



Citizen's Charter

Central Drugs Standard Control Organization,
Directorate General of Health Services,
Ministry of Health and Family Welfare,
Government of India

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Our Vision

To Protect and Promote public health in India.

Our Mission

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

Our Values

To achieve the mission and mandate of the CDSCO we will strive to act with transparency, accountability, punctuality, courtesy, openness, responsiveness, professionalism, impartiality, consistency, integrity and truthfulness

Our Strategies

- Initiate in framing of rules, regulations and guidance documents to match the contemporary issues in compliance with the requirements of Drugs & Cosmetics Act 1940 and Rules 1945.
- Facilitate in Uniform implementation of the provisions of the Drugs & Cosmetics Act 1940 and Rules 1945.
- Function as Central license Approving Authority under the provisions of Drugs and Cosmetics Act 1940 and Rules 1945.
- Collaboration with other similar International agencies.
- Providing training to the Indian regulatory personnel.

Main Acts & Rules Enforced:

1. Drugs & Cosmetics Act, 1940 (D&C Act, 1940)
2. Drugs Rules 1945
3. New Drugs and Clinical Trials Rules, 2019 (NDCT Rules, 2019)
4. Medical Devices Rules, 2017 (MDR, 2017)
5. Cosmetics Rules, 2020

Name of the service, eligibility criteria, procedure and mode of application and applicable fee (if any)**a. Service available on SUGAM PORTAL i.e (www.cdscoonline.nic.in) portal**

S. No.	Departments / Stakeholders	Divisions	Processes	Forms Available	Eligibility criteria, details of documents & Fee (if any)
1	CDSCO HQ	Import & Registration	Fresh Registration certificate(RC), Endorsement & re-registration of drugs and Biologicals products Post submission & Post Approval Changes (PAC) of already registered drugs and Biologicals products	Form 40 / 41 Form 8 / 10 Form 8A,/10A PAC	Details checklist is available on portal and fee details as per the Drugs Rules 1945
2	CDSCO HQ	Veterinary	Fresh Registration certificate(RC), Endorsement & re-	Form 40 / 41 Form 8 / 10	Details checklist is available on

			<p>registration of drugs</p> <p>Post submission & Post Approval Changes (PAC) of already registered drugs</p> <p>Application for license to import drugs for purpose of examination, test or analysis</p>	Form12 (Integration with DAHD)	portal and fee details as per the Drugs Rules1945
3	CDSCO HQ	New Drugs/ SND/ FDC/IND	<p>Permission to manufacturing / Import / Conduct Clinical trials of New Drugs</p> <p>Application for permission to Test Licence.</p>	<p>Form CT-04/CT-18/CT-21</p> <p>Form CT-06/CT-19/20/CT-22/23</p> <p>Form CT-10/CT-12/CT-13/CT-16</p>	Details checklist is available on portal and fee details as per the NDCT Rules, 2019
4	CDSCO HQ	Cosmetics Registration	Application for Fresh RC, Endorsement, Re-registration for import of cosmetics in India & Post Approval Changes (PAC) of already registered Cosmetics	<p>COS-1/ COS-2</p> <p>COS-4/COS-4A</p> <p>PAC</p>	Details checklist is available on portal and fee details as per the Cosmetics Rules, 2020
5	CDSCO HQ	Ethics Committee Registration	Ethics committee registration & re-registration	Form CT-01/CT-02	Details checklist is available on portal and fee details as per the NDCT Rules, 2019
6	CDSCO HQ	Global Clinical Trials	<p>Permission to conduct Clinical Trials</p> <p>Import license for Test & Analysis</p>	<p>Form CT-04 / CT-06</p> <p>Form CT-16/CT-17</p> <p>PAC</p>	Details checklist is available on portal and fee details as per the NDCT Rules, 2019
7	CDSCO HQ	BA/BE	Permission to conduct BA/BE	Form CT-05/CT-07	Details checklist is

			studies, Import license for Test & Analysis. BABE site registration	Form CT-16/CT-17 CT-08	available on portal and fee details as per the NDCT Rules, 2019
8	CDSCO HQ	Biological – New Drugs- Vaccines	Permission to manufacturing / Import / Conduct Clinical trials of New Drugs. Application for permission to Test Licence.	Form CT-04/CT-18/CT-21. Form CT-06/CT-19/20/CT-22/23 Form CT-10/CT-12/CT-13/CT-16	Details checklist is available on portal and fee details as per the NDCT Rules, 2019
9	CDSCO HQ	SAE Reporting	Serious Adverse Events Reporting		Details checklist is available on portal and fee details as per the NDCT Rules, 2019
10.	CDSCO Port Offices	Port Offices	Permission to Import Drugs in small quantity for personal use	Form 12A/12B	Details checklist is available on portal
11	CDSCO HQ	International Cell	Grant/Renewal of Written Confirmation		Detail checklist is available on portal
12	CDSCO Zonal Office		Application for permission to Test Licence.	Form CT-10/CT-12/CT-13/CT-16	Details checklist is available on portal and fee details as per the NDCT Rules, 2019
13	CDSCO Zonal Office		Dual Purpose NOC		Details checklist is available on portal
14	CDSCO Zonal Office		Export NOC		Details checklist is available on portal

b. Service available on MEDICAL DEVICE/IN-VITRO DIAGNOSTICS KITS PORTAL i.e (www.cdscmdonline.nic.in)

S. No.	Departments	Processes	Forms Available	Eligibility criteria, details of documents & Fee (if any)
1	CDSCO Zone & CDSCO HQ	Application for Grant of Licence to Manufacture for Sale or for Distribution of Class C or Class D Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D	Form MD-7/Form MD-9 Form MD-8/Form MD-10, Cases of PAC	Details checklist is available on portal and fee details as per the Medical Device Rules, 2017
2	CDSCO HQ	Application for Grant of Permission to Conduct Clinical Investigation of an Investigational Medical Device	Form MD-22/Form MD-23	Details checklist is available on portal and fee details as per the Medical Device Rules, 2017
3	CDSCO HQ	Application for Grant of Permission to Conduct Clinical Performance Evaluation of New in vitro Diagnostic Medical Device	Form MD-24/Form MD-25	Detail checklist is available on portal and fee details as per the Medical Device Rules, 2017
4	CDSCO HQ	Application for Grant of Permission to Import/Manufacture for Sale or for Distribution of Medical Device which does not have Predicate Medical Device Application for Grant of Permission to Import or Manufacture for Sale or for Distribution of new in vitro Diagnostic Medical Device	Form MD-26/Form MD-27 Form MD-28/Form MD-29	Details checklist is available on portal and fee details as per the Medical Device Rules, 2017
5	CDSCO HQ	Application for issue of import licence to import medical device	Form MD-14/Form MD-15, Cases of PAC	Details checklist is available on portal and fee details as per the Medical Device Rules, 2017
6	CDSCO HQ	Application for Grant of Registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer	Form MD-39/Form MD-40	Detail checklist is available on portal and fee details as per the Medical Device Rules,

				2017
7	District Office of each state	Sell, Stock, Exhibit or Offer For Sale or Distribute	Form MD-41/Form MD-42	Available on Medical Device Rules, 2017
8	CDSCO Port Office, CDSCO HQ	Application for personal licence Application for licence to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients	Form MD-20/Form MD-21 Form MD-18/Form MD-19	Available on Medical Device Rules, 2017
9	State Licensing Authority	Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B Medical Device Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B Medical Device	Form MD-3/Form MD-5 Form MD-4/Form MD-6, Cases of PAC	Details checklist is available on portal and fee details as per the Medical Device Rules, 2017
10	State Licensing Authority, CDSCO Zone, CDSCO HQ	Free Sale Certificate, Market Standing Certificate, Non Conviction Certificate	FSC, MSC, NCC	Details checklist is available on portal and fee details as per the Medical Device Rules, 2017

c. Service available National Single Window System (NSWS) PORTAL i.e (www.nsws.gov.in)

S. No.	Departments / Stakeholders	Divisions	Processes	Forms Available	Eligibility criteria, details of documents & Fee (if any))
1	CDSCO Zone	Zonal / Sub Zonal Offices (Test License and Form 12)	Import License for Test & Analysis, for Drugs more than 4 years (Old Drugs)	Form 12 / 11 Form CT-10/CT-11, CT-12/CT-14, CT-13/CT-15, CT-16/CT-17	Details checklist is available on portal and fee details as per the Drugs Rules 1945 and NDCT Rules, 2019
2	CDSCO HQ & CDSCO Zone	Medical Device & IVD Division & Zonal Office	Application for Licence to Manufacture	Form MD-12/MD-13	Details checklist is available on

			Medical Device for Purpose of Clinical Investigation, Test, Evaluation, Examination, Demonstration or Training		portal and fee details as per the Medical Device Rules, 2017
3	CDSCO HQ	Medical Device & IVD Division	Application for Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training	Form MD-16/Form MD-17	Details checklist is available on portal and fee details as per the Medical Device Rules, 2017
4.	CDSCO HQ	Medical Device & IVD Division	Application for grant of Certificate of Registration of a Notified Body	Form MD-1/Form MD-2	Details checklist is available on portal and fee details as per the Medical Device Rules, 2017

d. Service available on Online National drugs Licensing System (ONDLS) PORTAL i.e (www.statedrugs.gov.in)

S. No.	Departments	Processes	Forms Available	Eligibility criteria, details of documents & Fee (if any)
1	CDSCO Zone & CDSCO HQ	<p>Application for grant/renewal* of licence for the operation of a Blood Bank for processing of whole blood and/or* preparation of Blood Components.</p> <p>Application for grant or renewal and of a licence/loan licence to manufacture for sale or for distribution of [Large Volume Parenterals/Sera and Vaccines /recombinant DNA (r-DNA) derived drugs]excluding those specified in Schedule X</p>	<p>Form 27C/28C</p> <p>Form 27D/28D</p> <p>Form 27DA/28DA</p>	Details checklist is available on portal and fee details as per the Drugs Rules, 1945

Targeted internal timeline for processing and disposal of applications by CDSCO

A) Drugs & Biologicals

Sr. No.	Type of application	Targeted internal timeline in working days
1.	New Drugs / Investigational New Drugs	
	a. IND Applications in consultation with Subject Expert Committee (SEC)	30
	b. New Drug including Biological / Clinical Trials / Global Clinical Trials / New Claims in consultation with Subject Expert Committee(SEC)	90
	c. Subsequent New Drugs (SND) with Subject Expert Committee (SEC)	90
	d. Fixed Dose Combination in consultation with Subject Expert Committee (SEC)	90
2.	Import Registration of Drugs & Biologicals	270
3.	Import License in Drugs & Biological	45
4.	Import post approval changes for drugs:	
	a. Major	180
	b. b. Minor	90
5.	Endorsement of Additional Product in Registration certificate	120
6.	Rule37& Neutral Code	60
7.	Grant of permission for manufacturing of:	
	a. New drug or investigational new drug for CT, BA or BE study or for examination, test and analysis (CT-11)	7
	b. Formulation of unapproved API for test or analysis or CT or BA or BE study (CT-14)	
	c. Unapproved active pharmaceutical ingredient for the development of formulation for test or analysis or CT or BA or BE study (CT-15)	
8.	CLAA in Form28, 28A, 28D, 28-DA, 28-C, 26-G, 28-E, 26-I, 28-F, 26-J.and etc	60
9.	Licence to import new drug or investigational new drug for the purpose of clinical trial or bioavailability or bioequivalence study or for examination, test and analysis(CT-I7)	7

10.	Permission to conduct Bioavailability/ Bioequivalence (BA/BE) Study for new drug or investigational new drug (CT-07)	90
11.	Extension of Shelf Life for export	45
12.	Registration of Ethics Committee(CT-02)	45
13.	Biological Post Approval Changes	
	a. Major in consultation with CDL, SEC	180
	b. Minor	90
14.	Permission for BA-BE study and its Post Approval Changes for export purpose	15
15.	Registration of BA / BE study center(CT-09)	90
16.	Written Confirmation (WC) as per EU Directives	20
17.	Permission to Import small quantity of drugs for personal use	3

B. Medical Device & In-vitro Diagnostics:

Sr.no	Type of application	Timeline in Working days
1.	Grant of Test license to manufacture for test, evaluation, clinical investigations, etc.(MD-13)	30
2.	Grant of Import License (MD-15)	270
3.	Grant of test License for import for test, Evaluation and Clinical investigations.(MD-17)	30
4.	Permission to Import small quantity of medical device for personal use.(MD-21)	7
5.	Permission to conduct Clinical Investigation(MD-23)	90
6.	Permission to conduct clinical performance evaluation of new in vitro diagnostic medical device (MD-25)	90
7.	Permission to import or manufacture medical devices which does not have its predicate device(MD-27)	120
8.	Permission to import of manufacture new invitro diagnostic medical devices(MD-29)	90
9.	Certificate of registration to Medical Device Testing Laboratory for carryout Test or Evaluation of a medical device on behalf of manufacturer(MD-40)	45
10.	Licence/Loan License to Manufacture for Sale Or for Distribution of Class C or Class D medical device(MD-9)/(MD-10):	
	a. Completion of scrutiny from the date of online submission of application	45
	b. Inspection of manufacturing premises from the date of application	60
	c. Grant of license from the date of receipt of Inspection report.	45
11.	Application for post approval change in manufacturing licenses Prior approval to be obtained from CLA/SLA in major change	45

12.	Application for post approval change in Import Licenses Prior approval to be obtained from CLA/SLA in major change	60
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C. Cosmetics

Sr.No	Type of application	Targeted internal timeline in working days
1.	Fresh RC, Endorsement, Re-registration (Cos- 1/Cos-2)	180
2.	Application for license to import cosmetics already registered (Cos-4/Cos-4A)	180

Note: In case of query or examination, the time line will be from the date of receipt of the response from the applicant.

Right to Information

Information is available on the website of CDSCO i.e. www.cdsco.gov.in

Public Grievance

Public Relations Office at CDSCO is a dedicated office set up with a mandate to act as an interface between CDSCO and its stakeholders including general public for the exchange and dissemination of information to below mentioned objectives.

- Acting as 'Single Window' for disposal of grievances of Stakeholders.
- Provide information to the innovators regarding regulatory requirements for commercialization of their products
- Provide clarifications pertaining to Drugs & Cosmetics Act, 1940 and Rules made there under.
- Guide and assist to handhold investors in various phases of business life cycle as per existing focus on "Invest India/ Make in India".

Public Relations Office (PRO) is headed by Assistant Drugs Controller (India) and supported by competent technical staff. PRO is located behind the Reception of CDSCO, FDA Bhawan at Ground Floor and is functional from 10:00 AM to 05:30 PM on all working days. PRO division directly reports to DCGI.

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