Indian regulatory requirements

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- Resolution strategies of CDSCO
- Organization locations of CDSCO.
- Central drug testing laboratories send functions
- Other Major activities of CDSCO

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REGULATORY REQUIREMENTS AND APPROVAL PROCEDURE FOR NEW DRUGS

- IND
- CLINICAL TRIALS
- CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP)

  NDA

INTRODUCTION TO INDIAN REGULATORY REQUIREMENTS

- The Central Drug Standard Control Organization (CDSCO) regulates drugs, cosmetics, diagnostics and devices in India.
- It is headed by the Drug Controller General of India (DCGI), responsible for safety, efficiency and quality standards for pharmaceuticals and medical device and publisher of the Indian Pharmacopoeia.
- The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Commission (DCC).
- State Government is responsible for licensing, approvals, inspection and recalls of drugs manufactured within their domain.
- India is main regulatory body for regulation of pharmaceuticals and medical devices and the Drug Controller General of India (DCGI) is responsible for the regulation of pharmaceuticals and medical devices.
-

INTRODUCTION TO INDIAN REGULATORY REQUIREMENTS Cont....

- The CDSCO works with the World Health Organization to promote Good Manufacturing Practice (GMP) and international regulatory harmony.
- The organization responsible for approved issuance of license for various categories of drugs such as blood and blood products, I.V. fluids, vaccines, sera etc., either manufacturing in India or imported.
- It regulates the manufacturing, sale, distribution of drugs through the state authorize and register manufacturing, sale and distribution of drugs.

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)

- The CDSCO is the main regulatory body for regulation of pharmaceuticals, 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.
- The head office of CDSCO is located in New Delhi and it is functioning under the Control of Directorate General of Health Services, Ministry of Health and Family Control of Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.
- Drug Controller General of India (DCGI): He/She is responsible for approval of new drugs, medical devices and clinical Trials to be conducted in India. The person who is appointed by the Central Government under the DCGI the state drug control organization will be functioning. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).


WHO declares CDSCO
as Functional
NRA (National Regulatory Authority)


Drugs Controller General of India
Dr. V.G. Somani

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

Dr. V. G. Somani

Dr. S.Eswara Reddy

Dr. P. B. N. Prasad

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Phone (Office) : [illegible]

E-mail : [illegible]

Deputy Drugs Controller (INDIA)
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Dr. S P Shani
Sh. R Chandrashekar
Smt. Swati Srivastava
Sh Sanjeev Kumar
Sh. R.K Samantray
Dr. Ravi Kant Sharma
Sh. Gulshan Taneja

Asst. Drugs Controllers (India)	
Name	Name
Dr. Santosh Vitthalrao Indrakala	Sh. Navneet Pratap Singh
Sh. Gaurav Kumar	Sh. Ankit Sharma
Dr. Rikta Saha	Sh. K Narendran
Sh. Vijay Vitthalrao Chandurkar	Sh. Kishore Deodikar
Sh. Rajesh Kumar Verma	Dr.Gouri Shankar
Sh.Srinivasan K.H	Smt.Indira P
Sh.Nishtrun Pramod Amar Rao	Sh.Y K Shelar
Sh.Somnath Basu	Smt. Shradha Srivastava

Director (Administration)		
Name	Phone	E-Mail
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Deputy Director Administration (Drugs)		
Name	Phone	E-Mail
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Section Officer (Administration)		
Name	Phone	E-Mail
Shri Thaokhelal Bodo	(OR) 91-11-23216367 Ext 319	[illegible]

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)

- The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India.
- Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has Six zonal offices, Four sub zonal offices, Thirteen Port offices and Seven laboratories spread across the country. Laboratories spread across the country.
- The Drugs & Cosmetics Act,1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics.
- It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well being of the patients by regulating the drugs and cosmetics.
-


Drugs Controller General (I)
(Dr.V.G Somani)
Head Quater
(New Delhi)
Zonal Offices
(6)
Sub-Zonal Offices
(7)
Port/Air Port Offices
(13)
Laboratories
(7)
Head Quater :
New Delhi
Zonal Offices:
North Zone- Ghaziabad
South Zone-Chennai
West Zone- Mumbai
East Zone - Kolkatta
Hyderabad Zone
Ahmedabad Zone
Sub-Zonal Offices:
Bangalore
Varanasi
Goa
Jammu
Indore
Guwhati
Rohtk
Port Offices:
Ahmedabad
Chennai Port
Chennai Airport
Bangalore
Hyderabad
Goa
Kochi
Delhi
Kolkata Port
Kolkata Air Cargo
Mumbai Air Cargo
Mumbai Nhava Sheva
Mumbai Custom House
Laboratories:
CDL, Kolkata
CDTL, Mumbai
RDTL, Guwahati
RDTL, Chandigarh
CDL, Kasauli
CDTL, Hyderabad
CDTL, Chennai
*IVRI Izatnagar
*NDR Noida
*IPC Ghaziabad
AYUSH
STAFF:
DDC (Ayurveda)
DDC (Homeopathy)
ADC (Ayurveda/Unani/Siddha)
DI(Ayurveda/Unani /Homeo/Siddha)
STAFF:
JDC(I)
DDC(I)
ADC(I)
DI
ADI
TDAs
Supporting Staff
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DDC(I)
ADC(I)
DI
ADI
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STAFF:
ADC(I)
DI
TDAs
Supporting Staff
STAFF:
ADC(I)
DI
TDAs
Supporting Staff
STAFF:
Director
Dy. Director
Sr. Scientific Officer I
Sr. Scientific Officer II
Research Officer
Sr. Scientist Assistant
Jr. Scientist Assistant
Supporting Staff

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)

- CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.

- 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 and coordination of the activities of State quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act. 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.

FUNCTIONS OF CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)

- **VISION :** To protect and promote health in India.
- **MISSION :** To safeguard and enhance the public health by assuring the safety, efficacy, and quality of drugs, cosmetics and medical devices.
- **Major functions of CDSCO**: Regulatory control over the import of drugs
- Approval of new drugs and clinical trials
- Meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB)
- Approval of certain licenses as Central License Approving Authority is exercised by the CDSCO headquarters.
- Central Drugs Standard Control Organization Head quarter is located at FDA Bhawan, Kotla Road, New Delhi and functions under the Directorate General of Health Services.
-

FUNCTIONS OF CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO) Cont....

FUNCTIONS of CDSCO Under the Drug and Cosmetics Act,

- **State authorities:** - The regulation of manufacture, sale and distribution of Drugs is primarily the concern of the state authorities.
- **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 bring about the uniformity in the

    enforcement of the Drugs and Cosmetics Act.

- **Drug Controller General of India is responsible for:** Approval of licenses of specified

  categories of Drugs such as blood and blood products, I.V. Fluids, Vaccine and Sera.

Functions of CDSCO

- Approval of new drugs and clinical trials
- Import Registration and Licensing
- License approving of Blood Banks, LVPs, Vaccines, r-DNA products & some Medical Devices (CLAA Scheme)
- Amendment to D &C Act and Rules
- Banning of drugs and cosmetics
- Grant of Test License, Personal License, NOCs for Export
- Testing of New Drugs
- Oversight and market Survillance through Inspectorate of Centre Over and above the State Authority

VALUES/ STRATEGIES of CDSCO

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.

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.

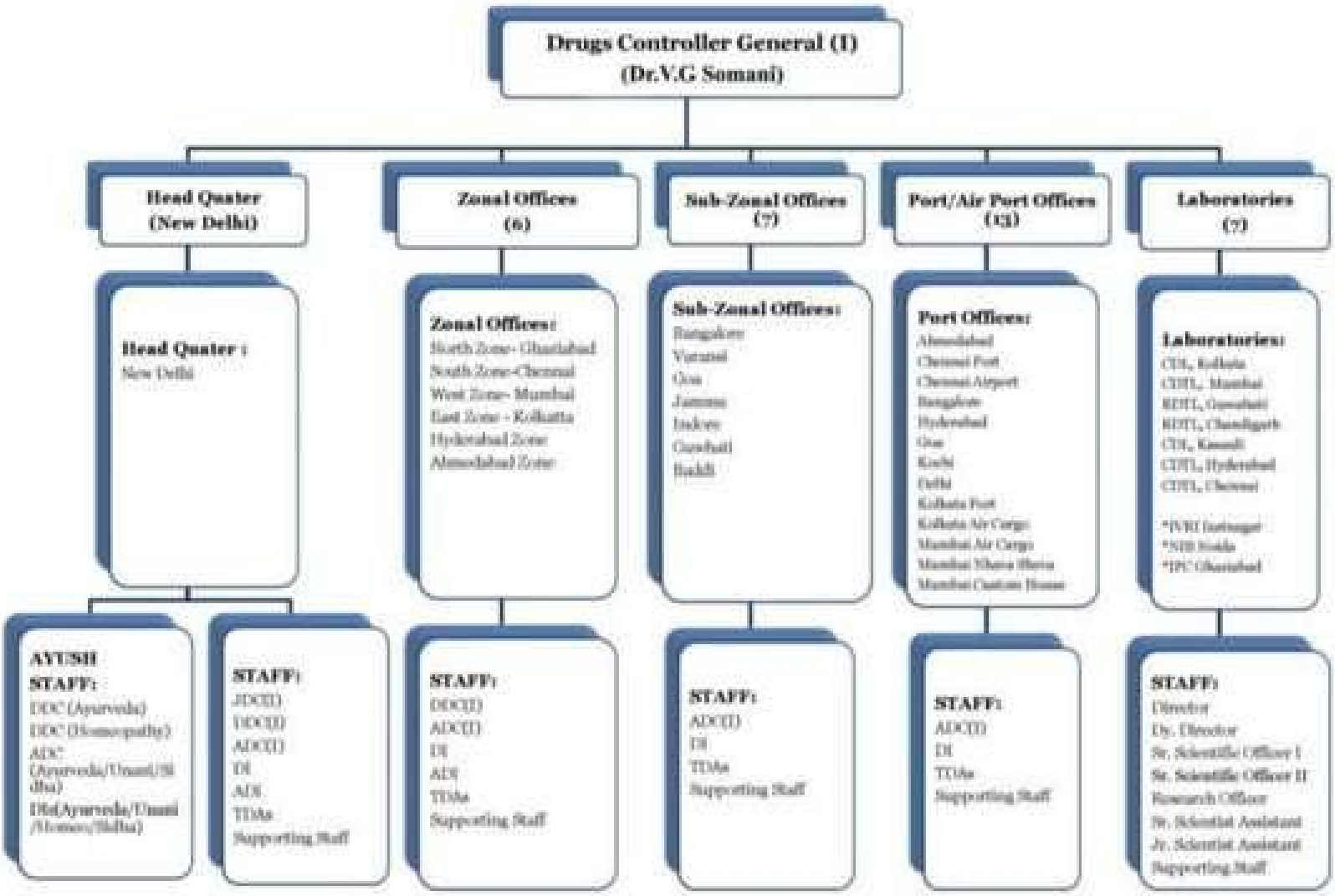

Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
icdrc
Contact Us

ORGANIZATION LOCATIONS

OF

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)

Organization Chart


Drugs Controller General (I)
(Dr.V.G Somani)
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Port/Air Port Offices
(13)
Laboratories
(7)
Head Quater :
New Delhi
Zonal Offices:
North Zone- Ghaziabad
South Zone-Chennai
West Zone- Mumbai
East Zone - Kolkatta
Hyderabad Zone
Ahmedabad Zone
Sub-Zonal Offices:
Bangalore
Varanasi
Goa
Jammu
Indore
Guwhati
Baddi
Port Offices:
Ahmedabad
Chennai Port
Chennai Airport
Bangalore
Hyderabad
Goa
Kochi
Delhi
Kolkata Port
Kolkata Air Cargo
Mumbai Air Cargo
Mumbai Nhava Sheva
Mumbai Custom House
Laboratories:
CDL, Kolkata
CDTL, Mumbai
RDTL, Guwahati
RDTL, Chandigarh
CDL, Kasauli
CDTL, Hyderabad
CDTL, Chennai
*IVRI Izatnagar
*NDI Noida
*IPC Ghaziabad
AYUSH
STAFF:
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DDC (Homeopathy)
ADC (Ayurveda/Unani/Siddha)
DI(Ayurveda/Unani/Homeo/Siddha)
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JDC(I)
DDC(I)
ADC(I)
DI
ADI
TI/Ms
Supporting Staff
STAFF:
DDC(I)
ADC(I)
DI
ADI
TI/Ms
Supporting Staff
STAFF:
ADC(I)
DI
TI/Ms
Supporting Staff
STAFF:
ADC(I)
DI
TI/Ms
Supporting Staff
STAFF:
Director
Dy. Director
Sr. Scientific Officer I
Sr. Scientific Officer II
Research Officer
Jr. Scientist Assistant
Jr. Scientist Assistant
Supporting Staff

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO) Cont....

HEAD QUARTER: Central Drugs Standard Control Organization Head quarter is located at FDA Bhawan, Kotla Road, New Delhi-110002 and functions under the Directorate General of Health Services.

Zonal Offices (6): Ahmadabad, Chennai, Ghaziabad, Hyderabad, Kolkata and Mumbai. These centers are involved in GMP audits and inspection of manufacturing units of large volume, parental, sera, vaccine and blood products.

Sub-Zonal Offices (7): Bangalore, Varanasi, Goa, Jammu, Indore, Guwahati, Baddi.

Port Offices (13): Ahmedabad, Chennai port, Chennai Sea port, Delhi, Hyderabad, Indore port, Kolkata Port, Kolkata Air Cargo, Mumbai Port, Mumbai Sea port, Cochin Sea- port, Vishakhapatnam Sea- port and Krishnapatnam Sea- port

These centers are coordinated with state drug control authorities under their jurisdiction for uniform standard of inspection and enforcement

CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO) Cont....

Central Drugs Testing Laboratories (7):

1. Central Drugs Laboratory, Kasauli.
2. Central Drugs Laboratory, Kolkata.
3. Central Drugs Testing Laboratory, Chennai.
4. Central Drugs Testing Laboratory, Hyderabad.
5. Central Drugs Testing Laboratory, Mumbai.
6. Regional Drugs Testing Laboratory, Chandigarh.
7. Regional Drugs Testing Laboratory, Guwahati.

- IVRI (Indian Veterinary Research Institute) – Izatnagar, Bareilly, UP
- NIB (National Institute of Biologicals) – Noida, UP
- IPC (Indian Pharmacopoeia Commission) - Ghaziabad, UP

These laboratories are responsible for quality control of Drugs and Cosmetics in India.

CENTRAL DRUG TESTING LABORATORIES

FUNCTIONS

CENTRAL DRUGS LABORATORY (CDL) KOLKATA

The Central Drugs Laboratory, Kolkata is the national statutory laboratory of the Government of India for quality control of Drug and Cosmetics and is established under the Indian Drug & Cosmetics Act, 1940. It is the oldest quality control laboratory of the Drug Control Authorities in India. It functions under the administrative control of the Director-General of Health Services in the Ministry of Health and Family Welfare.

The functions of the Laboratory include:

Statutory Functions:

- Analytical quality control of majority of the imported Drug available in Indian market.
- Analytical quality control of drug and cosmetics manufactured within the country on behalf of the Central and State Drug Controller Administrations.
- Acting as an Appellate authority in matters of disputes relating to quality of Drug.

CENTRAL DRUGS LABORATORY (CDL) KOLKATA Cont. . . .

II. Other Functions:

a) Collection, storage and distribution of International Standard International Reference Preparations of Drug and Pharmaceutical Substances.

b) Preparation of National Reference Standards and maintenance of such Standards. Maintenance of microbial cultures useful in drug analysis Distribution of Standards and cultures to State Quality Control Laboratories and drug manufacturing establishments.

c) Training of Drug Analysts deputed by State Drug Control Laboratories and other Institutions.

d) Training of World Health Organization Fellows from abroad on modern methods of Drug Analysis.

e) To advise the Central Drug Control Administration in respect of quality and toxicity of drug awaiting license

- f) To work out analytical specifications for preparation of Monographs for the Indian Pharmacopoeia and the Homoeopathic Pharmacopoeia of India.
- g) To undertake analytical research on standardization and methodology of Drug and cosmetics.
- h) Analysis of Cosmetics received as survey samples from Central Drug Standard Control Organization.
- i) Quick analysis of life saving Drug on an All-India basis received under National Survey of Quality of Essential Drug Programme from Zonal Offices of Central Survey of Quality of Essential Drug Programme from Zonal Offices of Central Drug Standard Control Organization.
- j) In addition to the above functions the Central Drug Laboratory also actively collaborates with the World Health Organization in the preparation of International Standards and Specifications for International Pharmacopoeia. It also undertakes collaborative study on behalf of the Indian Pharmacopoeia Committee. The senior Officers of the Laboratory have been appointed as Government Analysts on behalf of most of the States of the Union for analysis of drug samples.

CENTRAL DRUGS TESTING LABORATORY, HYDERABAD

Accredited By: NABL (ISO/IEC-17025:2017 in Chemical Testing)

The CDTL, Hyderabad is one of the National Statutory Laboratories of the Government of India, functioning under administrative control of the Drug Controller General (India), Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi.

The functions of the Laboratory include:

- Analysis of Drugs and Pharmaceuticals, Cosmetics and Medical Devices
- Analysis of Drugs and Pharmaceuticals, Cosmetics and Medical Devices manufactured in the country.
- Analysis of Import drugs & Cosmetics samples entering through the port offices of CDSCO.
- Analysis of Drugs & Pharmaceutical formulations received as Survey Samples from Central Drugs Standard Control Organization and its Zonal Offices.
- Analysis of Drugs & Pharmaceuticals formulations received as national Survey samples from CDSCO or other offices under Ministry of Health & Family Welfare
- Imparting Training to Drugs Analysts deputed by the Government laboratories from time to time.

CENTRAL DRUGS TESTING LABORATORY (CDTL), MUMBAI

Accredited By: NABL (ISO/IEC-17025:2017 in Chemical and Biological Testing)

Certified for: IMS (ISO-9001:2015, ISO-14001:2015, ISO-45001:2018

The CDTL, Mumbai is one of the National Statutory Laboratories of the Government of India, functioning under administrative control of the Drug Controller General (India), Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi.

The functions of the Laboratory include:

a. Analysis of Drugs and Pharmaceuticals, Cosmetics and Medical Devices. Analysis of Drugs and Pharmaceuticals, Cosmetics and Medical Devices manufactured in the country.

b. The Director, CDTL Mumbai Acts as "Appellate Authority" as per Drugs & Cosmetics Act, 1940 for the testing of Copper T and Tubal Rings (Intrauterine Contraceptive Devices.)

c. Analysis of Import drugs & Cosmetics samples entering through the port offices.

d. Analysis of Registration samples for approval of site registration as per GMP.

e. Analysis of New Drugs to get license for manufacturing the same.

f. Analysis of Drugs & Pharmaceutical formulations received as Survey Samples from Central Drugs Standard Control Organization and its Zonal Offices.

g. Analysis of Drugs & Pharmaceuticals formulations received as national Survey samples from CDSCO or other offices under Ministry of Health & Family Welfare.

h. Imparting Training to Drugs Analysts deputed by the Government laboratories form time to time.

I. To undertake analytical research on standardization and methodology of Drugs.

j. To act as Sub-Office/Lab of IPC, in developing standards both of Monographs and Reference Standards development process of Indian Pharmacopoeia.

Central Drugs Testing Laboratory (CDTL) Chennai, Tamil Nadu

Central Drug Testing Laboratory is one of the Seven National Laboratories in India engaged in the research and analysis of Drug and Cosmetics as per Drug and Cosmetics Act, 1940.

Regional Drugs Testing Laboratory (RDTL) Chandigarh

The Regional Drugs Testing Laboratory (RDTL) – Chandigarh is one of the Seven National Drugs Testing Laboratories of Central Drugs Standard Control Organization (CDSCO), set-up under the requirement for the testing of Drugs & Cosmetics products, working since November-2007. The Laboratory has been developed for the Quality Control of Drugs & Cosmetic products with respect to Infrastructure, Equipment and Manpower for the Chemical, Instrumentation and Microbiological analysis.

The RDTL - Chandigarh is regularly testing number of Legal (Form-18), Survey and imported samples of Drugs & Cosmetics received from the Central Survey and imported samples of Drugs & Cosmetics received from the Central Officers / Drugs Inspectors of CDSCO North Zone – Ghaziabad, Sub Zone - Baddi, Jammu, Varanasi and Assistant Drugs Controller (India), Indira Gandhi International Airport, New Delhi.

Apart from this, laboratory is notified for the State of Haryana, Himachal Pradesh, Jammu & Kashmir, Union Territories of Chandigarh and Delhi for the analysis of Drugs & Cosmetic samples drawn by their Drug Officers. The laboratory is having testing capacity of about 5000 - Samples, per annum, and is NABL Accredited as per ISO / IEC 17025:2005, since 2016.

Central Drugs Laboratory, CDL Kasauli

Central Drugs Laboratory at Central Research Institute (CRI) Kasauli is a Central laboratory engaged in the testing of vaccines. It is a notified laboratory under the Drugs and Cosmetics Act, 1940 to function as Central Drugs Laboratory for testing of the following drugs or classes of drugs;

a. Sera

b. Solution of serum proteins intended for injection

c. Vaccines

d. Toxins

e. Antigens

f. Anti-toxins

g. Sterilized surgical ligature and sterilized surgical suture

h. Bacteriophages, including Oral Polio vaccine.

Regional Drugs Testing Laboratory (RDTL) Guwahati

The Regional Drugs Testing Laboratory Guwahati is the one of the five National Laboratory of the Govt. of India for quality control of Drugs and Cosmetic and is established under the Indian Drugs & Cosmetics Act 1940 functioning under administrative control of the Drugs Controller General of India and sub ordinate office under Directorate General of Health Services, Ministry of Health & Family Welfare.

The laboratory was set up in the year 2002 for entire North Eastern State including Sikkim and is housed in its own building at Guwahati.

The functions of the Laboratory include:

a. Analytical quality control of drugs and cosmetic manufactured within the country on behalf of the Central and State Drugs Controller Administration.

b. To assists the Central Drugs Standard Control Organization in the testing of Drugs and cosmetic.

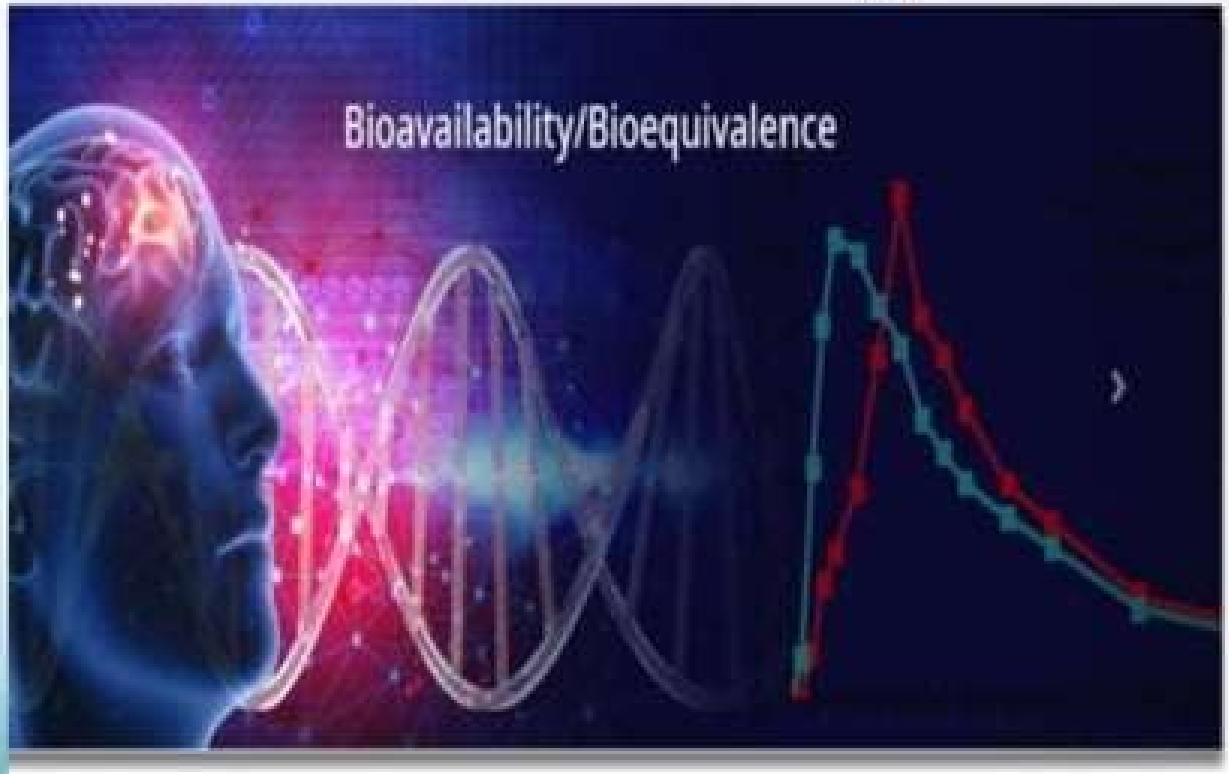
CDSCO OTHER MAJOR ACTIVITIES

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

About Us | BA/BE | Biologics | Clinical Trial | Committees | DTAB/CDCC | Drugs | International Cell | Medical Devices & Diagnostics | Notifications | Committees | PMS

BA/BE

BA/BE



About BA/BE

Bioavailability (BA): Bioavailability refers to the relative amount of drug from an administered dosage form which enters the systemic circulation and the rate at which the drug appears in the systemic circulation.

Bioequivalence (BE): Bioequivalence of a drug product is achieved if its extent and rate of absorption are not statistically significantly different from those of the reference product when administered at the same molar dose.

Functionalities

Processes

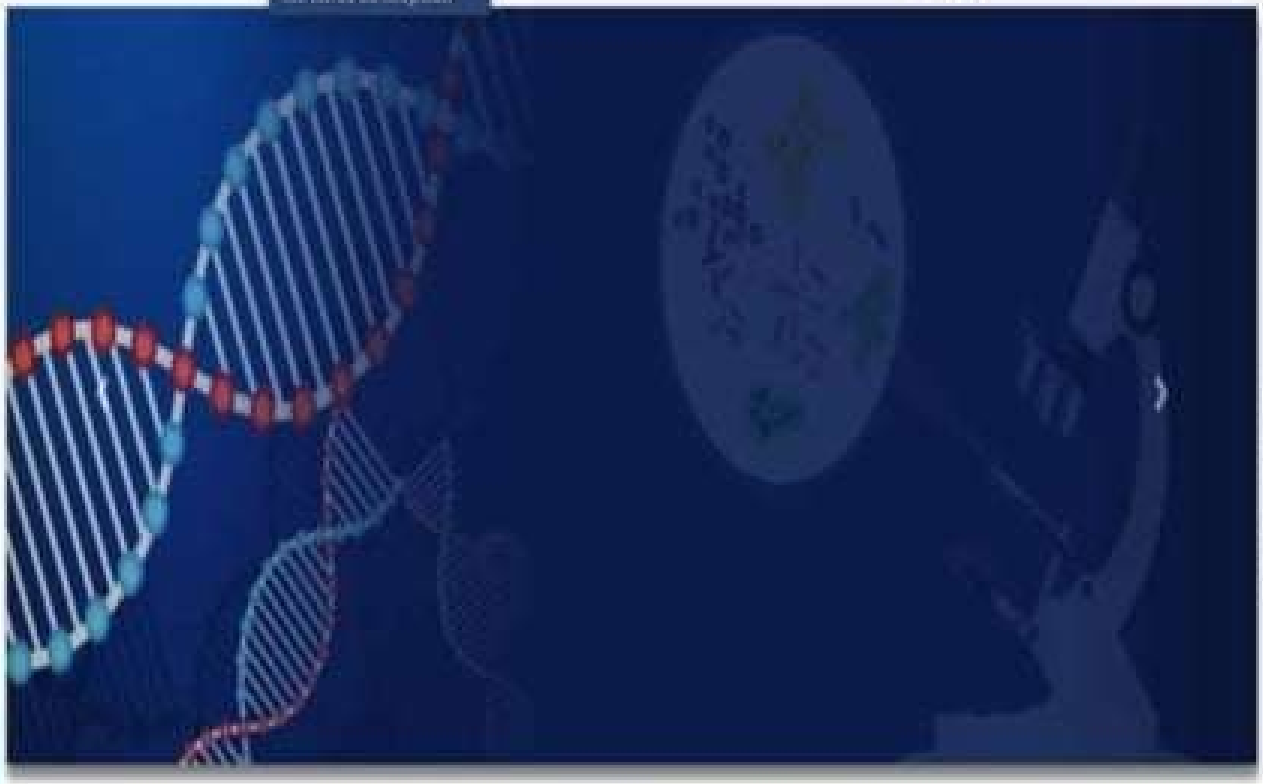
Organogram

Guidelines

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

Vaccines
Blood Products
rDNA
Stem Cells and Cell based products

Biologics



About Biological

Functionalities

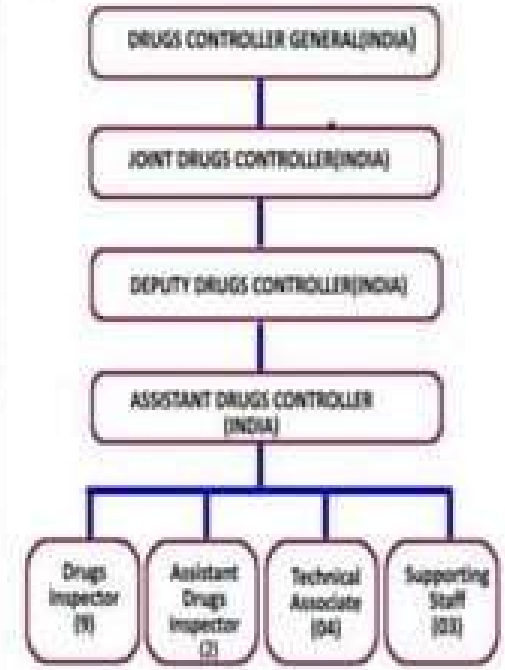
Processes

Organograms

Guidelines

Central Drugs Standard Control Organization

Clinical Trial



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

Cosmetics

About Cosmetics

Cosmetics is defined under section 3(aaa) of the Drugs and Cosmetics Act, 1940 as, any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and includes any article intended for use as a component of cosmetic.

Under the provisions of Drugs and Cosmetics Act, 1940 and Rules made there under, the manufacture of cosmetics is regulated under a system of inspection and licensing by the State Licensing Authorities appointed by the respective State Governments, while the import of cosmetics is regulated under a system of registration by the Central Licensing Authority appointed by the Central Government. The Drugs Controller General (India) functions as the Central Licensing Authority who grants the Import Registration Certificate and regulates the import of cosmetics into India vide Gazette notification G.S.R 765(E) under the provisions of Drugs and Cosmetics Act, 1940.

Any article falling within the definition of cosmetic is required to be registered along with pack size, variant(s) and manufacturing premises before its import into the country.

No cosmetic shall be imported into India unless the product is registered under the rules by the Central Licensing Authority appointed by the Central Government under rule 3(f) or by any person to whom such powers may be delegated under rule 5. [As per rule 22(1) of the Cosmetic Rules, 2020]

No cosmetic shall be imported or manufactured unless it complies with the specifications prescribed under the Fourth Schedule or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case, the cosmetic is not included under the Fourth Schedule, it shall meet the requirements under these rules and specifications and standards applicable to it in the country of origin. [As per rule 39 of the Cosmetic Rules, 2020]

No cosmetic may purport or claim to purport or convey any idea which is false or misleading in the intending user. [As per rule 36 of the Cosmetic Rules, 2020]

Functionalities

Processes

Organogram

Guidelines

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

DTAB-DCC Division

About DTAB-DCC
Functionalities
Processes
Organogram

ORGANOGRAM OF DTAB-DCC DIVISION

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

icdra

Home | Drugs | New Drugs

Fixed Dose Combination
Investigational New Drugs
New Drugs
Subsequent New Drugs

New Drugs

About New Drugs

Demonstration of safety and efficacy of the drug product for use in humans is essential before the drug product can be approved for import or manufacturing and marketing in the country. The Rules 122A, 122B, 122 D(4), 122DAC, 122 DD and 122E of Drugs and Cosmetics Rules and Appendix I, 1(i) of Schedule Y, describe the information/data required for approval of clinical trial and/or for import or manufacture of new drug for marketing in the country.

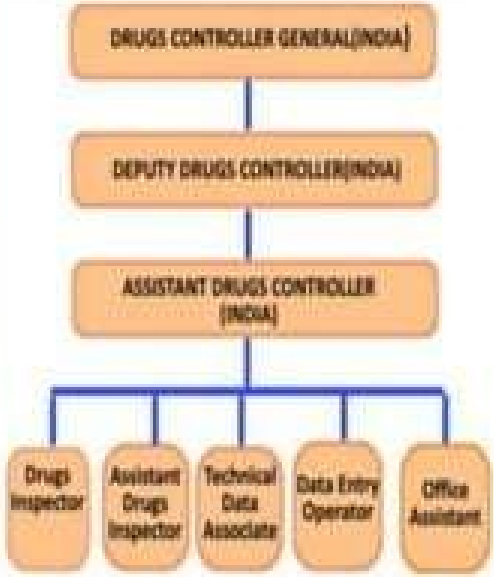
New drugs as define under Rule 122 E of Drugs and Cosmetics Rules as drug, including bulk drug substance or pharmaceutical drug which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labeling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 23 for the proposed claims. A drug already approved by the Licensing Authority mentioned in Rule 23 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage forms) and route of administration. Fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage, dosage form (including sustained release dosage forms) and route of administration. All vaccines and Recombinant DNA (rDNA) derived drugs shall be new drugs unless specified otherwise by the Licensing Authority under Rule 21. A new drug shall continue to be considered as new drug for a period of four years from the date of its first approval.

RULES GOVERNING CLINICAL TRIALS

1. **Rule 122-A** - Application for permission to import new drug.
2. **Rule 122-B** - Application for approval to manufacture new drug.
3. **Rule 122-DA** - Mandatory requirement of permission from CDSCO for conduct of clinical trial of new drug.
4. **Rule 122 DAB** - Provision for examination of serious adverse events (SAE) of injury and death and payment of compensation in clinical trial related cases. Provision for debarment of the applicant in case of failure to pay compensation.
5. **Rule 122 DAC** - Conditions of permission for conduct of clinical trial which includes mandatory requirement to follow Good Clinical Practice (GCP) guidelines, guidelines and requirements specified in Schedule Y of Drugs and Cosmetics Rules and other applicable regulations. Provision for debarment of applicant and investigators in case of non- compliance.
6. **Rule 122-D** - Extension of new drug.
7. **Schedule Y** - Requires guidelines and requirements for conduct of clinical trial and approval of new drug.
8. **Good Clinical Practice Guidelines** - issued by CDSCO, Directorate General of Health Services, Govt. of India.

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

New Drugs



Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health & Family Welfare

Government of India

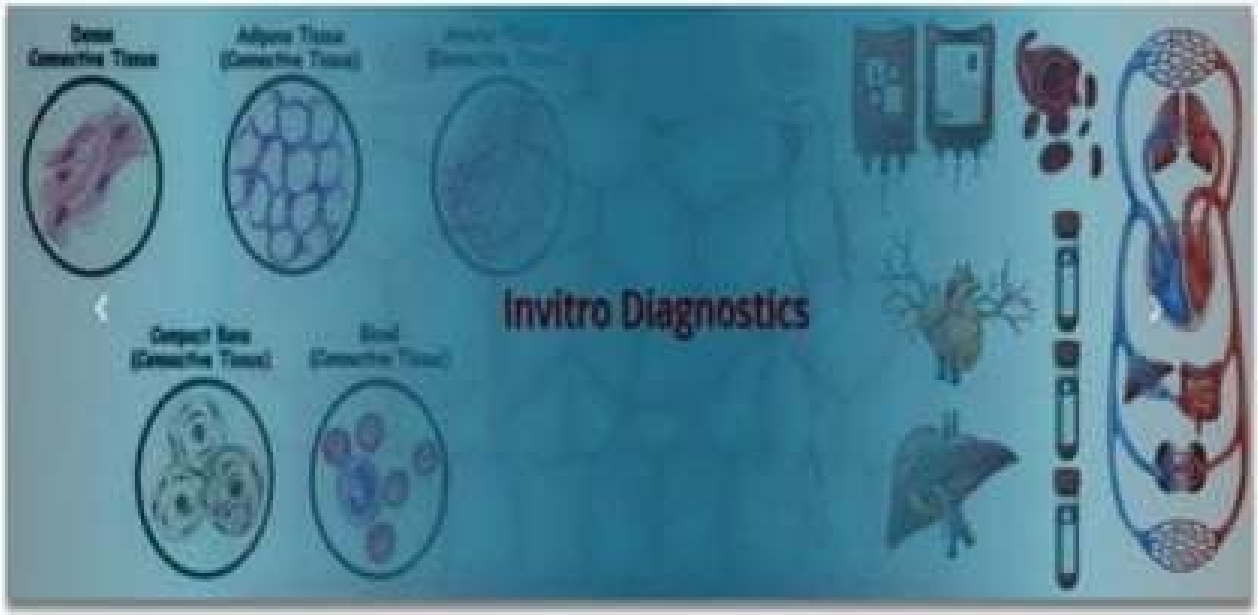
Medical Devices & Diagnostics

In Vitro Diagnostics

Medical Devices

Home > Medical Devices & Diagnostics > In Vitro Diagnostics

In Vitro Diagnostics



About IVD

i. In India, import, manufacturing, sale and distribution of In Vitro Diagnostic Medical Devices are regulated as 'Drug' under sub-clause (i) of clause (b) of section 3 and sub-clause (iv) of clause (b) of section 3 of Drugs and Cosmetics Act and Rules.

ii. The requirements for grant of licence to Manufacture, Import, Clinical Performance, Sale and Distribution are prescribed in MDR, 2017.

iii. In vitro diagnostic medical devices shall be classified on the basis of risk parameters as specified in Part B of the First Schedule, as under:

i. Low risk - Class A;

ii. Low moderate risk - Class B;

iii. Moderate high risk - Class C;

iv. High risk - Class D;

iv. Classification list of In Vitro Diagnostic Medical Devices have been published on the website of the Central Drugs Standard Control Organization approved by CLA.

v. The Central Licensing Authority shall be the competent authority for enforcement in matters relating to:

i. Import of all Classes of In Vitro Diagnostic Medical Devices

ii. Manufacture of Class C and Class D In Vitro Diagnostic Medical Devices

iii. Clinical Performance evaluation and approval of new in vitro diagnostic medical devices

iv. Co-ordination with the State Licensing Authorities

vi. The State Drugs Controllers for enforcement matters within shall be the State Licensing Authority and shall be the competent authority for enforcement in matters relating to:

i. Manufacture for sale or distribution of Class A or Class B In Vitro Diagnostic Medical Devices

ii. Sale, stock, exhibit or offer for sale or distribution of In Vitro Diagnostic Medical Devices of all classes.

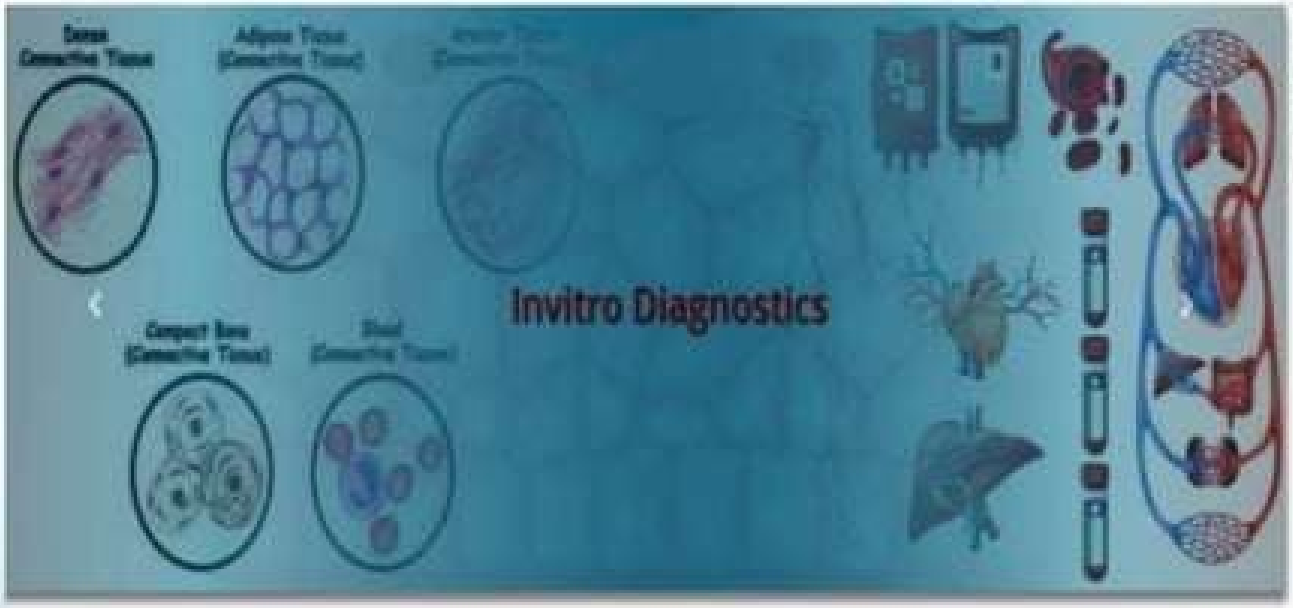
Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health & Family Welfare

Government of India

In Vitro Diagnostics



About CDSCO

Functionalities

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Organogram

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

Medical Devices & Diagnostics

Medical Devices & Diagnostics

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Medical Device

Medical Device & Diagnostics

About Medical Devices

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VARIOUS COMMITTES

- DCC
- OTAB
- SEC
- TECHNICAL
- APEX
- IND
- NDAC
- MISCELLANEOUS

DCC

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S.no	Title	Release Date	Download Pdf	Pdf Size
1	60th DCC held on 7th April 2021	2021-04-07		369 KB
2	59th DCC held on 2nd March 2021	2021-03-02		236 KB
3	58th DCC held on 14th July 2020	2020-07-14		275 KB
4	57th DCC held on 20 August 2019	2019-09-10		401 KB
5	56th DCC held on 01st June 2019	2019-06-01		263 KB
6	55th DCC held on 31.01.2019 and 01.02.2019	2019-02-20		4482 KB
7	54th DCC held on 30th Jul, 2018	2018-07-30		355 KB
8	53rd DCC held on 9th Apr, 2018	2018-04-09		474 KB

State Licensing Authority: Organization, Responsibilities

State Licensing Authority: Organization, Responsibilities

Under the Drug and Cosmetics Act,

State authorities: The regulation of manufacture, sale and distribution of Drugs is primarily the concern of the state authorities.

Functions of State Licensing Authorities:

1. Licensing of drug testing laboratories.

2. Approval of drug formulation for manufacture.

3. Monitoring of quality of Drugs and Cosmetics, manufactured by respective state and those marketed in the state.

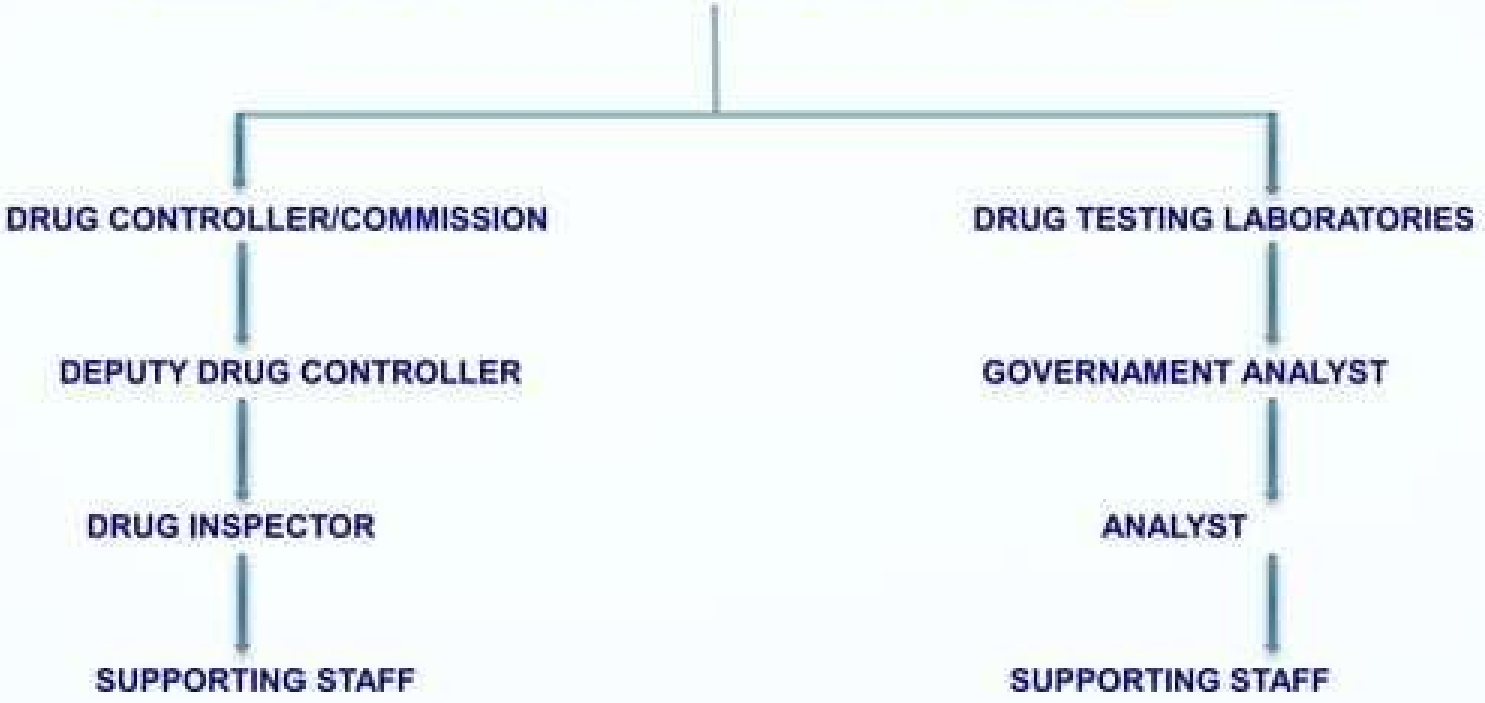
4. Investigation and prosecution in respect of contravention of legal provision.

5. Administrative actions.

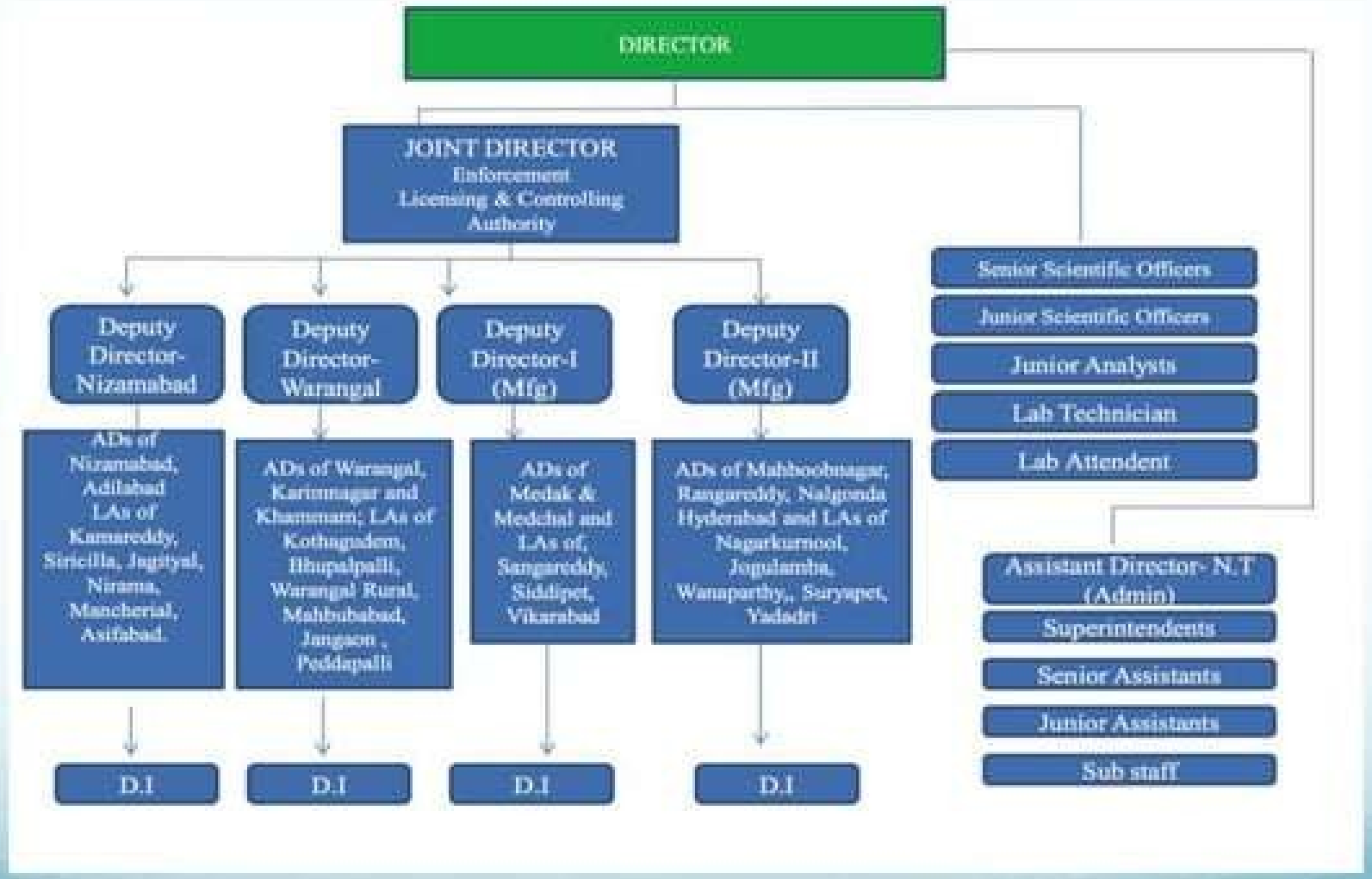
6. Pre and post licensing inspection.

7. Recall of substandard drugs.

STATE DRUG CONTROL ORGANIZATION



STATE DRUG CONTROL ORGANIZATION OF TELANGANA



Regulatory requirements and approval procedures for New Drugs

Regulatory requirements and approval procedures for New Drugs

APPROVAL OF NEW DRUG

1. The drug approval process varies from one country to another.
2. In some countries, only a single body regulates the drugs and it is responsible for all regulatory tasks such as approval of new drugs.
3. **New drug will not be imported, except under permission granted by the Licensing Authority, accomplished by fifty thousand rupees.**
4. The licensing authority, after being satisfied that the drug if permitted to be imported as raw material (bulk drug substance) or a finished permutation will be effective and safe for use in the country may issue import permission will be effective and safe for use in the country may issue import permission.
5. For new drug discovered in other countries, phase-I trials are not usually allowed to be initiated in India.

Regulatory requirements and approval procedures for New Drugs

APPROVAL FOR CLINICAL TRIALS:

1. Approval for clinical trials and application to conduct clinical trials in India should be submitted along with the date of chemistry, manufacturing, control and animal studies to DCGI.

2. The data regarding the trail protocol investigators brochures and informed consent documents should also be attached.

3. A copy of the application must be submitted to the ethical committee and the clinical trials are conducted only the after approval of DCGI and ethical committee.

Regulatory requirements and approval procedures for New Drugs

Approval of Clinical trials, Import and Manufacture of New Drugs: Requirements and Guidelines:

Schedule Y

1. Rule 122A – Permission to import new drug.
2. Rule 112B – Permission to manufacture new drug.
3. Rule 122DA – Definition of clinical trials.
4. Rule 122E – Definition of new Drugs.
    1. New substance having therapeutic indication.
    2. Modified on new claims, new route of administration for already approved drug.
    3. Fixed dose combination.

APPROVAL OF IND:

Time Line:

Phase-I: 90Days

Phase-II: 45 Days

Phase-III: 60Days

Regulatory requirements and approval procedures for New Drugs

Import, Registration and Licensing: Manufacturing sites and products are required to be registered.

Issue of import license in form 10/10 A.

Rules 21 to 30: Rules related to grant of registration certificate and import license.

Schedule DI and DII: Information required for registration of manufacturing site and product.

Time line for RC: As per D and C rules, 9 months; however in practice, 2 months. For import license 2-3 weeks.

As per Rules 21A (5), there is provision to import manufacturing site for which manufacture has to pay 5000 USD.

REQUIREMENTS FOR IMPORT AND REGISTRATION

Registration of Overseas Manufacturing Site and Drugs: Registration certificate is issued in form 41 by licensing authorities. Import license issued in form 10 and 10A.

Central Licensing

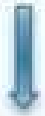
CLAA approval and grant of license

Manufacture

State licensing Authorities (license prepared by state licensing authority)

Joint Inspective by State and Central Inspectors.

Examination of Report



For biological, Large volume parenteral (LVP),

Blood Bank and Blood products and some medical devices

Global Clinical Trials: Permission is required from CDSCO for conducting global clinical trials in the country. Phase-I for new drugs substance is developed outside India, whereas inside is not permitted

CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP)

CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP)

The certificate of pharmaceutical product is a certificate issued in the format recommended by the World Health Organization (WHO), which establishes the status of the pharmaceutical product and of the applicant for this certificate in the exporting country. It is issued for a single product, because manufacturing arrangements and approved information for different pharmaceutical forms and strengths can vary.

Importance:

1. It is needed by the importing country when the product in question is infected for Registration (Licensing and Authorization) or renewal of registration. For Registration (Licensing and Authorization) or renewal of registration.

2. With the scope of commercialization or distribution in that country.

3. 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

CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP) Cont.....

Scope:

- The Certificate of a Pharmaceutical Product is needed by the importing country when the product in question is intended for registration (licensing, authorization) or renewal (prolongation) of registration, 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. Prerequisite of registration or importation.

- In the presence of such COPP, WHO recommends the national authorities to ensure that analytical methods can be confirmed by the national laboratory, to review and if necessary to adapt the product information as per local labeling requirements, and to assess bioequivalence and stability data if necessary.

- However, regulatory practices often vary in importing countries. Thus, in addition to CPP, assessment of application dossiers to support drug registrations, with different levels and complexity of requirements are considered necessary to satisfy full assurance on the appropriate quality of drugs.

CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP) Cont.....

WHO:

The application for grant of WHO GMP Certificate of Pharmaceutical Product should be made to respective zonal/sub-zonal officers as per the requirement. The COPP should 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.

CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP) Cont....

General Requirements for Submission of Application for Issue of COPP:

A forwarding letter/application should be addressed to DDC (I) / ADC (I) of respective CDSCO zonal/sub-zonal offices with copy of covering letter and product summary sheet to DCG (I) by authorized person only.

1. Application should clearly indicate for fresh certification (Grant) or reissue of products applied, accordingly it will be scrutinized for the products applied.

2. Applications should be reviewed by CDSCO officers and completed applications in all respects should be accepted for inspection on first come first serve basis.

3. The forwarding letter/application shall be accompanied with list of products3. The forwarding letter/application shall be accompanied with list of products applied for grant of COPP, along with a product permission copy (manufacturing license issued by the SLA) and notarized product summary sheet, site master file as per WHO-GMP requirement.

List of major/master documents like master validation plan, quality manuals, specifications, master formula records maintained by firm and list of SOPs (to indicate the documentation system of firm).

CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP) Cont..

Manufacturing Layout:

1. List of personnel (with designation, qualification and experience), List of equipment's, instruments, utilities along with make and model and capacity.

2. List of primary and 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:

The certificate of pharmaceutical product has been issued under WHO-GMP based on guidelines laid down by health agency and also aimed at diminishing the risk inherent in pharmaceutical productions. The certificate helps the regulator to inherent in pharmaceutical productions. The certificate helps the regulator to ensure that drugs are consistently produced and are quality controlled before they leave the country.

Documents Required for Applying for Grating or Revalidation of COPPs:

1. Application from manufacturer.

2. Site master file (as specified under WHO TRS 823).

3. Cost of manufacturing license.

4. List of approval 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 equipments and instruments.

9. List of technical staff, their qualification, and 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.

15. Product money sheet.

CDSCO- New Drug Application

Time Line and Fees for NDA: It generally takes about one year to secretaries these documents by technical data associates/Drug inspector of CDSCO during the period clarification if any, are required by them are answered and there after the imported gets the approved TR Challan of Rs. 50000 is required for fresh application's Challan of Rs.15000 is required subsequent application.

Documents for NDA:

Legal Documents:

1. Documents to be submitted by Indian agent.

2. **Form 40:** It should be signed and stamped by Indian agent.

3. Documents to be submitted by manufacturer.

4. **POA:** Power of attorney should be consulate from Indian embassy of the other country of origin, and should be co-jointly signed by both the parties i.e. manufacturer and Indian agent.

Schedule DI and DII: They should be signed and stamped by manufacturer (Need not to be notarized).

Regulatory Documents:

1. Notarized plant registration certificate.

2. Notarized manufacturing and marketing license

3. Notarized free sale certificate

4. GMP/COPP certificate notarized.

Documents for NDA Cont....

Technical Documents:

(A)Plant master file: It should include the following points:

- Sketch of the plant.
- Profile of the company.
- Organogram of the company.
- Plant and machinery.
- Hygienic and sanitary measure details.
- DQ,IQ,OQ,PQ.
- HVAC system.
- Men material movement.

(B) Drug master file: It should include the following points:

- Manufacturing process/flow chart.
- Quality assurance procedures/process controls.
- The provision to control contamination and cross contamination in the final product.
- Process control, control of critical steps and intermediates.
- Container closure system.
- Risk Assessment as per ISO 14971.
- Process validation/verification.
- Stability data.
- Biocompatibility and toxicological data.
- Clinical studies and reports.

Post marketing Surveillance: It is the part of Device Master File.

- Procedures for distribution of records.
- Complaint handling.
- Adverse incident reporting.
- Procedure for product recall.
- Corrective action taken.

Documents for NDA Cont.....

(C) Labels and Inserts: Product labels should show the address of manufacturer. Product inserts should describe the brief description of the product and its intended use.

Processing Procedure: After ensuring all documents correctly as per the requirements of FDA, it generally takes about 2-3 months to scrutinize these documents by Technical Data Associates/Drug inspectors of CDSCO and during this period, clarifications if any, required by them are answered and thereafter we get the Registration Certificate (RC) in Form 41.

Import Processing: After getting the registration certificate from CDSCO, the Indian agent is to import the products from the manufacturer. Following documents are further agent is to import the products from the manufacturer. Following documents are further required to get Form 10 (Import license).

Form 8: TR Challan - (Rs 1000 for 1st product then Rs 100 for each additional product).

Form 9: Copy of Wholesale License (Indian agent)-Notarized.

Copy of Registration Certificate-Notarized.

Time Line For Import License:

The Importer (Indian agent) is not authorized to import the products from foreign manufacturer unless he obtains Import license (Form 10) from CDSCO.

It generally takes about one month to scrutinize these documents by Technical Data Associates/Drug inspectors of CDSCO and during this period, clarifications if any, required by them, are answered after that the importer gets the Import license.

For Import license application TR Challan of Rs 1000 for 1st product then Rs 100 for each additional product is required.

THANK YOU