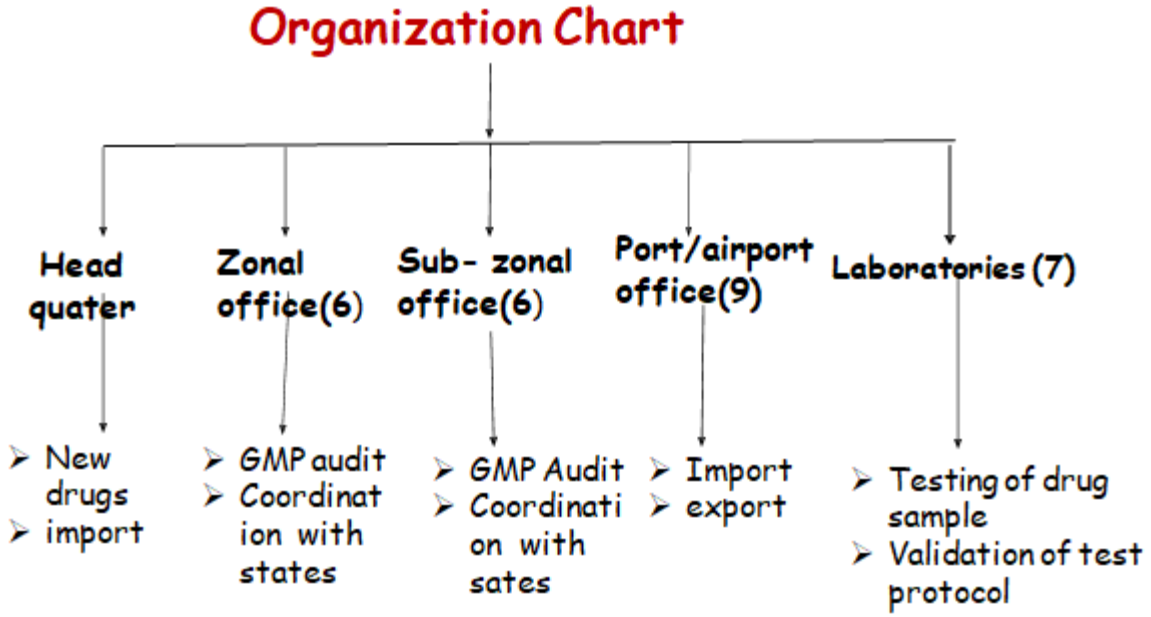
Central drug standard and control organization (CDSCO)

The Central drug standard and control organization (CDSCO) is the main regulatory body of India for regulation of pharmaceutical, medical devices and Clinical Trials. CDSCO is the Central Drug Authority for discharging function assigned to the Central Government under the Drug and cosmetics Act. CDSCO is functioning under the control of Directorate General of Health Services, Ministry of health and family welfare, Government of India. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi.

The Vision of CDSCO is to Protect and promote public health in India. The Mission is to safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.



Zonal offices

These are involved in GMP audits and inspection of manufacturing units of large volume parental, sera, vaccines and blood products.

Mumbai, Kolkata, Chennai, Ghaziabad, Ahmedabad, Hyderabad,

Sub-zonal offices

These centre co-ordinate with state drug control authorities under their jurisdiction for uniform standard of inspection.

Bengaluru, Varanasi, Goa, Jammu, Indore, Guwahati, Baddi

Port/airport office

Delhi, Chennai, Hyderabad, Indore port, Kolkata port, Mumbai port, Cochin port, Vishakhapatnam sea-port, Krishnapatanam sea-port

Laboratories

CDL (Kolkata), CDL (Kasauli), CDTL (Mumbai), CDTL (Hydrabad), CDTL (Chennai), RDTL (Chandigadh), RDTL (Guwahati)

Functions of Central Authority

1. Laying down standards of drugs, cosmetics, diagnostics and devices.
2. Laying down regulatory measures, amendments to Acts and Rules.
3. To regulate market authorization of new drugs.
4. To regulate clinical research in India
5. To approve licenses to manufacture certain categories of drugs as Central License approving Authority i.e. for Blood Banks, Large Volume Parenteral and Vaccines & Sera.
6. To regulate the standards of imported drugs.

- Testing of drugs by Central Drugs Labs- CDSCO also works in close context with Central Drug Laboratories to perform quality control tests.

7. Publication of Indian Pharmacopoeia.

- To regulate imported drugs as authority, the CDSCO works with the Drugs Technical Advisory Board and the Drugs Consultative Committee, while the Central Drugs Laboratory undertakes testing of such drugs.
- The central authorities are responsible for approval of new drugs, clinical trials in the country, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control Organizations and providing expert advice with a view of bringing about the uniformity in the enforcement of the Drugs and Cosmetics Act.

- The state authorities on the other hand are concerned with the regulation of manufacture, sale and distribution of Drugs licensing drug testing laboratories, approving drug formulations for manufacture, carrying out pre- and post-licensing inspections, and overseeing the manufacturing process, for drugs manufactured by respective state units and those marketed in the state. These authorities are formed under the Drug and Cosmetics Act 1940 and Rules 1945.

Functions of Port Offices of CDSCO

- Scrutiny of bills of entry with a view to ensuring imported drugs complies with the regulations.
- To check the shipping bills for export for statistical data and keep control under the regulations
- To ensure that no New Drug is imported into the country unless its import is permitted by the Drugs Licensing Authority under Rules 122 A & 30-AA.
- To ensure that small quantities of drugs imported for clinical trials or for personal use are duly permitted under Test License (11 or 11-A) or Permit License as (12 B) as the case may be.
- Maintenance of Statistics regarding import and export of drugs and cosmetics.
- Coordination with Customs authorities.
- Coordination with States Drugs Controllers and Zonal Offices for post-import checks.
- Preparation of monthly / quarterly / annual reports.
- To draw samples from import/export and re-import consignments

Functions of State Authority

- Licensing of drug manufacturing and sales establishments.
- Licensing of drug testing laboratories.
- Approval of drug formulations for manufacture.
- Monitoring the quality of Drugs & Cosmetics, manufactured by respective state units and those marketed in the state.
- Investigation and prosecution in respect of contravention of legal provisions.
- Administrative actions.
- Pre- and post- licensing inspection
- Recall of sub-standard drugs.

Clinical Trials Process

Schedule Y of drug and cosmetics act explain the guidelines for grant of permission for conducting clinical trials in India.

The protocol for such trials is examined by the office of DCGI before the permission is granted.

Office of DCGI also gives grant permission for conducting bioequivalence studies.

Registration of clinical trials has been made mandatory with centralized clinical trials.

Drug cosmetics rule are being amended to make mandatory the registration of clinical research organization.

Drug and cosmetics act is proposed to be amended to include a separate chapter on clinical trials.

Cosmetics

For import of cosmetics in India required to be registered with central drugs standard control organisation (CDSCO) by giving application in Form 42 to obtain registration certificate in Form 43.

The manufactured person/ the authorised agent can be an applicant for issuance of registration certificate for import of cosmetics into India.

License will grant within 6 months.

The following licenses are required for cosmetic products:

License on Form 32 is issued for manufacturer/sale distribute of cosmetics.

License on form 32A is issued for loan license for manufacture/sale distribute of cosmetics.(Form 31A)

MEDICAL DEVICES

New Guidelines were effective from Jan 1, 2018

The Risk based classification for medical devices

Class A- Low Risk (Thermometer, Tongue Depressor)

Class B- Low Moderate Risk (Suction Equipment, Hypodermic Needle)

Class C-High Moderate Risk (Ventilator, Bone Fixation Plate)

Class D- High Risk (Heart Valves)

Type of license which can be applied through SUGAM portal

Registration certificate – Form 41 for drug

Registration certificate – Form 41 for medical device

Registration certificate – Form 41 for diagnostic kit

Import license- form 10 for drug

Import license- form 10 for medical device
Import license- form 10 for diagnostic kit
Test license for clinical trails
Registration certificate for cosmetics.

Certificate of Pharmaceutical Product (CoPP)

- The certificate of pharmaceutical product (CPP or CoPP) is a certificate issued in the format recommended by the World Health Organization (WHO).
- The WHO GMP certificate is mandatory in most global markets for pharmaceutical companies to be able to sell medicines.
- The manufacturer of an exporting country must be licensed by the regulatory authority of that country and comply with the WHO GMP guidelines
- The Central Drugs Standard Control Organization (CDSCO), which is the national drugs regulatory authority, regulates the import and export of the drugs in the country, through the port offices located in different parts of the country.
- The importing country is required to register (license, authorize) or renew (extend) the registered with the scope of commercialization or distribution in that country.
- Certification has been recommended by WHO to help undersized drug regulatory authorities or drug regulatory authorities without proper quality assurance facilities in importing countries to assess the quality of pharmaceutical products as prerequisite of registration or importation.
- The application for grant of WHO GMP Certificate of Pharmaceutical Product shall be made to respective zonal/sub zonal officers as per the requirement.
- The COPP will be issued by zonal/sub zonal officers on behalf of Drugs Controller General (India) after inspection and satisfactory clearance by CDSCO officers as per WHO – GMP guidelines

General requirements for submission of application for issue of COPP.

A forwarding letter/application shall be addressed to DDC(Department of Drug control) (I)/ADC(Assistant Drug Controller)(I) of respective CDSCO zonal/sub zonal offices with copy of covering letter & product summary sheet to DCG(I) by authorized person only.
Application should clearly indicate for fresh certification (Grant) or reissue of products applied, accordingly it will be scrutinized for the products applied.
Applications will be reviewed by CDSCO officers and completed applications in all respects would be accepted for inspection on first come first serve basis.
The forwarding letter/application shall be accompanied with

1. List of products applied for grant of COPP, along with the a product permission copy (manufacturing license issued by the SLA) &
2. notarized product summary sheet,
3. site master file as per WHO-GMP requirement
4. List of major/master documents like master validation plan, quality manuals, specifications, master formula records maintained by firm and list of SOP's (to indicate the documentation system of firm).
5. Manufacturing layout.
6. List of personnel (with designation, qualification & experience), List of equipments, instruments, utilities along with make and model & capacity.

7. List of primary & secondary Impurity and Reference standards/cultures available with the firm (relevant to the applied products for grant of COPP).

Procedure for accepting the application for issue of COPP

- All applications received will be scrutinized by CDSCO Officials after receipt and query letter will be sent to applicant, if any or otherwise will be considered for inspection.
- Inspection will be carried out by CDSCO Officers as per WHO GMP guidelines of TRS 823/908 for non sterile products, TRS 822/902 for Sterile Products and other relevant guidelines in TRS937, TRS 929, TRS 863 etc. as applicable from time to time.
- Self appraisal checklist should be filled and submitted to CDSCO officer before inspection.
- Inspection teams verify the checklist at the time of inspection.
- Inspectors brief the inspection findings at the exit meeting
- The report should clearly define deficiencies as per WHO GMP guidelines.
- Respective Zonal/ Sub-Zonal certifying authority prepare "Review Report" based on review of observations of check list and written inspection report as per WHO GMP guidelines.
- Firm may reapply, if required after proper compliance after 5 months from date of rejection.

  If the same firm applies after 5 months, scrutiny of such application should be asked for earlier compliance with documentary evidences in addition to the usual general requirements for submission of application for issue of COPP

Format

This certificate conforms to the format recommended by the World Health Organization

No. of certificate

Exporting (certifying country):

Importing (requesting country):

1. Name and dosage form of the product:

   1.1. Active ingredient(s) and amount(s) per unit dose

   1.2. Is this product licensed to be placed on the market for use in the exporting country? (Yes/no)

   1.3 Is this product actually on the market in the exporting country?

   If the answer to 1.2. Is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B:

   2. A.1 Number of product license and date of issue:

   2. A.2 Product license holder (name and address)

   2. A.3 Status of product license holder:

2. A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:

2. A.4 Is a summary basis for approval appended? (Yes/no)

2. A.5 Is the attached, officially approved product information complete and consonant with the license? (yes/no/not provided)

2. A.6 Applicant for certificate, if different from license holder (name and address):

2. B.1. Applicant for certificate (name and address):
2. B.2. Status of applicant:
2. B.3. Why is marketing authorization lacking? (Not required/not requested/under consideration/refused)
2. B.4. Remarks:
3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (Yes/no/not applicable)

- If not or not applicable, proceed to question 4

3.1. Periodicity of routine inspections (years)

3.2. Has the manufacture of this type of dosage form been inspected? (Yes/no)

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? (Yes/no/not applicable)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product: (yes/no)

If no, explain:

Telephone: Fax: Name of authorized person:

Signature:

Address of certifying authority: Stamp and date

Documents required for applying for granting or revalidation of COPPs:

1. Application from Manufacturer
2. Site Master file (as specified under WHO TRS 823)
3. Copy of Manufacturing License
4. List of Approved Products
5. List of products applied for issuance of COPPs
6. List of SOPs and STPs
7. Stability Data (3 batches) Accelerated/Real Time
8. List of equipment and Instruments
9. List of Technical staff, their qualification, experience and approval status
10. Manufacturing Layout Plan
11. Process validation for 3 batches of each product
12. Schematic diagram of Water system specifying circulation loop and MOC (Material of Construction)
13. Schematic diagram of HVAC system specifying terminal filter configuration
14. Export data of last 2 years in case of revalidation