
**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**

- Drugs & Cosmetics Act, 1940
- Drugs Rules1945
- New Drugs and Cosmetics Rules, 2019
- Medical Devices Rules, 2017
- Cosmetics Rules, 2020

**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. Minor | 90 |
| 5. | Endorsement of Additional Product in Registration certificate | 120 |
| 6. | Rule37& Neutral Code | 60 |
| 7. | Grant of permission for manufacturing of:<br>a. New drug or investigational new drug for CT, BA or BE study or for examination, test and analysis(CT— 11)<br>b. Formulation of unapproved API for test or analysis or CT or BA or BE study (CT-14)<br>c. Unapproved active pharmaceutical ingredient for the development of formulation for test or analysis or CT or BA or BE study (CT-15) | 7 |
| 8. | CLAA in Form28/28-D128-E/27-C 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 | 7 |

| | | |
|---|---|---|
| | examination, test and analysis(CT-l7) | |
| 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 | l5 |
| 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 Iicense to manufacture for test, evaluation, clinical investigations, etc.(MD-15) | 30 |
| 2. | Grant of Import License (MD-15) | 270 |
| 3. | Grant of test License for import for test. evaluation. Clinical investigations.(MD-17) | 30 |
| 4. | Permission to Import small quantity of medical device for personal use.(MD-2I) | 7 |
| 5. | Permission to conduct Clinical Investigation(MD-23) | 90 |
| 6. | Permission to conduct clinical performance evaluation of new invitro 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 A or Class B Medical Device (MD-5)/(MD-6): | |
| | For Class A Medical Devices: | |
| | Grant of license by SLA | 45 |
| | ii)Audit of the manufacturing site by the registered Notified Body from the date of issue of License by SLA | 120 |
| | For Class B Medical Devices: | |

| | | |
|---|---|---|
| | Audit of the manufacturing site by the registered Notified Body from the date of application | 90 |
| | ii)Inspection Report submitted to SLA | 30 |
| | iii)Grant of license by SLA | 20 |
| 1I. | 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. | 4,; |
| 12. | Application for post approval change in manufacturing licenses Prior approval to be obtained from CLA/SLA in major change | 45 |
| 13. | Application for post approval change in Import Licenses<br>Prior approval to be obtained from CLA/SLA in major change | 60 |

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 commercialisation 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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