

**Current Regulatory Requirements for Conducting Clinical Trials in India**  
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**Lecture – L4**  
**Drugs and Cosmetics Act & Rules**

Welcome back to lecture 4 for the course Current Regulatory Requirement for Conducting Trial in India. In the lecture 4 Drug and Cosmetic Act and Rules there under we are going to see the objective of Drug and Cosmetic Act 1940 and those their under 1945.

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## LEARNING OBJECTIVES

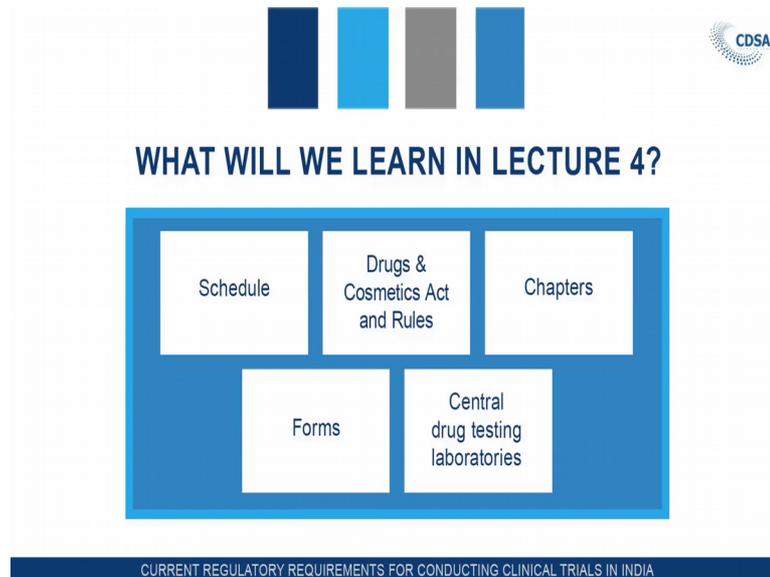
**Upon completion of this online course, the trainees will:**

- Be able to understand the objective of D&C Act 1940 & Rules 1945.
- Different chapters available in the Act.
- Rules pertaining to new drugs and clinical trials.
- Different schedules to the rules.
- Familiar with the drug testing laboratories.

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Then the different chapters available in this act, then rules pertains to new drug and clinical trial, different schedules available in the rules that is from schedule A to schedule Y. Then you will be familiar with the drug testing laboratories. So, what will we learn in lecture 4?

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As I have said in this lecture we are going to see the objective of drug and cosmetic act. The different chapter that is chapter from first to five we will see in detail, then the different forms required for the permission of the clinical trial and other forms, then different schedules and the different drug testing laboratories. So, this is the drug and cosmetic act, it is available on our web or website that is [www dot cdsc dot gov dot in](http://www.cdsc.gov.in).

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The slide features a decorative header with four vertical bars in dark blue, light blue, grey, and medium blue. The CDSA logo is in the top right corner. The main title is "DRUGS & COSMETICS ACT". Below it is a grey-bordered box containing text and a logo. The text lists: "GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE (Department of Health)", "THE DRUGS AND COSMETICS ACT AND RULES", "THE DRUGS AND COSMETICS ACT, 1940 (As amended up to the December 31, 2016) and", and "THE DRUGS AND COSMETICS RULES, 1945 (As amended up to the December 31, 2016)". The logo is the Central Drug Standard Control Organization (CDSO) emblem. A dark blue footer bar contains the text "CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA".

The act is exercised by government of India Ministry of Health and Family Welfare. The act is available as I have said as a web version and it is amended up to 31st December 2016. So, let us see the objective of the Drug and Cosmetic Act and rules their under.

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## OBJECTIVES OF THE D&C ACT

The D&C act was passed on April 10, 1940 with the main objective to regulate:

- 01 Import
- 02 Manufacture
- 03 Distribution
- 04 Sale of Drugs and Cosmetics

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The Drug and Cosmetic Act was passed on 10th April 1940 with the main object to import, manufacture to regulate import, manufacture, sale and distribution of drug and cosmetic. Cosmetic has been added letter on, how does the act do it.

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## OBJECTIVES OF THE D&C ACT

- The act regulates import of drugs in India, so that no substandard or spurious drug will enter into the country.
- The act prohibits the manufacture of substandard or spurious drug in our country.
- The act provide for the control over the sale & distribution of drugs by only trained and qualified persons.
- The act also provide for the control over the manufacture, sale & distribution of Ayurvedic, Sidha, Unani & Homeopathic.

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The drugs are available in market by two ways either by import or by the manufacture and it reaches to the patients through sale or distribution. So, it is very important to regulate the manufacture, import, sale and distribution of this drug to reach the authenticated standard drug to the patients. The act regulate the import of drug in India so, that no sub standard or spurious drug will enter into our country. And the act does it by issuing the import license to the importer and registration certificate after satisfying that the drug where it is manufactured is in compliance with the schedule M or good manufacturing practices.

The act prohibits the manufacture of sub standard or spurious drug in the country. See the manufacturing is also given the manufacturing license and before giving the manufacturing license, the applicant has to apply to the licensing authority either state or the centre. The drug inspector in this regard then verify the compliance of these applicant whether it is a complaint with the good manufacturing practice or not. And after the satisfaction then they submit its report and verification of the report, it confirms that the facility provided for the manufacturing of the drug are compliance with the schedule M and good manufacturing. And after that the manufacturing license is issued by the state licensing authority.

The act provides for the control over the sale and distribution of drug by only trained and qualified persons. As I have said the drugs are reaching to the patient either sale or by distribution. To control this sale and distribution the act provides control over the sale and distribution by resting it to the qualified person. The person who is selling or distributing this drug required to be having a qualification of pharmacy. The facility provided for sale and storage of the drug should be adequate and as per the norms of the Drug and Cosmetic Act; qualified pharmacists, then proper storage facility should be there then only we can be ensure that the correct drug is reaching to the patient.

The act also provide for the control over the manufacture sale and distribution of some other types of drug that is we call traditional drug: Ayurvedic, Sidha, Unani and homeopathic drugs. So, in this presently we are not regulating the sale of ayurvedic drugs, but why regulating the manufacturing of this ayurvedic drug; however, the homeopathic drug for its sale it require license.

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- Certain provisions of the act regulates the import, manufacture, sale & distribution of cosmetics.
- To have a regular inspection of licensed premises by drug inspectors.
- To have control over the standards of drugs & cosmetics by taking samples & analysing them at approved laboratories.
- To provide special provisions to regulate the preparation, standardisation & storage of biological & special products.
- To prescribe the manner of labeling & packing of the various classes of drugs & cosmetics.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

Certain provision of the act regulate the import, manufactures, sale and distribution of cosmetics. So, we have seen the drug is for the both drug and the cosmetics. So, it is the duty of the regulator to ensure the safety and quality of cosmetics also. So, whatever the cosmetic available in the market for its manufacturing it required to take prior license. And if that facility provided for manufacturing is in compliance with the norms then the manufacturing permission can be given; same is for the import of the cosmetics. In this case the applicant has to apply to the licensing authority then they will get a registration certificate, after verifying the data submitted permission can be granted.

To have regular inspection of licensed premises by drug inspector; so, after giving the manufacturing permission to have the routine checkup of the quality of the drug and the compliance of the premises whether it is as per schedule M or not; there is a provision for the routine inspection. The state licensing authority drug inspectors and the central licensing authority drug inspector they are routinely checking of the compliance. Even after the batch is in market there is a provision to withdraw the samples of the available product. And these samples can be sent to the testing for its equality and after satisfying result then that can be sold.

To have the control over the standard of drug and cosmetic taking sample and analyzing them at appropriate laboratories. So, this laboratory what are these laboratory, we will see in our next slide. To provide special provision to regulate the preparation,

standardization and storage of biological and special products. So, act is provided with the special provision for the biological; biological products like vaccines, blood products. These are very sensitive product and permission for which is given through the central licensing authority and the specific rules and regulations are there in this act and rules.

To prescribe the manner of labeling and packaging of the various classes of drug and cosmetic so, the act is provided with the labeling and packaging of the various classes of the drug. So, it means the what should be the content on the label that is also given in the rules and the act. Say for example, what is the manufacturing date, what should be the its expiry date and what should be its storage condition.

The name of the ingredient, the composition of ingredient that should available on the label of this marketed drugs and it is mentioned under the drug and cosmetic rule that is rule 92, 93 and other rules. Now, let us see what is this Drug and Cosmetic Act and rules; we have seen the objective now we will see the content.

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**DRUGS & COSMETICS ACT & RULES**

- The Act contains two parts
  - Part I - 06 chapters which includes 38 different sections
  - Part II of the Act is – Drugs and Cosmetics Rules 1945.
- The D&C Rules contains 19 parts (Part XIX).
- Part X-A is for 'Import or manufacture of new drug for clinical trials or marketing'.
- There are currently 174 Rules, followed by Schedule A to Y.
- Schedule Y includes 'requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials'.

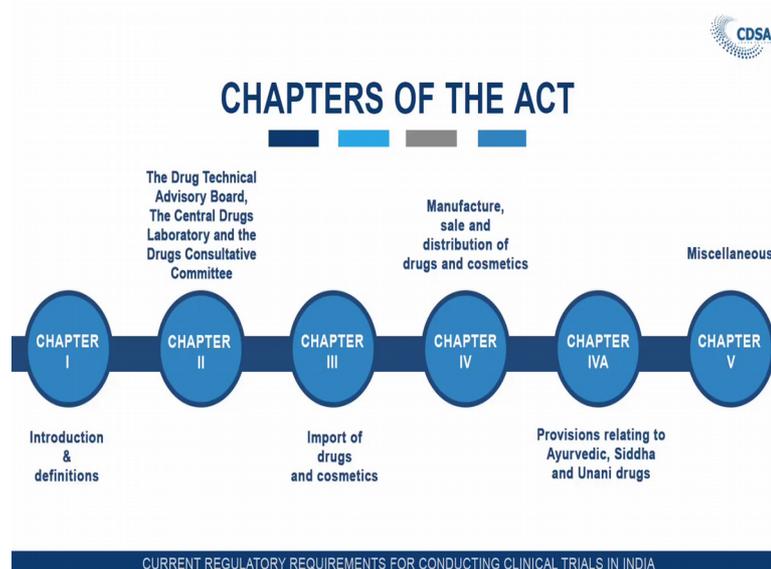
CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

So, the we can say that Drug and Cosmetic Act and rule we can divide it into two part. The first part is the Drug and Cosmetic Act, the act is having 6 chapters and two schedules. The this two 6 chapters are from chapter first to chapter 5 including chapter 4 A. We will see in detail about this chapter in our subsequent slides. Part II of the act is Drug and Cosmetic Rules and this rule for the sake of convenience again divided into 19

parts. The part 10 A is specifically for import or manufacture of new drug for conducting clinical trials or for marketing.

At present there are 174 rules followed by schedule and the schedules are from A to schedules Y. We have seen in our previous lecture schedule Y, it is a for requirement and guideline for permission to import and or manufacture of new drug for sale or to undertake clinical trials. All these clinical trials, new drug, then manufacture import, the definition, what it mean by we have already seen in our previous slides; so, coming to the next slide.

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So, the chapters available in the Drug and Cosmetic Act 1940. First chapter is the introductory chapter, it is introduction and the definitions. So, in this chapter the short title then extent and commencement of the act is given, different types of definition what we have seen in our lecture 1 that is definition of Ayurvedic, Sidha and Unani. Definition of drug section 3 B, then definition of cosmetic, what is means by board that is GTAV board, government analyst, what is I mean by inspector, what is mean by import, manufacturing and some other definitions are given in this chapter first.

Chapter second is related to the DTAB and DCC DTAB is Drug Technical Advisory Board, DCC is a Drug Consultative Committee. This committees are provided in the act to provide the technical guidance in any matter related there of the drugs, DCC committee is also there. So, in this committee ensures the uniform implementation of

Drug and Cosmetic Act and rules there under across the country. The detail composition, function, then who should be the chairman of the committee and what are the other members of this committee and the frequency of their meeting that everything is given in this chapter.

Chapter III is of import of drug and cosmetic. So, in this chapter standards of quality; what is mean by standard of quality, what is mean by miss branded, what is mean by spurious drug, then what is mean by adulterated drug? Everything is about given in this chapter. All the definitions and the if somebody manufactures such type import such type of miss branded, spurious drug what should be the penalties, what should be the punishment that is also given in this chapter.

Chapter IV is related to the standard of chapter IV standard of this miss banded, adulterated, spurious and this chapter is for the manufacturing. The previous chapter is for the import and this chapter is for the manufacture, sale and distribution of drug and cosmetic.

So, here also the standard of quality for the manufacturing what is means by the miss branded, what is mean by adulterated drug, what is spurious drug and all this definition for in related to the manufacturing has been given. The definitions of all these spurious drug also given in this chapter. Then the power of inspector, then procedure of sampling, then the procedure for government analyst, then penalties, of offences for the manufacturing the sub standard drugs all these things are given in this chapter.

Chapter IV A that is related to the traditional system of medicine: Ayurvedic, Siddha and Unani drug. So, the manufacturing, sale, distribution how it has to be regulated, who has to manufacture which schedule, which forms are required for the application that everything regarding Ayurvedic, Siddha and Unani system has been given in this chapter IV A. Chapter V is a miscellaneous chapter, in this chapter whatever is not covered in earlier up to IV A chapter is given in this chapter like a special course, then power of the government to give the direction and some other provisions given in this chapter.

Coming to the next slide that is rules related to new drugs and clinical trials. We have seen what are the rules which were related to the clinical trial and new drug in our previous lecture; so, we will see these rules in detail one by one.

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## DRUGS AND COSMETICS RULES

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<b>Rule 122DA</b>	Application for permission to conduct clinical trials for new drug/Investigational new drug (IND).
<b>Rule 122DA</b>	Definition of clinical trial - For the purpose of this Part, "Clinical trial" means a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetic) and/or adverse effects with the objective of determining safety and/or efficacy of the new drug.
<b>Rule 122DB</b>	Suspension or cancellation of permission/approval.

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Rule 122 DA this rule is for application for permission to conduct clinical trial for new drug or investigational new drug. Definition of both of these that is IND and new drug we have seen in our lecture first. So, in this rule it is also mention that the no clinical trial for new drug whether for clinical investigation that is for medical device or any clinical experiment by any institution shall be conducted except under and in accordance with the permission in writing by the licensing authority defined in clause B of rule 21.

It means as per this rules the clinical trial is required prior permission from the licensing authority which is defined in clause B of rule 21 which is a DCJ or CDSCO. Then further in this rule it is given how to apply for the new drug permission, how to apply for the clinical trial phase 1, phase 2 and phase 3 also for the phase 4. And what is the different different fees required, what are the different forms required, in which pro-forma it has to be given that everything about the application, about the application for permission to conduct the clinical trial and new drug given in this rules.

We have seen in our first lecture that academic (Refer Time: 16:28) that is for the research purpose does not require any regulatory permission. So, that also mention in this rule only, then we have seen the definitions of clinical trials GCT and DNCA; this is also given in this rule 122 DA under the heading explanation. The next tool that is a rule 122 DB is related to the suspension or cancellation of permission or approval. So, whatever the permissions given if the licensing authority found that the permission which is given

with certain condition has not been complied by the importer or manufacturer under this part; then the licensing authority after giving him a show cause notice may suspend or cancel that permission as per this rule 122 DB.

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**DRUGS AND COSMETICS RULES**

**Rule 122DA** Application for permission to conduct clinical trials for new drug/Investigational new drug (IND).

**Rule 122DA** Definition of clinical trial - For the purpose of this Part, "Clinical trial" means a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetic) and/or adverse effects with the objective of determining safety and/or efficacy of the new drug.

**Rule 122DB** Suspension or cancellation of permission/approval.

**Rule 122DC** Reapplication appeal within 60 days to the Central Authority for reinstating a cancelled/suspended licence.

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The next rule that is 122 DC, it is related to the appeal. So, if the permission has been cancelled for the manufacturing or for the import then that applicant can again apply or appeal to the central government within a 60 days. And the central government if find the justification has been given properly then the central government can decision take a decision as it deem fit.

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## DRUGS AND COSMETICS RULES

<b>Rule 122DAB</b>	Compensation in case of injury or death during clinical trial [G.S.R. 53(E) dated January 30, 2013].
<b>Rule 122DAC</b>	Permission to conduct clinical trial [G.S.R. 63(E) dated February 1, 2013].
<b>Rule 122DD</b>	Registration of Ethics Committee, [G.S.R. 72(E) dated February 8, 2013].
<b>Amendment to Rule 122DAB</b>	G.S.R. 889(E) dated December 12, 2014 clarifications on the criteria for eligibility of compensation (effective from June 13, 2015).

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The next rule that is rule 122 DAB, it is related to the compensation in case of injury or death the clinical trial. This rule has been added in 2013 by the GSR 53. So, in this rule the clauses regarding the compensation how to give the compensation, in which cases the compensation has to be given whether the compensation is in the form of the free medical management. Or, whether it is a in form of the financial assistance and whether that injury or SAE is related to the clinical trial or not, how to ascertain it that is given in this rule. How to relate this injury or SAE and when we can say that the injury or SAE is related to the clinical trials, the process reasons are also given in these rules. This possible reasons like a failure to comply with the protocol.

Then the failure of the failure of the investigational drug likewise the reasons are given if these reasons are there then the sponsor has to give the compensation to the subjects. Rule 122 DAC it is related to the permission to clinical trial. This rule has also been inserted in the drug and cosmetic rules in 2013 vide GSR 63. So, this is a to give the permission in which cases the licensing authority can give the permission to conduct clinical trial. The applicant has to apply to the central licensing authority in a prescribed format and along with the documents.

This documents after verifying if the data found adequate and licensing authority satisfied the data given are adequate then the licensing authority can issue a clinical trial, permission to conduct phase 1, phase 2 or phase 3 with for that drug. This permissions

can be given with the condition and that applicant has to follow this conditions of the permissions. The conditions like clinical trial to be conducted as per approval and as per the schedule Y guidelines as per the GCP guidelines.

The condition like ethics committee approval is required for prior approval before initiation of the any clinical trial. Then registration of CTRI that is clinical trial has to be registered on the site Clinical Trial Registry of India that is also mentioned in the condition. Then regarding SAE reporting the ethics committee and the sponsor will report the SAE, if occur within a particular time to the licensing authority that condition also stipulated there. Then regarding the compensation clause, that in case of injury or death the sponsor will be entitled to provide the detailed compensation that is also given there.

Rule 122 DD this rule is related to the registration of ethics committee and it has been introduce in the drug and cosmetic rules in 2013 vide GSR 72. As per this rule the no ethics committee, if it is not registered cannot review or approve the protocol for the regulatory purpose. So, application for ethics committee, registration how to apply, where to apply it is given under this rules; the license licensing authority after satisfying that the documents submitted by the applicant are well formed then can give the permission of the registration.

Also in case in case of SAE the opinion has to be forwarded by the ethics committee that is also stipulated there and the registration of this ethics committee is valid for 3 years. The amendment has been made to this rule 122 DAB and this is regarding the clarification on the criteria for eligibility of compensation, this is given in 2015. Coming to the next slide the different forms related to the new drug and clinical trials. So, form 44 it is the most important form because, it is application for grant of permission to import or manufacture a new drug to undertake a clinical trial. So, the applicant has to apply in the form 44 pro-forma given under the rules of this act.

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## FORMS RELATED TO CLINICAL TRIAL AND NEW DRUG

- FORM 44:** Application for grant of permission to import or manufacture a new drug or to undertake clinical trial.
- FORM 45:** Permission to import finished formulation of new drug.
- FORM 45A:** Permission to import raw materials (new bulk drug substance).
- FORM 46:** Permission/approval for manufacture of a new drug formulation.
- FORM 46A:** Permission/approval for manufacture of raw material (new bulk substance).

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In this form the applicant has to submit the name of the form who is applying then the particulars of new drug that its dose, dosage forms, strength, name of the drug, centre national name. Then the regulatory status of the drug whether this drug is withdrawn from some country whether it is prohibited in any other country in the reason there off or if it is approved in country or it is a market in that country in that regulatory status to be given in this form.

Then about the marketing information, then proposed a draft label, what should be the draft label, what indication they are going to give on this label of the drug and the monograph and other things also given in this form. In this form it is also given that data required to be submitted should be as per schedule Y. So, we are going to see the schedule Y and what is the data requirement in detail in our next slide, then form 45 it is permission to import finish formulation of a new drug.

So, if somebody want to import new drug then he has to apply in form 45 and if it is a new drug again it will require first clinical trials. So, in this form again the name of company, then detail of drug like name, dosage form, dosage from, strength indication of the drug which is to be imported that is given in this form. Condition of permissions are also given in this permission and these conditions are regarding that the applicant will follow the specification of the drug what he has submitted. Then the labeling condition, what are the draft is approved that label will be there on the final package.

And also the warning if any that applicant has to be given on the label that is also given; warning like to be sold by retail prescription of gynecologist, diabetologist or whatever the approved by the licensing authority that warning is also has to be written by the applicant. Form 45 A is permission to import raw material that is a bulk drug in ingredient. So, above form was for the formulation and this form is for the raw material.

So, for this also the conditions have been mentioned in the form, the condition of permission to confirm to the specification. So, whatever the specification approved by licensing authority, the applicant while manufacturing or while importing that drug has to follow that specification that condition is stipulated there. Even though this permission has been given for the raw material, it does not mean that the formulation he can import or manufacture. He has to take a separate approval for the formulation, for import or the manufacture of these drugs.

The next form that is form 46, it is permission approval for manufacture of new drug formulation. So, again in this forms the details of the company, detail of the drug with respect to name dosage form, composition has to be given. Condition of permissions are given that the applicant will follow the specification, labeling rules and the warning if any stipulated in the condition of the permission that he will follow, that will given in this form.

Then form 46 A is a permission approval for manufacture of raw material. It is also the same that the permission for the manufacture what we have seen in the permission for the import of the raw material. There are some conditions given that the applicant will follow the specification and he will take the separate approval for its manufacturing of the formulation; coming to the next slides.

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- A- Forms for applications for permission to import or manufacture (license) or sending the sample for testing
- B- Fees for testing/analysis by CDL/SDL
- C/C1- Import/manufacture/sale/distribution of biological products
- D- Import of substances not intended for medical use
- D-I & D-II- Information required to be submitted along with application for import registration certificate
- E- Omitted, E-1 – List of poisonous substances under ayurvedic system

CDL- Central drugs laboratories, SDL- State drugs laboratories

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Now, what I have said that the rules contain the schedules that schedules are from the schedule A to schedule Y. So, we will see this schedules in detail what you what are these schedules. Schedule first is the pro-forma of the forms. So, what the forms we have seen above that is form 44, form 45, form 46, 46 A, 45 A and many other forms are given in this schedule A. Form from first to the form up to the form 50 with different sub form that is form 40 A 46 A 46 B likewise the forms of all the pro-forma is given in this schedule A, schedule B is related to the fees.

So, what is the fees requirement for the testing of this drug it is given in the schedule B. For example, if somebody want to conduct a pyrogen test than required fees 500 rupees, if it is a for biography of antibiotic than 400 rupees fees. If somebody want to test or the test requirement is for the potential testing of DPT or DT vaccine then the fees charged by this laboratories are 2700. So, many of the testing fees and for each test an analysis is given in this schedule B.

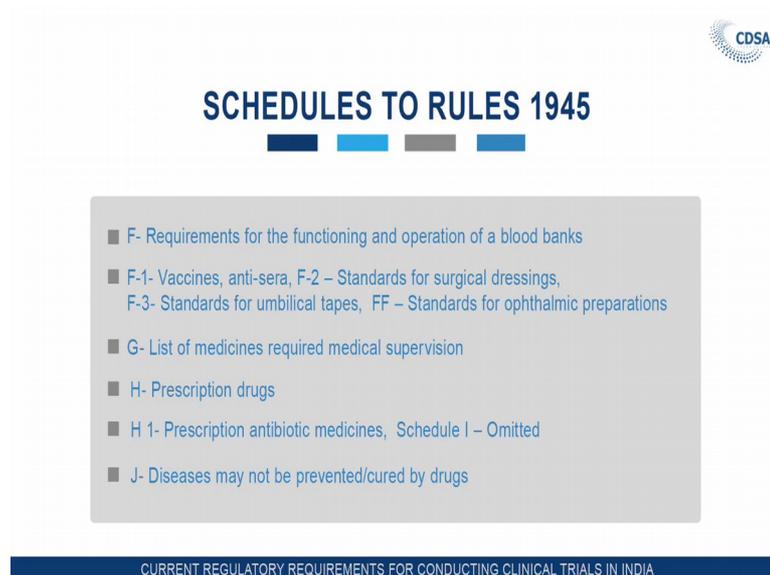
Schedule C and schedule C 1 these are related to the import, manufactures, sale distribution of some biological products. The biological products like a sera, vaccine, toxine, antigen, insulin, fish liver and other the formulation which are to be administered apparently. Schedule D is for import of substances not intended for medicinal use; some of the substances which are not for medicinal use does not require the permission from licensing authority. So, which are the substances which do not require permission from

licensing authority for its input is given in this schedule. The substances like oats, then lactose, than cereals, pepper, gingers. So, all these which are not require the permission is given in this schedule D.

Schedule D I and D II is a related to the information required to submit along with application for import and registration certification, while applying for the permission to import or have the registration certificate from licensing authority what data the applicant has to be submitted, what are the particulars, how it has to be submitted, what is the fees that everything is given in schedule D I and D II. Schedule E earlier it was there now it has been omitted and schedule E 1 has been inserted. The schedule E 1 consists of list of poisonous substances under ayurvedic systems.

So, whatever the poisonous substances mentioned in the ayurvedic system that has been given in schedule E 1. And this poisonous substances like sarpvish, then hartala, then arka all this substances whatever mentioned that is given in this schedule E 1.

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- F- Requirements for the functioning and operation of a blood banks
- F-1- Vaccines, anti-sera, F-2 – Standards for surgical dressings, F-3- Standards for umbilical tapes, FF – Standards for ophthalmic preparations
- G- List of medicines required medical supervision
- H- Prescription drugs
- H 1- Prescription antibiotic medicines, Schedule I – Omitted
- J- Diseases may not be prevented/cured by drugs

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Schedule F is requirement for the functioning and operation of the blood bank. So, blood bank blood product comes under the biological product and the Drug and Cosmetic Act has been provided to give some provisions; how to operate the blood bank, what should be the norms, what should be the specification of the blood, blood products, what is the area requirement for the blood donation and for the blood collection? That all is given in the schedule F.

Schedule F 1 is vaccine antisera, schedule F 2 standards for surgical dressing, schedule F 3 standard for umbilical tape, schedule FF is for standard for ophthalmic preparations, schedule G is list of medicines required medical supervision. So, those the substances are medicines which require special supervision by the medicinal practitioner that the list of these drugs have been given in the schedule G. The medicines like bleomycin, then insulin and other medicines the list is given in this schedule G.

The next schedule that is schedule H, it is a prescription drug, the retailer has to sold the drug with the prescription only. So, these types of drug what are these which can only be sold by the prescription, the list of these drugs has been given in this schedule H. The drug like acyclo acyclovir then the bimatoprost, dosetocs scril, enalapril this drug which require the special supervision and to be prescribed by the doctor or RMP mention under the Drug and Cosmetic Act; the list of such drug is given in this schedule.

Schedule H 1 is also prescription drug and this is related to the prescription of antibiotic medicines. In this schedules the drug like alprazolam, then safexin, diafarm, isoniazid and other drugs these are mentioned in the schedules. Schedule I is omitted one, then schedule J is the schedule for which applicant cannot claim to prevent this diseases through the list of the diseases like a (Refer Time: 33:50), cancer, then malaria and other things AIDS. All these diseases which the applicant or medicine cannot claim that this drug can be cured or prevented or treated by this drugs. The list of such diseases and elements are given in schedule J.

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The slide features the CDSA logo in the top right corner. The main title is 'SCHEDULES TO RULES 1945' in bold blue text, centered. Below the title is a list of schedules, each preceded by a small square icon: K- Drugs exempted from provisions that are applicable to manufacture; L-1- Good laboratory practice (GLP); M- Good manufacturing practice (GMP), M-1, for homeopathic, M-II, for cosmetics, and M-III- QMS for notified medical devices and *in vitro* diagnostics; N- Minimum equipment in pharmacy; O- Standards for disinfectant fluids; P- Life period of drug/drug products, P-1- Pack size of drugs. At the bottom of the slide, a dark blue bar contains the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA' in white capital letters.

Let us see schedule K, schedule K is the drug exempted from provision that are applicable to manufacture. For the manufacturing the certain provisions has to be exempted for special type of drugs. So, what are this provision and which type of the drug like a quinine another anti malarial drug then antacid preparation. So, some of the provision of the manufacturing has been relaxed and are exempted to give while giving the permission. So, this is given in the schedule K.

Schedule L 1 is a good laboratory practices, the practices to be applied in the laboratory are given in schedule L 1. Schedule M is a good manufacturing practices. So, this schedules again divided into schedule M 1, M II and M III, the good manufacturing practices for the manufacturing of homeopathic drug is given in schedule M 1. For the manufacturing of cosmetic it is given in M II and for the medical device it is given in M III, that is QMS for notified medical devices and *in vitro* diagnostics.

Schedule N is the minimum requirement of equipment in pharmacy that what are the equipment minimum equipment the pharmacy should have that all equipment has been mentioned in schedule N. schedule O is standard for the disinfectant fluids all the standards which is required to be followed by the manufacturer of a disinfectant has been given in the schedule. Schedule P is life period of a drug that is a shelf life of the drug, what should be the shelf life of a particular drug. The list of this drug along with its storage and along with its shelf life has been mentioned in this schedule P.

Schedule P 1 is the package size of drug; for example, you can say the amoxicillin is the storage condition and the shelf life as given is 36 months. For the penicillin tablet it is given 18 months. And in schedule P 1 package size of the drug like albendazole to be packed in 10 ml or the or the piperazine granules to be packed in 5 gram size or if it is cereals it should be a 30 ml. So, all this the pack size and the shelf life is given in schedule P; coming to the next slide.

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Schedule Q is related to the dyes, color, pigment permitted to be used in a cosmetics. So, as we have said that the cosmetics is also regulated. So, whatever the colors, pigments and the dyes used in cosmetic color like a sunset yellow, tartrazine in all these are given in part I and part II. Part II is the specially for the colour dyes used in the soap and part I is for the cosmetics, then schedule R is for the standard for condoms.

The how it should be the condom the standards are given in this schedule. Schedule S is standard for cosmetic, the standard to be followed by the manufacturer or importer in case of the cosmetic is given in the schedule. Schedule T is related to the GMP for ayurvedic medicine. So, in schedule M we have seen it is GMP for the routine normal drugs, then GMP for homeopathic, GMP for medical device and cosmetic only remaining is the GMP for the ayurvedic. So, what the practice are to be followed for manufacturing of ayurvedic medicine is given under the schedule T.

Schedule U is related to the record for manufacturing raw material in drugs. So, what are record the applicant has to be maintained and has to be shown while the inspection that the least of these records are given in the schedule U. Schedule V is a standard for patent and prosperity medicines. Scheduled W it was the list of drugs to be sold with the generator and it has been omitted now.

Schedule X is narcotic and psychotropic drugs. So, in this schedule whatever the narcotic and psychotropic drug which requires special attentions are given in the schedules. The drugs like amphetamine, barbital, ketamine that can be misused so all these drugs are given in this schedule. Schedule Y we have seen many time and it is more related to the our course that is the related to the clinical trials. So, it is the schedule Y is for the requirement and guideline for permission to import drugs, manufacture of drug of new drug for sale or to undertaker clinical trials. We will see this schedule in detail in our subsequent lectures; coming to the next slide the different drug testing laboratories.

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## CENTRAL DRUG TESTING LABORATORIES

<b>Central Drug Laboratories (CDL), Kolkata:</b>
Testing of new drugs, samples sent by court, drug inspectors, survey samples, preparation of standards.
<b>Central Drug Laboratories (CDL), Kasauli:</b>
Testing of vaccines, sera, biologicals, OPV testing.
<b>Indian Veterinary Research Institute (IVRI), Izzatnagar:</b>
Testing of veterinary vaccines, veterinary drugs.
<b>National Institute of Biologicals (NIB), Noida:</b>
In vitro diagnostic (IVD) kits (local and imported).

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So, where this all the product mention in our different schedules and the categories of the product can be tested, the list is also given here. The Central Drug Laboratory that is CDL at Kolkata is responsible for the testing of new drugs, samples send by the court and the drug inspector as we have seen the drug withdraw the sample for its testing analysis; they can send the sample to the CDL Kolkata.

Then the survey sample and the preparation of the standard, this is the responsibility of central drug laboratory Kolkata. Central drug laboratory is also available at Kasauli and this laboratory is particularly involved in the testing and analysis of the biological product that is a vaccine, sera, OPV testing. So, whatever the samples related to the vaccine, sera and other biological product has to be sent and are tested by the central drug laboratory at Kasauli.

Then another laboratory that is for the veterinary medicines that is Indian Veterinary Research Institute IVRI it is at Izzatnagar. This is involved in testing of veterinary vaccines, veterinary drugs. So, whatever the veterinary vaccine and the drug that can be tested here at Izzatnagar; the national institute of biological which is at Noida is mainly involved in testing of in vitro diagnostic kits, that is local and imported both that kits privates permission has to be undergo testing at this laboratory.

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Central Drug Testing Laboratory that is CDTL is at Mumbai and Chennai. So, this drug testing laboratories are also involved in testing of the samples send by the drug inspector. And all the new drugs and all the routine survey sample can be tested for that particular zone in this laboratory; let us say for this special biological products such as vaccine and another. Regional drug testing laboratories at Guwahati, Chandigarh and Indore; so, this laboratory has also been created to test this drug sample sent by the inspectors and sent

by the server samples or any other customer also can send the sample to this laboratory for that particular zone.

In the Indian pharmacopoeia commission it is the laboratory at Ghaziabad and this laboratory is mainly involved in preparation of drug monograph and then its standard. The pharmacovigilance centre is also available this is the coordination centre and publication of IP is also the responsibility of the Indian pharmacopoeia commission. Coming to the next slide so, what we have seen this where the central drug testing laboratory, the central government send the sample to this laboratories. Now, let us see the state drug laboratories.

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The slide features the CDSA logo in the top right corner. The main title is 'STATE DRUG LABORATORIES' in bold blue text, followed by a decorative bar with four colored segments (dark blue, light blue, grey, dark blue). Below this is a dark blue box containing the text 'Drug control laboratories in the state'. Three light grey boxes with blue text follow, each containing a point. At the bottom, a dark blue bar contains the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA'.

**STATE DRUG LABORATORIES**

**Drug control laboratories in the state**

- Every state has a laboratory for the analysis & testing of the drug & cosmetics manufactured or sold in that particular area.
- Samples sent by drug inspectors are analysed by these laboratories.
- Also analyses the drug sent by any person or purchaser on payment of a necessary fee.

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So, every state has a laboratory for the testing and analysis of the drug cosmetics manufacturer of sold in that particular area. So, few of the few of the states they are not having their own laboratory, they can send the sample to the central government laboratory. Few of the state they are having many laboratories to test the samples and the drug samples which are taken by their inspector. Sample send by drug inspectors are analyzed by such laboratory as I have said, then also analyze the drug send by any person or purchase on payment of necessary fees.

So, there is a provision in the act and rules that anyone who is aggrieved by the sample or would like to test the quality of the sample he can also send this sample in a particular format which is given in our format given in our schedule A what we have seen. He can

send their sample to these particular laboratories and these laboratories in particular format give its result to ensure that the drug is having the quality or not. So, this is all about this lecture. So, what we have seen let us now recap of this lecture; so, the question for this lecture for you.

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**RECAP**

**1** Name the laboratory responsible for testing of vaccines, sera, biologicals, OPV in India?  
Central Drug Laboratories (CDL), Kasauli.

**2** Name the rules that are related to new drug and clinical trial?  
Rules 122A, B, D, E, DAB, DA, DB, DC, DD, DAB, DAC.

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Laboratory responsible for testing of vaccines, sera and biological you have to mention the name of the laboratory and where it is. So, it is the central drug laboratory of Kasauli which is involved in testing of vaccines, sera, biological and OPV testing's. What rules are related to new drug and clinical trials? There are many rules you have to answer; the rules like 122 A, B, DAB, DA, DC, DAC all these rules are related to the new drug and clinical trial.

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**RECAP**

3 Under which rule, registration of Ethics Committee is mandatory?  
Rule 122DD.

4 What is Schedule L1?  
Schedule L1 is Good Laboratory Practice (GLP).

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Under which rule registration of ethics committee is mandatory? The specific rule is given for the registration of ethics committee. The rule 122 DD is for the registration of ethics committee. What is schedule L 1? We have seen all the schedules, schedule L 1 is a good laboratory practices. So, in lecture 4 let us have the recap and summarize it.

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**SUMMARY**

In lecture 4 we briefly learnt about:

- Objective of D&C Act, 1940 and Rules 1945.
- Different chapters are available in this Act.
- Rules pertain to new drugs & clinical trials.
- Different Schedules to the rules.
- Awareness about drug testing laboratories in India.

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We have learn about the objective and objective of Drug and Cosmetic Act and rules there under. The objective is to ensure the quality safety and efficacy of the drugs available in the market. Then we have seen the different chapters available in act there

are actually 6 chapter, but is up to 5 that is including IV A chapter and chapters are having different sections. Different schedules to the rule, we have seen the different schedules in the available in the rule that is schedule A to schedule Y.

Then we have seen the drug testing laboratory there are many laboratories at the central level and they are having the specific functions related to the biological drugs, then IVD and medical devices. We have also seen the different testing laboratories which are available at state level for the testing and analysis. So, this is all about this lecture, we will see something others in our next lectures; till then bye bye see you.

And thank you.