

**SUO MOTTO DISCLOSURE UNDER SECTION 4 OF RTI ACT, 2005**

(CDSCO, Port 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), PORT OFFICE,  
VISAKHAPATNAM

CDSCO Port Office (Air & Sea),  
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- [yskp.port@cdsco.nic.in](mailto:yskp.port@cdsco.nic.in)

[https://cdsco.gov.in/opencms/opencms/en/Departments/Port/Vishakapatnam\\_Sea-Port/](https://cdsco.gov.in/opencms/opencms/en/Departments/Port/Vishakapatnam_Sea-Port/)

**(ii) Head of the organization**

Smt. K. Bhuvaneshwari  
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**

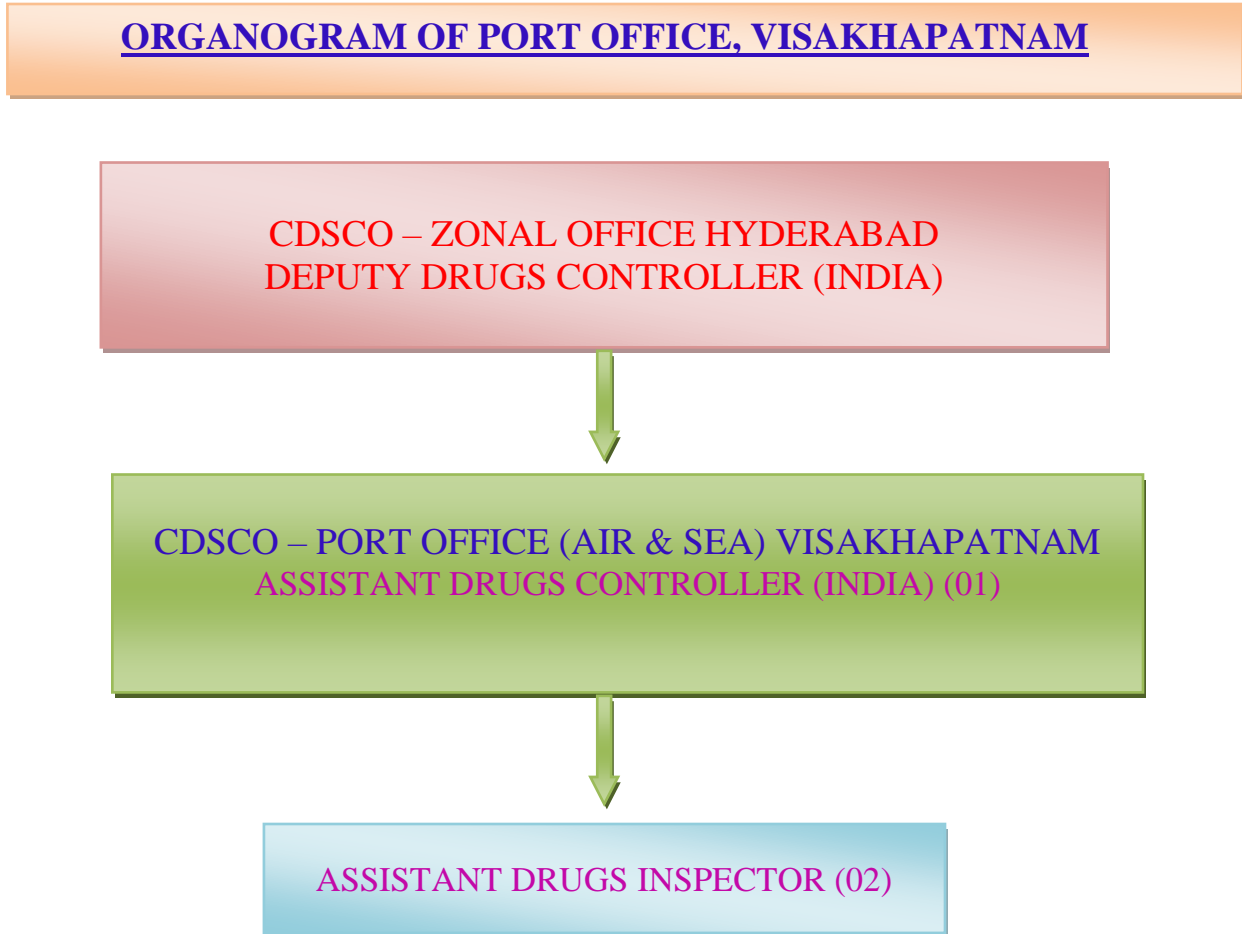
- (1) Scrutiny of the Bills of Entry with a view to ensure that the Import/Export of Drugs/Medical Devices/IVDs/Cosmetics comply with the provisions of Drugs and Cosmetics Act, 1940, Drug Rules, 1945 and made there under, Medical Device Rules, 2017, New Drugs and Clinical Trail Rules, 2019, Cosmetics Rules, 2020, Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules made there under, Narcotic Drugs and Psychotropic Substances Act & Rules made there under and any other laws for the time being in force and issuance of NOC for clearance of consignments.
- (2) Physical verification of the Import and Export consignments based on Risk based approach/ procedures/as and when required.
- (3) In the case of Narcotic Drugs and Psychotropic Substances Act & Rules, a certificate issued by the Central Bureau of Narcotics is verified for Import/Export and the details are furnished to the Drugs Controller General (India) through the Deputy Drugs Controller (India) of the respective Zone.
- (4) Ensuring that no Drugs/Medical Devices/IVDs/Cosmetics are exported/ imported into the Country unless its export/import is permitted by the Licensing Authority/ Competent Authority.
- (5) Ensuring that small quantities of drugs imported for Test, Examination and Analysis or Clinical trials or BA/BE studies or for Personal use are duly covered by Test License / Permit License as the case may be.
- (6) Maintenance of statistics data regarding Import/Export of all Drugs/Cosmetics/Medical Devices/IVD's and submission to the Deputy Drugs Controller (India) of the respective Zone/DCG(I) on monthly basis and also to other officers as and when required.

- (7) Coordination with the Commissioner of Customs for Import/Export related matters and acquaintance on Customs Act and DGFT policies.
- (8) Intimation to the concerned State Drugs Controller and the DDC(I), CDSCO of the concerned Zone regarding import of Drugs/Cosmetics/Medical Devices/IVD's under Advance Licenses/100% EOU cases for post-import check examination.
- (9) Performing Inspections with respect to Post-import check and also on other matters as directed by the DCG(I)/ DDC(I) of the concern zone.
- (10) Guidance/ Assistance given to the CHA/Trader/Importer/Exporter/Firm and providing information/ clarification on their query/ doubt.
- (11) Preparation and forwarding of Quarterly, Half yearly and Annual Reports to the DCGI (I) and DDC (I) of the concerned zone.
- (12) Examination of post parcels couriers for Import and Export of Drugs/Cosmetics/Medical Devices/IVD's referred by the Customs Authorities.
- (13) Examination and offering opinion / remarks/NOC for clearance for the bills / matters referred by the Customs Authorities/ Government Agencies.
- (14) Coordination with the Customs and other Investigating Agencies for the matters related to the violation of Import/Export under intimation to the DDC (I) of the concerned zone.
- (15) Examination of the re-import/re-export consignment and offering opinion / remarks/NOC as per the laid down procedures.
- (16) Sampling of import/ export/re-import/re-export consignments as per risk based approach and laid down procedures and forwarding to the laboratory for testing.

- (17) Examination of unclaimed/seized cargo when referred by Customs Authorities and offer opinion as per procedures laid down.
- (18) Test report received as Not of Standard Quality/Spurious for Drugs/Cosmetics/Medical Devices/IVD's is informed to the Customs Authority of the concerned area, DDC (I) of the concerned zone, DCGI (I), all port offices for necessary action.
- (19) Handling of Parliamentary Questions / RTI matters / data compilation and submission to DCG(I)/DDC(I) of concern zone.
- (20) Central Public Information Officer (CPIO) for RTI matters and providing information directly to the applicant/ to DCG (I) office as per requirements.
- (21) Handling of Administrative activities.
- (22) To organize workshops, meeting, seminar, trainings etc. as directed by the Directorate.
- (23) Coordination with subject experts and Customs Authorities and obtaining technical opinion as and when required.
- (24) Performing additional works as assigned by the DCG(I)/JDC(I)/DDC(I)/ADC(I) of CDSCO HQ/Zonal/ Sub Zonal/Port offices.

(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**

G.S.R 532(E) dated 18<sup>th</sup> May 2016– Visakhapatnam port (Air &Sea) as notified port.

G.S.R 410(E) dated 2<sup>nd</sup> June 2023 – Gangavaram port (Sea) as notified port.

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

**Table No.2**

<b>Designation</b>	<b>Duties</b>
<b>Assistant Drugs Controller (India)</b>	<p><b>Supervision and monitoring of the following activities:</b></p> <ul style="list-style-type: none"><li>(1) Scrutiny of the Bills of Entry with a view to ensure that the Import/Export of Drugs/Medical Devices/IVDs/Cosmetics comply with the provisions of 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, Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules made there under, Narcotic Drugs and Psychotropic Substances Act &amp; Rules made there under and any other laws for the time being in force and issuance of NOC for clearance of consignments.</li><li>(2) Physical verification of the Import and Export consignments based on Risk based approach/ procedures/as and when required.</li><li>(3) In the case of Narcotic Drugs and Psychotropic Substances Act &amp; Rules, a certificate issued by the Central Bureau of Narcotics is verified for Import/Export and the details are furnished to the Drugs Controller General (India) through the Deputy Drugs Controller (India) of the respective Zone.</li><li>(4) Ensuring that no Drugs/Medical Devices/IVDs/Cosmetics are exported/ imported into the Country unless its export/import is permitted by the Licensing Authority/ Competent Authority.</li></ul>

- (5) Ensuring that small quantities of drugs imported for Test, Examination and Analysis or Clinical trials or BA/BE studies or for Personal use are duly covered by Test License / Permit License as the case may be.
- (6) Maintenance of statistics data regarding Import/Export of all Drugs/Cosmetics/Medical Devices/IVD's and submission to the Deputy Drugs Controller (India) of the respective Zone/DCG(I) on monthly basis and also to other officers as and when required.
- (7) Coordination with the Commissioner of Customs for Import/Export related matters and acquaintance on Customs Act and DGFT policies.
- (8) Intimation to the concerned State Drugs Controller and the DDC(I), CDSCO of the concerned Zone regarding import of Drugs/Cosmetics/Medical Devices/IVD's under DEEC scheme/ Advance Licenses/100% EOU cases for post-import check examination.
- (9) Performing Inspections with respect to Post-import check and also on other matters as directed by the DCG(I)/ DDC(I) of the concern zone.
- (10) Guidance/ Assistance given to the CHA/Trader/Importer/Exporter/Firm and providing information/ clarification on their query/ doubt.
- (11) Preparation and forwarding of Quarterly, Half yearly and Annual Reports to the DCGI (I) and DDC (I) of the concerned zone.



- (12) Examination of post parcels couriers for Import and Export of Drugs/Cosmetics/Medical Devices/IVD's referred by the Customs Authorities.
- (13) Examination and offering opinion / remarks/NOC for clearance for the bills / matters referred by the Customs Authorities/ Government Agencies.
- (14) Coordination with the Customs and other Investigating Agencies for the matters related to the violation of Import/Export under intimation to the DDC (I) of the concerned zone.
- (15) Examination of the re-import/re-export consignment and offering opinion / remarks/NOC as per the laid down procedures.
- (16) Sampling of import/ export/re-import/re-export consignments as per risk based approach and laid down procedures and forwarding to the laboratory for testing.
- (17) Examination of unclaimed/seized cargo when referred by Customs Authorities and offer opinion as per procedures laid down.
- (18) Test report received as Not of Standard Quality/Spurious for Drugs/Cosmetics/Medical Devices/IVD's is informed to the Customs Authority of the concerned area, DDC (I) of the concerned zone, DCGI (I), all port offices for necessary action.
- (19) Handling of Parliamentary Questions / RTI matters / data compilation and submission to DCG(I)/DDC(I) of concern zone.

	<p>(20) Central Public Information Officer (CPIO) for RTI matters and providing information directly to the applicant/ to DCG (I) office as per requirements.</p> <p>(21) Handling of Administrative activities.</p> <p>(22) To organize workshops, meeting, seminar, trainings etc. as directed by the Directorate.</p> <p>(23) Coordination with subject experts and Customs Authorities and obtaining technical opinion as and when required.</p> <p>(24) Performing additional works as assigned by the DCG(I)/JDC(I)/DDC(I)/ADC(I) of CDSCO HQ/Zonal/ Sub Zonal/Port offices.</p> <p>(25) Monitoring &amp; Evaluation of the work performance/attendance/complaints &amp; discipline of the officers of CDSCO Port office Visakhapatnam.</p>
<p><b>Asst. Drugs Inspector</b></p>	<p>(1) Scrutiny of Import and Export bills related to Drugs/Cosmetic/ Medical devices/IVD's etc.</p> <p>(2) Clearance of Bills of Entries after final approval of ADC (I) through Customs-ICEGATE portal.</p> <p>(3) Physical verification of Import and Export consignments on Risk based approach.</p> <p>(4) Sampling of Import and Export consignments on Risk based approach and forwarding to the concerned laboratories for Testing.</p>

	<p>(5) Test report verification for the samples sent to the laboratory and intimation to the ADC(I) for further necessary action.</p> <p>(6) Verification of official email and intimating to the ADC (I) for further action.</p> <p>(7) Maintenance of Records related to Import and Export Bills of Entries, Sample forwarding letter, Test reports, L/G, CCFC/ PTFC Meeting, Monthly reports, Parliament related matters etc.</p> <p>(8) Data preparation with respect to Parliament queries received from HQ/Zonal/other departments</p> <p>(9) Preparation of reply to RTI related matters.</p> <p>(10) Preparing and maintaining monthly statistics of Import &amp; Export of Bulk drugs, Intermediates, Medical devices, Finished Formulations, Cosmetics, Excipients, etc.</p> <p>(11) Maintenance of Letter of Guarantee register, Movement register, Inspection register, Administrative communications/ approvals received from the DDC(I) etc.</p> <p>(12) Preparation of letters for reply to other department correspondence.</p> <p>(13) Other official work assigned by ADC(I), DDC(I) and other superior officers.</p>
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(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 Trial Rules, 2019, Cosmetics Rules, 2020, Guidance Document issued by the Directorate 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 timelimits 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 is listed in point no: 1.2 (i), (ii). NOC issued through the ICEGATE portal maintained by the Customs Department. Time limits are specified in the guidance document and instructions issued from the Customs Authority / Directorate on time to time basis. The grievances are redressed through Public Relation Officer/ Assistant Drugs Controller (I)/ Deputy Drugs Controller (I).

## 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. 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:

### 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 etc.

### B) Administrative:

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

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

**LIST OF EMPLOYEES OF CDS CO PORT OFFICE VISAKHAPATNAM**

<b>S. No.</b>	<b>NAME OF THE EMPLOYEE</b>	<b>DESIGNATION OF THE EMPLOYEE</b>	<b>LANDLINE</b>
1.	Mrs. K. Bhuvaneshwari	Assistant Drugs Controller (I)	0891-2729315, 2725315
2.	Mr. Santha Vardhan Malapolu	Asst. Drugs Inspector	0891-2729315, 2725315
3.	Ms. Vejjendla Manasa Rojamble	Asst. Drugs Inspector	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

<b>O/o THE ASSISTANT DRUGS CONTROLLER (INDIA), CDSCO PORT OFFICE VISAKHAPATNAM</b>		
<b>DETAILS OF POST WITH PAY BAND &amp; PAY LEVEL</b>		
<b>Sl. No.</b>	<b>Name of the Post</b>	<b>Pay Band &amp; Pay Level</b>
1.	Assistant Drugs Controller (India)	Pay Band : 15600- 39100 & Pay Level- 11
2.	Assistant Drugs Inspector	Pay Band : 9300- 34800 & Pay Level- 6

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.

<b>S.NO</b>	<b>Name of the Officer</b>	<b>Telephone No</b>	<b>Email ID</b>
1.	Dr. A. Ramkishan, Deputy Drugs Controller (India), First Appellate Authority, CDSCO Zonal office, Hyderabad.	040-23811481	<a href="mailto:hyderabad@cdsco.nic.in">hyderabad@cdsco.nic.in</a>
2	Smt. K. Bhuvanewari, Assistant Drugs Controller (India), Central Public Information Officer (CPIO), CDSCO Port office, Visakhapatnam.	0891-2729315, 2725315	<a href="mailto:vskp.port@cdsco.nic.in">vskp.port@cdsco.nic.in</a>

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 Commission are followed

<https://cic.gov.in/rti-notifications>

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

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

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 Port office, 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 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	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. Bhuvanewari, 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 is to be executed.

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

## 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/other institutions
- (ii) Annual accounts of all legal entities who are provided grants by public authorities

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

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

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#### 2.6 CAG & PAC Para's [F.No.1/6/2011-IRdt. 15.4.2013]

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

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### 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 thereof

[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	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/</a>
2.	Public Notices	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/</a>
3.	Bio equivalence and Bioavailability	<a href="https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html">https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html</a>
4.	Blood Products	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/</a>
5.	Vaccines	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/</a>
6.	Global Clinical Trial	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/</a>
7.	Ethics Committee	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/</a>
8.	New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/</a>
9.	Fixed Dose Combinations (FDCs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/">https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/</a>
10.	Investigational New Drugs (INDs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/</a>
11.	Subsequent New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/</a>
12.	Medical Device and In-Vitro Diagnostics	<a href="https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/">https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/</a>
13.	Cosmetics	<a href="https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/">https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/</a>

- 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 provide publications 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 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 revenues that may be collected under 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 Port office, 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 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	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/</a>
2.	Public Notices	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/</a>
3.	Alerts	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Alerts/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Alerts/</a>
4.	Bio equivalence and Bioavailability	<a href="https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html">https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html</a>
5.	Blood Products	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/</a>
6.	Vaccines	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/</a>
7.	Global Clinical Trial	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/</a>
8.	Ethics Committee	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/</a>
9.	New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/</a>
10.	Fixed Dose Combinations (FDCs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/">https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/</a>
11.	Investigational New Drugs(INDs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/</a>

12.	Subsequent New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/</a>
13.	Medical Device and In-Vitro Diagnostics	<a href="https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/">https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/InVitro-Diagnostics/</a>
14.	Cosmetics	<a href="https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/">https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/</a>

### 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	<a href="https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/SUGAM_user_manual.pdf">https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/SUGAM_user_manual.pdf</a>
2	E-sanchit	<a href="https://icegate.gov.in/eSANCHIT_Process_Guide_updated.pdf">eSANCHIT_Process_Guide_updated.pdf (icegate.gov.in)</a>

#### (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 Port office,

Ministry of Health & Family Welfare,

Directorate General of Health Services,

5<sup>th</sup> 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](http://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

10.00AM to 5.30 PM (Monday to Friday)

Saturday – Half day

Office remains closed on 2<sup>nd</sup> & 5<sup>th</sup> Saturday/Sunday/Closed holidays

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

Assistant Drugs Controller (I)  
CDSCO Port Office,  
Ministry of Health & Family Welfare,  
Directorate General of Health Services,  
5<sup>th</sup> Floor, Karmika Jyothi Building, Visakhapatnam Port Authority,  
Visakhapatnam-530001, A.P.  
Ph: 0891-2729315, 2725315  
[vskp.port@cdsco.nic.in](mailto:vskp.port@cdsco.nic.in)

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

(i) Grievance redressal mechanism

Public Relation office 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 and 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	2023-24	10	10

(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 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 the Directorate by compiling the information from the Field formations

- (vii) Frequently Asked Question (FAQs)

Sr.No.	Topic	URLs
1.	New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM0MA==">https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM0MA==</a>  Additional FAQs:  <a href="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=NDg1Ng==</a> <a href="https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU4OA==">https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU4OA==</a>
2	Medical Devices	<a href="https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Updated-FAQ-MDR_2017.pdf">https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Updated-FAQ-MDR_2017.pdf</a>
3	Phyto pharmaceuticals	<a href="https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzI0MA==">https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzI0MA==</a>
4	Import of small quantities of drugs for the purposes of Examination testing or analysis	<a href="https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html">https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html</a>
5	Blood Bank	<a href="https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html">https://cdsco.gov.in/opencms/opencms/en/FAQ/index.html</a>
6	Cosmetics	<a href="https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/cosmetics/FAQcos.pdf">https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/cosmetics/FAQcos.pdf</a>
7	BA/BE	<a href="https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/BA_BE/revidsefaqbabe.pdf">https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/BA_BE/revidsefaqbabe.pdf</a>

- (viii) Any other information such as

- a) Citizen's Charter
- b) Result Framework 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

<b>S. No</b>	<b>Year</b>	<b>RTI applications received</b>	<b>RTI applications disposed</b>
1	2023-24	10	10

(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	<a href="mailto:hyderabad@cdsco.nic.in">hyderabad@cdsco.nic.in</a>
2	Smt. K. Bhuvaneshwari, Assistant Drugs Controller (India), Central Public Information Officer (CPIO), CDSCO Port office, Visakhapatnam.	0891-2729315, 2725315	<a href="mailto:vskp.port@cdsco.nic.in">vskp.port@cdsco.nic.in</a>

(b) Earlier CPIO &FAAs from 1.1.2015

S. No.	Name of the office	CPIO	Appellate authority	Year
1	Assistant Drugs Controller(I) CDSCO Port Office, Ministry of Health & Family Welfare, Directorate General of Health Services, 5 <sup>th</sup> Floor, Karmika Jyothi Building, Visakhapatnam Port Authority, Visakhapatnam-530001, A.P.	Smt. K. Bhuvaneshwari, Assistant Drugs Controller (India), CDSCO Port office, Visakhapatnam.	Dr. A. Ramkishan, Deputy Drugs Controller (India), CDSCO Zonal office, Hyderabad.	2023- till date
2.	Assistant Drugs Controller(I) CDSCO Port Office, Ministry of Health & Family Welfare, Directorate General of Health Services, 5 <sup>th</sup> Floor, Karmika Jyothi Building, Visakhapatnam Port Authority, Visakhapatnam-530001, A.P.	Shri. Pramod A. Meshram, Assistant Drugs Controller (India), CDSCO Port Office, Visakhapatnam.	Dr. A. Ramkishan, Deputy Drugs Controller (India), CDSCO Zonal office, Hyderabad.	2022-23

3	Assistant Drugs Controller(I) CDSCO Port Office, Ministry of Health & Family Welfare, Directorate General of Health Services, 5 <sup>th</sup> Floor, Karmika Jyothi Building, Visakhapatnam Port Authority, Visakhapatnam-530001, A.P.	Shri. R. Srinivasan, Assistant Drugs Controller (India), CDSCO Port Office, Visakhapatnam.	Smt. A. Visala, Deputy Drugs Controller (India) CDSCO Zonal office, Hyderabad.	2018- 2021

(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 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 to obtain information

<b>Sr. No.</b>	<b>Type of Information</b>	<b>Related URLs</b>
1.	Gazette Notifications	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/</a>
2.	Public Notices	<a href="https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/">https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/</a>
3.	Bioequivalence and Bioavailability	<a href="https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html">https://cdsco.gov.in/opencms/opencms/en/bioequi_bioavail/index.html</a>
4.	Blood Products	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Blood-Products/</a>
5.	Vaccines	<a href="https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/">https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines/</a>
6.	Global Clinical Trial	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Global-Clinical-Trial/</a>
7.	Ethics Committee	<a href="https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/">https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/</a>
8.	New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/</a>
9.	Fixed Dose Combinations (FDCs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/">https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/</a>
10.	Investigational New Drugs (INDs)	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs-/</a>
11.	Subsequent New Drugs	<a href="https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/">https://cdsco.gov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/</a>
12.	Medical Device and In-Vitro Diagnostics	<a href="https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/In-Vitro-Diagnostics/">https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/In-Vitro-Diagnostics/</a>
13.	Cosmetics	<a href="https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/">https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/</a>

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)

(viii) Whether STQC certification obtained and its validity.

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

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