by Concerned persons dealing with RTI of this office.*

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

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

**(iii) Training of CPIO/APIO**

***Reply:*** *No*

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

***Reply:***

- *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***

**Transfer policy and transfer orders**

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

**Reply:** *Transfer policy and orders are issued by the Directorate, CDSCO, HQ, New Delhi*

## 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**

*Reply: Finacial control of CDSCO Subzone Guwahati is with Regional Drugs testing Laboartory,Guwahati*

iii) **Proposed expenditures**

*Reply: Finacial control of CDSCO Subzone Guwahati is with Regional Drugs testing Laboartory,Guwahati*

**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**

*Reply: No foreign visit by Head of department*

**(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 contract is to be executed.**

*Reply: Finacial control of CDSCO Subzone Guwahati is with Regional Drugs Testing Laboartory, Guwahati*

**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)**

*Reply: Finacial control of CDSCO Subzone Guwahati is with Regional Drugs Testing Laboartory,Guwahati*

**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**

*Reply: Finacial control of CDSCO Subzone Guwahati is with Regional Drugs Testing Laboartory,Guwahati*

**Particulars of recipients of concessions, permits of authorizations granted by the public authority [Section4 (1)(b)(xiii)]**

**(iii) Concessions, permits or authorizations granted by public authority**

**(iv) For each concessions, permit or authorization granted**

a) **Eligibility criteria**

b) **Procedure forgetting the concession/grant and/or permits of authorizations**

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

d) **Date of award of concessions/permits of authorizations**

Reply: Finacial control of CDSCO Subzone Guwahati is with Regional Drugs testing Laboartory,Guwahati

**`CAG &PAC paras [FNo. 1/6/2011- IRdt. 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.**

*Reply: Finacial control of CDSCO Subzone Guwahati is with Regional Drugs Testing Laboartory,Guwahati*

## 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)][FNo1/6/2011-IRdt.15.04.2013]**

*Reply:* 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, 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**

**Reply:** *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**

Reply: 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 and hold investors in various phases of business lifecycle 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 out puts and outcomes**

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

(ix) **All payment made under the PPP project**

Reply: 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;**

**(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**

Reply:- *Policy decisions / legislations are carried out by Directorate. Formulation of Policy and Implementation is also carried out by Directorate.*

***(*** *https:// cdsco.gov.in/opencms/opencms/en/Notifications/GazetteNotifications/)*

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

Reply: 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/* |

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

Reply: Information manual/hand book available in Electronic format
Printed format- Not Available

| ***Sr. No.*** | ***Topic*** | ***URLs*** |
|---|---|---|
| *1.* | *e-Governance* | *https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/SUGAM_user_manual.pdf* |
| *2* | *Online Licensing (ONDLS)* | *https://www.statedrugs.gov.in/SFDA/Homepage* |
| *3* | *Sugam portal* | *https://www.cdscoonline.gov.in/CDSCO/homepage* |
| *4* | *NSWS portal* | *https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/1janLaunch%20of%20NSWS%20portal.pdf* |
| *5* | *ONDLS portal* | *https://www.statedrugs.gov.in/SFDA/resources/app_srv/SFDA/startup/user-mannual/applicant_reg_login_v1.pdf* |
| *6* | *ONDLS Blood Centre Manual* | *https://www.statedrugs.gov.in/SFDA/resources/app_srv/SFDA/startup/user-mannual/Blood_Bank_Manual_v1.pdf* |
| *7* | *Medical Devices online application link* | *https://cdscomdonline.gov.in/NewMedDev/Homepage* |

**Whether information manual/handbook available free of cost or not**

[Section 4(1) (b)]

*Reply: List of materials available Free of cost and the Electronic format can be accessed through website 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

**Language in which Information Manual /Handbook Available**
**[F No. 1/6/2011-IR dt. 15.4.2013]**

Reply: English

**When was the information Manual/Handbook last updated?**

**[F No. 1/6/2011-IR dt 15.4.2013]**
**Last date of Annual updation**

**Reply:** *Updation of Manual is carried out by Directorate*

**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**

Reply: Please r*efer Para 3*

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

**(iv) Name & location of the facility**

**Reply:** *CENTRAL DRUG STANDARD CONTROL ORGANIZATION, SUBZONE GUWAHATI CDSCO Sub-Zone, Guwahati Regional Drugs Testing Laboratory campus, Six Mile, Panjabari Road, Guwahati-781022, Assam. 0361-2332628 (M) 8510806616 email-:subzone [dot]guwahati[at]cdsco[dot]nic[dot].in*
*https://cdsco.gov.in/opencms/opencms/en/Departments/Sub-Zone/Guwahati/*

**(v) Details of information made available**

***Reply:*** *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.*

**(vi) Working hours of the facility**

**Reply: 9.30AM to 6.00PM (except holidays)**

**(vii) Contact person & contact details(Phone, fax email)**

**Reply:** *Shri Dinesh Kumar, Assistant Drugs Controller (India)*
*CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, SUBZONE GUWAHATI CDSCO Sub-Zone, Guwahati Regional Drugs Testing Laboratory campus, Six Mile, Panjabari Road, Guwahati- 781022, Assam. 0361-2332628 Subzone [dot]guwahati[at]cdsco[dot]nic[dot].in*

**Such other information as may be prescribed under section4(i)(b)(xvii)**

**(i) Grievance redressal mechanism**

*Reply: Public Relation office was established*
*https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA4MTc=*

***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**

| S. No | Year | RTI applications received | RTI applications disposed |
|---|---|---|---|
| 1. | 2019 | 12 | 12 |
| 2. | 2020 | 08 | 08 |
| 3. | 2021 | 10 | 10 |
| 4 | 2022 | 7 | 7 |
| 5 | 2023 | 13 | 13 |

**(iii) List of completed schemes/projects/Programmes-**

**Reply:** This office has not been assigned any schemes/ projects /Programmes.

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

*Reply: 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.**

**Reply:** *This office has not entered in to any contract.*

**(vi) Annual Report**

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

**(vii) Frequently Asked Question (FAQs)**

*Reply: -*

| Sr. No. | Topic | URLs |
|---|---|---|
| 1. | New Drugs | https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM0MA==<br>Additional FAQs:<br>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 | Phytopharmaceuticals | 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/revidsefagbabe.pdf |
| 8 | NOC for manufacture of banned drug/ unapproved drug/ new drugs Solely for export purpose. | https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTExNDQ= |

**(viii) Any other information such as**

a) **Citizen's Charter**
b) **Result Frame work Document(RFD)**
c) **Six monthly reports on the**
d) **Performance against the benchmarks set in the Citizen's Charter**

*Reply: Nil*

**Receipt & Disposal of RTI Applications & Appeals**

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

***(i) Details of applications received and disposed***

| S. No | Year | RTI applications received | RTI applications disposed |
|---|---|---|---|
| 1. | 2019 | 12 | 12 |
| 2. | 2020 | 08 | 08 |
| 3. | 2021 | 10 | 10 |
| 4 | 2022 | 7 | 7 |
| 5 | 2023 | 13 | 13 |

**(ii) Details of appeals received and orders issued**

| S.No | Year | RTI applications received | RTI applications disposed |
|---|---|---|---|
| 1. | 2019 | 01 | 01 |
| 2. | 2020 | 01 | 01 |
| 3. | 2021 | 00 | 00 |
| 4 | 2022 | 00 | 00 |
| 5. | 2023 | 00 | 00 |

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

Reply: *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]**

**Reply:**

Name & details of

(a) Current CPIOs & FAAs

| S.N. | Name of the Officer | Telephone No | EmailID |
|---|---|---|---|
| 1. | Shri Dinesh Kumar<br>First Appellate Authority and Assistant Drugs Controller (I), CDSCO Subzone ,Guwahati & FAA | 0361-2332628<br>Ext: 311 | **Subzone[dot]guwahati[at] cdsco[dot]nic[dot].in** |
| 2. | Shri Baljeet Singh<br>Drugs Inspector, CDSCO Subzone , Guwahati & CPIO | 0361-2332628<br>Ext.No:312 | **Subzone[dot]guwahati[at]cdsco[dot]nic[dot].in** |

(b) Earlier CPIO & FAAs from Jan, 2021

FAA: Sh.Shiv Kumar, ADC (I) (Jan, 2021 to June 2023)
CPIO: Dr. Pranab Jyoti Das, DI (Jan 2021 to July 2023)

FAA: Sh.Gulshan Taneja, DDC (I) (Aug, 2023 to Oct 2023)
CPIO: Shri .Dinesh Kumar, ADC (Aug, 2023 to Oct 2023)

**(i) Details of third party audit of voluntary disclosure**

(a) **Dates of audit carried out**

(b) **Report of the audit carried out**

Reply: Not Available with this office

**(ii) Appointment of Nodal Officers not below the rank of Joint Secretary/Additional HoD**

(a) **Date of appointment**

(b) **Name &Designation of the officers**

*Reply: Not Applicable*

**(iii) Consultancy committee of key stakeholders for advice on Suo-Moto disclosure**

(a) **Dates from which constituted**

(b) **Name & Designation of the officers**

*Reply: No such consultancy committee was constituted so far.*

**(iv) 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**

*Reply: 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://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/ |

**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?**

*Reply: Website of CDSCO (www.cdsco.gov.in) is maintained by Directorate.*

## RTI-Online portal

***Note: An applicant who desires to obtain information under the RTI Act, 2005 can make a request through the RTI Online Portal to the Central Ministries/Departments and other Central Public Authorities mentioned in ONLINE RTI request form.***

| *S.No.* | *Type of information* | *Link* |
|---|---|---|
| *1* | *RTI Online Portal* | *chromeextension://efaidnbmnnnibpcajpcglclefindmkaj/https://rtionline.gov.in/um_citizen.pdf* |
| *2* | *RTI Online portal FAQ* | *https://rtionline.gov.in/faq.php* |
| *3* | *Guidelines for applicant/users* | *https://rtionline.gov.in/guidelines.php?appeal* |

## Details of activities carried out by CDSCO,Subzone Guwahati Since last 03 years

| S.No | Year | No. of Inspection carried out (COPP/SchM) |
|---|---|---|
| 1. | 2021 | 18 |
| 2 | 2022 | 19 |
| 3. | 2023 | 15 |

| S.No | Year | No. of prosecution launched. |
|---|---|---|
| 1. | 2021 | 01 |
| 2 | 2022 | 09 |
| 3. | 2023 | 16 |

| S.No | Year | GCP Inspection |
|---|---|---|
| 1. | 2021-2022 | Nil |
| 2 | 2022-2023 | Nil |
| 3. | 2023-2024 | 01 |
| 4 | 2024- till date ( July24) | 02 |

| S.No | Year | No. of Drugs Samples drawn |
|---|---|---|
| 1. | 2021 | 265 |
| 2 | 2022 | 166 |
| 3. | 2023 | 200 |