SUO MOTTO DISCLOSURE UNDER SECTION 4 OF RTI ACT, 2005

(CDSCO, Sub Zonal Office, Visakhapatnam)

1. Organisation and Function

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

(i) Name and address of the Organization

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO), SUB ZONAL OFFICE,VISAKHAPATNAM

CDSCO Sub Zonal Office,
Ministry of Health & Family Welfare,
Directorate General of Health Services,
5th Floor, Karmika Jyothi Building, Visakhapatnam Port Authority,
Visakhapatnam-530001, A.P.

Phone- 0891-2729315, 2725315
Email- **vskp.subzone@cdsco.nic.in**

(ii) Head of the organization

Smt. K. Bhuvaneswari
Assistant Drugs Controller (India)

(iii) Vision, Mission and Key objectives

Vision:

To protect and promote Public Health in India.

Mission:

To safeguard and enhance the Public Health by assuring the Safety, Efficacy and Quality of Drugs, Cosmetics and Medical |Devices.

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

(iv) Function and duties

1. Joint inspection of Drug Manufacturing facilities by the officers of CDSCO & State Licensing Authority (SLA), Andhra Pradesh for Grant / Re-Validation of Certificate of Pharmaceutical Products (COPPs) as per WHO Certification Scheme.

2. Joint inspection of Blood Centres by the officers of CDSCO & State Licensing Authority (SLA), Andhra Pradesh for Grant/Renewal of Blood Centre license/ Additional endorsement of Blood Components/ Follow up inspections etc.

3. Participation in the joint inspection carried out by CDSCO & State Licensing Authority (SLA), Andhra Pradesh for Grant/Renewal of license for LVP manufacturing units, Bio-Tech & Bio-similar products manufacturing units and r-DNA manufacturing units.

4. Joint inspection by the officers of CDSCO & State Licensing Authority (SLA), Andhra Pradesh for Grant/Renewal of license/ Additional products etc. for Vaccine / Sera manufacturing units.

5. Participation in the joint inspection carried out by CDSCO & State Licensing Authority (SLA), Andhra Pradesh for Drug Testing Laboratory for the purpose of Grant/Renewal of Approval for testing Drugs & Cosmetics.

6. Participation in the joint inspection carried out by CDSCO & State Licensing Authority (SLA), Andhra Pradesh for Grant/Renewal of registration to BA/BE centers.

7. To conduct inspection of Clinical Trial facilities and BA/BE study centers as directed by the Drugs Controller General (India) from time to time.

8. To conduct inspection for Grant of license for Class C and Class D notified Medical Devices & In vitro diagnostics.

9. To conduct inspection for the purpose of Registration of Medical Device Testing Laboratory.

10. Coordination with subject experts and involving in inspections for obtaining technical opinion as and when required.

11. To carry out Investigations, Raids, Surprise check etc. independently or with the officers of other Zone/Sub zone/Port offices of CDSCO & SLA based on the complaints received under Whistle Blower scheme / other sources and as directed by the DCG(I).

12. Sampling (Statutory/Survey) of Drugs/Medical Devices/IVDs/Cosmetics etc. from the premises of manufacturing/sales/distribution/Govt. establishments etc. and forwarding to the Laboratory for testing.

13. When the samples drawn by the Central Drugs Inspector are declared spurious / adulterated / grossly sub-standard etc., the cases are investigated and prosecutions are launched in the appropriate court after obtaining necessary sanction from the Drugs Controller General (India).

14. Follow up action with State Licensing Authority of the respective zone and also with other zonal/sub zonal offices regarding Not of Standard Quality (NSQ) drugs.

15. Information regarding cancellation/suspension of manufacturing licenses or withdrawal of product permission by the State Licensing Authority, NSQ drugs etc. are circulated to zonal and sub zonal offices for further circulation to State Licensing Authorities of India.

16. To pursue the court cases of the office pending in the Courts under the jurisdiction of Andhra Pradesh.

17. Technical survey as directed by the Drugs Controller General (India) fromtime to time.

18. Co-ordination with the State Licensing Authority of the zone for uniform enforcement of the provisions of D&C Act 1940 & Rules made there under.

19. Co-ordination with the CDSCO (HQ) and division heads of International/ Intelligence/PRO/Legal/BloodCentre/Cosmetics/r-DNA/Import/Biologicals/RTI/ other divisions of CDSCO (HQ) on need requirements.

20. Co-ordination and data collection with SLA, Andhra Pradesh w.r.t. technical matters (Parliament questions/RTI/Sampling/Investigations/Inspections/Trainings etc) and submission to CDSCO (HQ) on need requirements.

21. Preparation of Monthly/Quarterly/Annual Reports and submission to the DCG(I), CDSCO(HQ), New Delhi and officers concerned.

22. Participation in the joint inspection carried out by CDSCO & State Licensing Authority (SLA), Andhra Pradesh with respect to grant of permission in Form CT-11/CT-14/CT-15/ CT-17/ Form-11 etc. as per need requirements.

23. To participate as an observer in International Regulatory Agency inspections as and when directed by the Directorate.

24. To organize workshops, meeting, seminar etc. as directed by the Directorate.

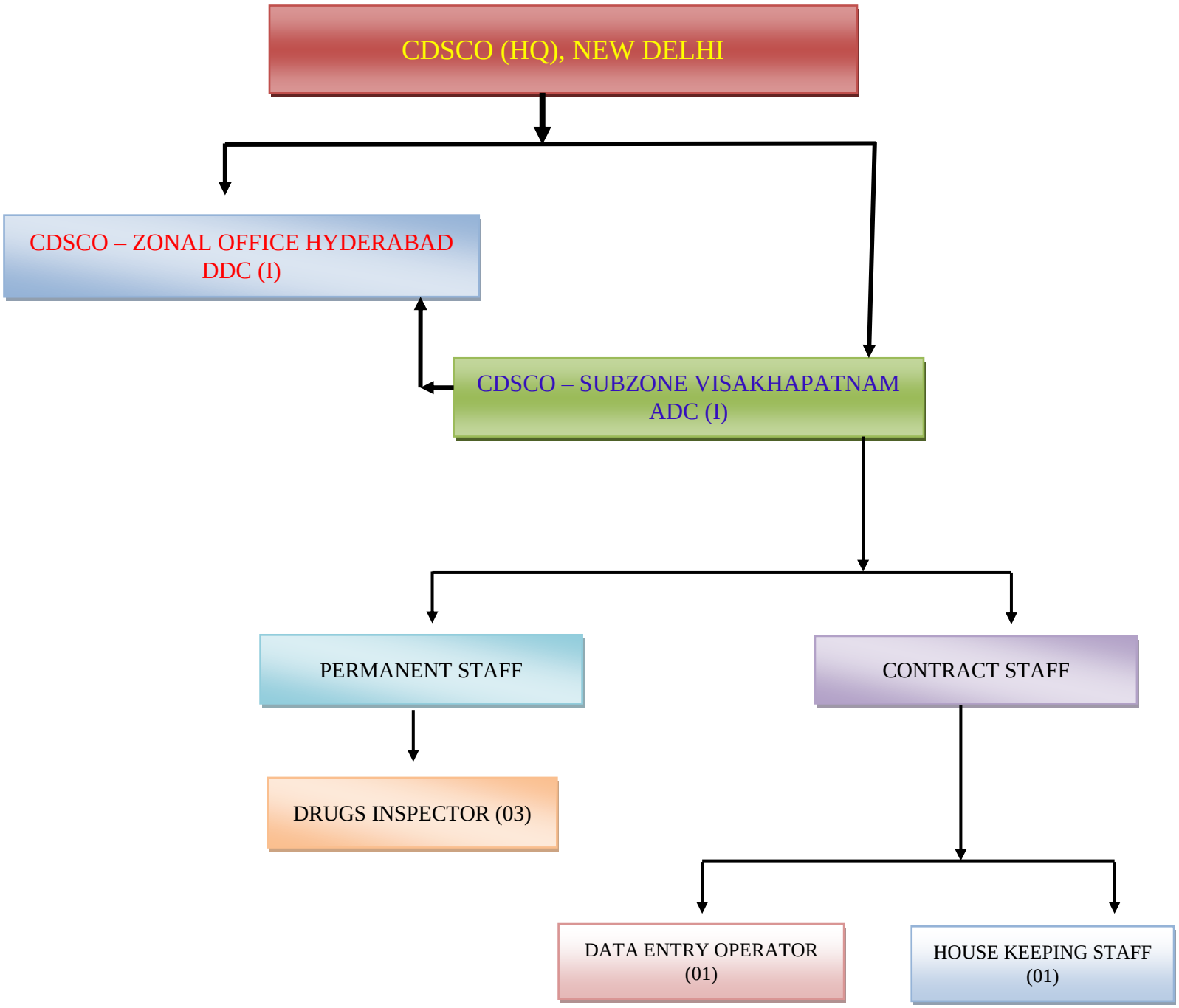
25. Work Performance on behalf of CLAA with respect to delegation of powers-
    a. Grant of Permission in Form CT-11/ CT-14/ CT-15 to manufacture drugs for the purpose of examination, test or analysis.
    b. Grant of Permission in Form-11& CT-17 to import drugs for the purpose of examination, test or analysis.
    c. Grant of No objection certificate for Import of dual use items.

26. Any other work as assigned by the DCG (I)/JDC(I)/DDC(I) of CDSCO HQ/Zonal and Sub Zonal offices.

(v) Organization Chart:

Table No.1

ORGANOGRAM OF CDSCO, SUB-ZONE OFFICE, VISAKHAPATNAM



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

Competent Authority approval for creation of Sub Zonal office of CDSCO at Visakhapatnam, Andhra Pradesh was issued vide F.no.D.21013/78/2023-DC dated 21.07.2023

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1.2 Power and duties of its officers andemployees [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 (India)	1. As a Sub Zonal Head, ensure uniform implementation of Drugs and Cosmetics Act, 1940 and Rules made there under in coordination with the State Licensing Authority of Andhra Pradesh. 2. Monitoring the activities of Drugs Inspectors/Assistant Drugs Inspectors/Data Entry Operator under the Sub Zone. 3. Handling/Monitoring Court cases of CDSCO Sub Zone, Visakhapatnam under jurisdiction of Andhra Pradesh. 4. Preparation of Monthly/Quarterly/Annual Reports in coordination with office staff and submission to the DCG(I), CDSCO(HQ), New Delhi and other concerned officers. 5. Central Public Information Officer (CPIO) for RTI matters. 6. Allotment of the applications received by the CDSCO, Sub Zone, Visakhapatnam w.r.t WHO-COPP (Grant & Re-validation), Grant of Form-25 & Form-28, Blood Center - Grant /Renewal/Additional endorsement of Blood Components, Approval of Testing Laboratory (Form-37), EU-WC Issuance, etc. to the Inspectors for review, to carry out inspection at the applicant manufacturing facility independently or with state officers where ever required and submission of report for taking necessary action on the submitted application. 7. Application documents if found inadequate by the reviewing officers- Assistant Drugs Inspector/ Drugs Inspector, letter is forwarded to the applicant /firm for submission of additional documents/ information.

	8. After application scrutiny/ inspection report review, the Remarks/ Recommendation letter of this office is forwarded to the State Licensing Authority, Andhra Pradesh for necessary action on the applications received from the applicants falling under the jurisdiction of Andhra Pradesh w.r.t. CoPP/Blood centre/ Grant of manufacturing license under Form 25 & 28, Approval of Testing Laboratory etc. 9. Issuing permissions for CT applications as Licensing Authority in Form CT-11, CT-14, CT-15, CT-17 & Form 11 in Online - NSWS Portal if the submitted documents are in order. 10. Issuing permissions for applications of Dual use NOC in Online SUGAM Portal if the submitted documents are found satisfactory. 11. Forwarding the remarks w.r.t. Issuance of EU-WCC in Online SUGAM Portal to the International cell division, CDSCO(HQ), New Delhi for the EU-WC applications . 12. Forwarding the remarks w.r.t. Inspections of Vaccine manufacturing unit, Clinical Trial site, BA-BE Study Centre, Ethics Committee etc. to the DCG(I)/Concerned division of CDSCO for necessary action. 13. Attending meetings/conferences/trainings as directed by DCG(I)/DDC(I). 14. Enlightenment to the Inspectors/ADI/DEO in Investigations/Court case matters/Inspections/other office correspondence. 15. Forwarding the requested information for the RTI applications received by this office to applicant/RTI Cell of CDSCO (HQ). 16. Co-ordination with the CDSCO (HQ) and division heads of International/Intelligence/PRO/Legal/Blood Centre/Cosmetics/ r-DNA/Import/Biologicals/RTI/other divisions of CDSCO (HQ) on need requirements.

	17. Co-ordination and data collection with SLA, Andhra Pradesh w.r.t. technical matters (Parliament questions/RTI/Sampling/Investigations/Inspections/Trainings etc) and submission to CDSCO (HQ) on need requirements. 18. Meeting with Stakeholders to clarify the queries and assisting in the work process. 19. Monitoring & Evaluation of the work performance/attendance/complaints & discipline of the officers of CDSCO, Sub zone, Visakhapatnam. 20. Coordination with subject experts and involving in inspections for obtaining technical opinion as and when required. 21. Submission of monthly report to DCG(I), CDSCO(HQ), New Delhi and officers concerned. 22. Coordination with Administrative division of CDSCO, Zonal office, Hyderabad and CDSCO(HQ), New Delhi for approvals/permissions for Recruitments/ Budget/ Stationary/ Infrastructure etc. 23. Submission of requested data/information to the DCG(I) and divisions of CDSCO(HQ) on the sought information. 24. Imparting training to the officers/staff w.r.t. office activities/discipline/technical/administration matters etc. 25. Monitoring all other technical and administrative works of CDSCO, Sub Zone, Visakhapatnam.
Drugs Inspector	1. Scrutiny of the documents w.r.t. the applications of WHO-COPP (Grant & Re-validation), Grant of Form-25 & Form-28, Blood Center - Grant /Renewal/Additional endorsement of Blood Components, Approval of Testing Laboratory (Form-37), EU-WCC Issuance, Medical Devices & IVD – Grant/ Additional endorsement (Class C & D) etc.

	2. CDSCO-SLA Officers Joint Inspection: Inspection of manufacturing facility along with the officers of State Licensing Authority, Andhra Pradesh w.r.t. the applications of WHO-COPP (Grant & Re-validation), Grant of Form-25 & Form-28, Blood Center - Grant /Renewal/Additional endorsement of Blood Components, Approval of Testing Laboratory (Form-37), Vaccine/Sera manufacturing units, Biotech & Biosimilar products manufacturing units etc. and report submission for the allotted files to the Head of Office. 3. CDSCO Inspection : Inspection of API manufacturing facilities for Issuance of EU-WC Certificate, Class C & D Medical Device & IVD manufacturing firms, Medical Device Testing laboratories (Form-MD-40) & Clinical Trail sites, Ethics Committee etc. and submission of the report. 4. To carry out Investigations, Raids, Surprise checks etc. independently or with the officers of other Zone/Sub zone/Port offices of CDSCO & SLA if required based on the complaints received and as directed by Head of Office and DCG(I). 5. Sampling (Statutory/Survey) of Drugs/Medical Devices/IVDs/Cosmetics etc. from the premises of manufacturing/sales/distribution/Govt. establishments etc. and forwarding to the Laboratory for testing. 6. Follow up with the manufacturers to obtain the details requested by the Laboratory (CoA, MOA, Working/Impurity standards) and forwarding of the same to the laboratories to facilitate testing. 7. Follow up with the Laboratory to obtain the Test report within time frame and to take necessary action after receipt of test report. 8. Manufacturing facility Investigation for the sample declared as Not of Standard Quality Drug by the testing laboratory and

	following the procedures as per D & C Act, 1940 & Rules made there under. 9. Case filing in the Hon'ble Court of Law against the manufacturer for manufacturing NSQ drug etc. on approval of Competent Authority and follow up of the cases by attending court hearings in the Lower Court and High Court. 10. Participating as an observer along with other Regulatory Agencies of the Globe during the inspection of Indian manufacturing facilities. 11. To co-ordinate with International/Intelligence/PRO/Legal/other divisions of CDSCO (HQ) on need requirements. 12. Data submission for RTI applications/Public Grievances/ Sampling/Court case etc. requested by Head of Office/ O/o.DCG(I). 13. Review/Scrutiny of the applications of Dual Use NOC/ CT applications- CT-10, CT-12, CT-13, CT-16 & Form-12. 14. Performing the works (Administrative & Technical work) assigned by the Head of Office and DCG(I) as and when directed.
Data Entry Operator	1. Applications inward 2. Letters dispatch activity 3. Data maintenance 4. Work assigned by ADC(I)/DI

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

(iv) Exercised

Drugs and Cosmetics Act, 1940, Drug Rules, 1945 and made there under, Medical Device Rules, 2017, New Drugs and Clinical Trail Rules, 2019, Cosmetics Rules, 2020 and subsequent office orders and guidance issued by the Directorate from time to time.

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

As per Standard operating Procedure (SOP) the process of decision making is based on the identified key decision making points and 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 Directorate order/internal orders issued from time to time. Final Decision making authority is vested with the Assistant Drugs Controller (I)/ Deputy 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: 1.2 (i), (ii). Various Licenses/Permissions are issued through the SUGAM PORTAL (www.cdsconline.gov.in), NSWS portal (https://www.nsws.gov.in/) and ONDLS portal (https://www.statedrugs.gov.in/SFDA/Homepage). Time limits are specified in the SOP/Guidance document/Directorate orders. The grievances are redressed through Public Relation Officer/ Assistant Drugs Controller (I)/ Deputy Drugs Controller (I).

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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

Drugs and Cosmetics Act, 1940, Drug Rules, 1945 and made there under, Medical Device Rules, 2017, New Drugs and Clinical Trail Rules, 2019, Cosmetics Rules, 2020, Guidance document for Zonal, Sub-zonal & Port Offices, Subsequent office orders/ GSR /circulars/SOPs issued by the Directorate are followed by this office for discharging functions. Further, Manual of Office Procedure, Sugam portal User Manual, ONDLS user manual etc. 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 thefollowing:

A) Technical:

a. Manual of Office Procedures
b. Drugs and Cosmetics Act, 1940
c. Drug Rules, 1945 and made there under
d. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
e. Medical Device Rules, 2017
f. New Drugs and Clinical Trail Rules, 2019
g. Cosmetics Rules, 2020
h. Guidance document for Zonal, Sub-zonal & Port Offices
i. Directorate SOPs/Circulars/Orders/GSR issued from time to time
j. Electronic manual – SUGAM, ONDLS, NSWS etc.

B) Administrative:

Documents and records are maintained as per the normsof 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 [Section 4(1) (b) (ix)]

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

LIST OF EMPLOYEES OF CDSCO SUBZONE VISAKHAPATNAM

S. No.	NAME OF THE EMPLOYEE	DESIGNATION OF THE EMPLOYEE	LANDLINE
1.	Smt. K. Bhuvaneswari	Assistant Drugs Controller (I)	0891-2729315, 2725315
2.	Shri. Raghuvaran Gunda	Drugs Inspector	0891-2729315, 2725315
3.	Shri. Pradeep Kumar Jarajana	Drugs Inspector	0891-2729315, 2725315
4.	Shri. Venugopal Racha	Drugs Inspector	0891-2729315, 2725315
5.	Shri. Veeraiah Banothu	Drugs Inspector	0891-2729315, 2725315
6.	Shri. B. Varun Kumar	Data Entry Operator	0891-2729315, 2725315

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 SUBZONE VISAKHAPATNAM		
DETAILS OF POST WITH PAY BAND & PAY LEVEL		
Sl. No.	**Name of the Post**	**Pay Band & Pay Level**
1.	Assistant Drugs Controller (India)	Pay Band : 15600- 39100 & Pay Level- 11
2.	Drugs Inspector	Pay Band : 9300- 34800 & Pay Level- 8

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.	Dr. A. Ramkishan, Deputy Drugs Controller (India), First Appellate Authority, CDSCO Zonal office, Hyderabad.	040-23811481	hyderabad@cdsco.nic.in
2	Smt. K. Bhuvaneswari, Assistant Drugs Controller (India), Central Public Information Officer (CPIO), CDSCO Sub Zonal office, Visakhapatnam.	0891-2729315, 2725315	vskp.subzone@cdsco.nic.in

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

(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 program related to RTI attended by CPIO

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

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

(iii) Training of CPIO/APIO

CPIO-Training on Dynamics of RTI Act attended on 15.07.2015 & 16.07.2015 at Regional Training Centre, Rajaji Bhawan, Besan nagar, Chennai.

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

A guidance document related to RTI is published in web site of CDSCO

https://cdsco.gov.in/opencms/opencms/en/RTI/

Further, the guidelines issued by Central Information Commissionairefollowed

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

2. Budget and Programme

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

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

The administration of CDSCO Sub Zone, Visakhapatnam is under the control of the DDC(I), CDSCO Zonal office, Hyderabad.

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 tothe 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**	**Places Visited**	**The period of visit**	**Number of members in the official delegation**	**Expenditure on the visit**
1	**2**	**3**	**4**	**5**	**6**
1.	Smt. K. Bhuvaneswari, 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 contract isto be executed.

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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)

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

(i) Discretionary and non-discretionary grants/allocations to State Govt./NGOs/otherinstitutions

(ii) Annual accounts of all legal entities who are provided grants by public authorities

The administration of CDSCO Sub Zone, Visakhapatnam is under the control of the DDC(I), CDSCO Zonal office, Hyderabad.

2.5 Particulars of recipients of concessions, permits of authorizations granted by the publicauthority [Section 4(1) (b) (xiii)]

(i) Concessions, permits or authorizations granted by public authority

(ii) For each concessions, permit or authorization granted

a) Eligibility criteria
b) Procedure for getting the concession/grant and/orpermits of authorizations
c) Name and address of the recipients given concessions/permits or authorizations
d) Date of award of concessions/permits of authorizations

The administration of CDSCO Sub Zone, Visakhapatnam is under the control of the DDC(I), CDSCO Zonal office, Hyderabad.

2.6 CAG & PAC Para's [FNo.1/6/2011-IRdt. 15.4.2013]

CAG and PAC Para's and the action taken reports (ATRs) after these have been laid on thetable of both houses of the parliament.

The administration of CDSCO Sub Zone, Visakhapatnam is under the control of the DDC(I), CDSCO Zonal office, Hyderabad.

3. **Publicity Band Public interface**

3.1 Particulars for any arrangement for consultation with or representation by the members of thepublic in relation to the formulation of policy or implementation there of
[Section 4(1)(b)(vii)] [F.No.1/6/2011-IRdt. 15.04.2013]

Formulation of Policy and Implementation is carried out by the 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.	Bio equivalence 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

b) Day & time allotted for visitors

Formulation of Policy and Implementation is carried out by the Directorate

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

Public Relation office has been established

https://cdsco.gov.in/opencms/opencms/en/PRO/

Functions of PRO Office:

1. To act as single window for disposal of grievance of stake holders onregulatory issues.
2. To provide information to the innovator regarding regulatory norms
3. To guide, assist hand hold investors in various phases of business life cycleas 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 collectedunder authorisation 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

The administration of CDSCO Sub Zone, Visakhapatnam is under the control of the DDC(I), CDSCO

Zonal office, Hyderabad.

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 the Directorate (https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/)

Formulation of Policy and Implementation is also carried out by the Directorate.

3.3 Dissemination of information widely and in such form and manner which is easily accessibleto 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.	Bio equivalence 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

Sr. No.	Topic	URLs
1.	e-Governance	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/SUGAM_user_manual.pdf www.cdsconline.gov.in https://www.nsws.gov.in/ https://www.statedrugs.gov.in/SFDA/Homepage

(ii) Printed format

Available

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/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 the Directorate

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

(i) Details of information available in electronic form

(ii) Name/title of the document/record/other information(iii)Location where available

Refer Para 3

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

(i) Name & location of the facility

CDSCO Sub Zonal Office,
Ministry of Health & Family Welfare,
Directorate General of Health Services,
5th Floor, Karmika Jyothi Building, Visakhapatnam Port Authority,
Visakhapatnam-530001, Andhra Pradesh.

(ii) 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 laptops.

(iii)Working hours of the facility

9.30AM to 6.00 PM (Monday to Friday)
Office remains closed on Saturday/Sunday/Closed holidays

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

Assistant Drugs Controller (I)

CDSCO Sub Zonal Office,

Ministry of Health & Family Welfare,

Directorate General of Health Services,

5th Floor, Karmika Jyothi Building, Visakhapatnam Port Authority,

Visakhapatnam-530001, A.P.

Ph: 0891-2729315, 2725315

vskp.subzone@cdsco.nic.in

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

(i) Grievance redressal mechanism

Public Relation office was established

https://cdsco.gov.in/opencms/opencms/en/PRO/

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 asper 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
Competent Authority approval for creation of Sub Zonal office of CDSCO at Visakhapatnam, Andhra Pradesh was issued vide F.no.D.21013/78/2023-DC dated 21.07.2023			
1	2023-24	03	03

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

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

(iv) List of schemes/projects/programme under way-

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

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

This office has not entered into any contract.

(vi) Annual Report

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

(vii) Frequently Asked Question(FAQs)

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== 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 forthe purposes of Examination testingor analysis	https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html
5	Blood Bank	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 on the

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

Nil

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

(i) Details of applications received and disposed

S. No	Year	RTI applications received	RTI applications disposed
Competent Authority approval for creation of Sub Zonal office of CDSCO at Visakhapatnam, Andhra Pradesh was issued vide F.no.D.21013/78/2023-DC dated 21.07.2023			
1	2023-24	03	03

(ii) Details of appeals received and orders issued

Nil

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]

(iii) Name & details of

(a) Current CPIOs & FAAs

S. No	Name of the Officer	Telephone No	Email-ID
1.	Dr. A. Ramkishan, Deputy Drugs Controller (India), First Appellate Authority, CDSCO Zonal office, Hyderabad.	040-23811481	hyderabad@cdsco.nic.in
2	Smt. K. Bhuvaneswari, Assistant Drugs Controller (India), Central Public Information Officer (CPIO), CDSCO Sub Zonal office, Visakhapatnam.	0891-2729315, 2725315	vskp.subzone@cdsco.nic.in

(b) Earlier CPIO &FAAs from 1.1.2015

S. No.	Name of the office	CPIO	Appellate authority	Year
1	Assistant Drugs Controller(I) CDSCO Sub Zonal Office, Ministry of Health & Family Welfare, Directorate General of Health Services, 5th Floor, Karmika Jyothi Building, Visakhapatnam Port Authority, Visakhapatnam-530001, A.P.	Smt. K. Bhuvaneswari Assistant Drugs Controller (India), CDSCO Sub Zone, Visakhapatnam	Dr. A. Ramkishan Deputy Drugs Controller (India) CDSCO Zonal office, Hyderabad.	2023-24

(iv) Details of third party audit of voluntary disclosure

(a) Dates of audit carried out

(b) Report of the audit carried out

The check list for the Transparency Audit was duly filled and submitted

(v) 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

(vi) Consultancy committee of key stakeholders for advice on suo-motu disclosure

(a) Dates from which constituted

(b) Name & Designation of the officers

No such consultancy committee was constituted so far.

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

(a) Dates from which constituted

(b) Name & Designation of the Officers

No such consultancy committee was constituted so far.

6. Information Disclosed on own Initiative

Item / information disclosed so that public have minimum resort to use of RTI Act toobtain 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 ClinicalTrial	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 andIn-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, Ministryof Personnel, Public Grievance and Pensions, Govt. Of India)

(viii) Whether STQC certification obtained and its validity.

(ix) Does the websites how the certificate on the Website?

Website of CDSCO (www.cdsco.gov.in) is maintained by Directorate (FDA Bhawan,Kotla Road, New Delhi).