Current Regulatory Requirements for Conducting Clinical Trials in India for IND/New Drug Version 2.0

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Lecture – 03
Overview of Drugs & Cosmetics Act and Rules thereunder

Hello friends, welcome back to lecture 2, I hope you are doing well and enjoyed our lecture first which was about CDSCO and State Licensing Authority, wherein we have seen different functions of the state government, different function of the CDSCO. CDSCO its different offices, then the hierarchy of the CDSCO and the functions which are exercise by the state and central government which are associated with the Drug and Cosmetic Act and Rules thereunder. So, now, it is the time to see what is this Drug and Cosmetic Act, what is its objective and what are the rules under which.

So, in this lecture we are going to see about Overview of Drug and Cosmetic Act and the Rules thereunder.

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So, this lecture will cover the overview of Drug and Cosmetic Act and Rules thereunder; then different chapters available in the Drug and Cosmetic Act 1940, the different rules cover under drug and cosmetic rules 1945, the various schedules which are available in the act and various schedules which are available in the rules.

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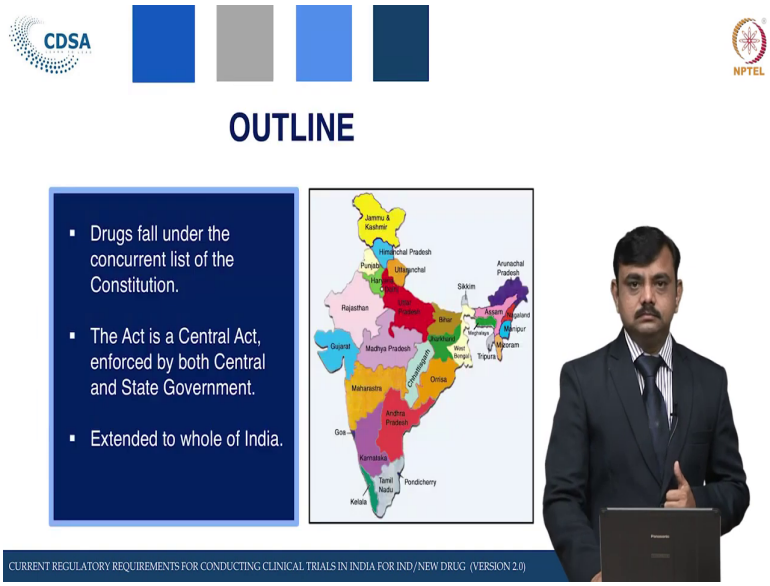

Dear friends, we have seen that the drug subject is in the 7th schedule of Indian Constitution and it is in the concurrent list. Hence it has been exercise at two level, that is central government level and state government level.

This act is extended to the whole of India. We have seen in our first lecture that every state is having its own state licensing authority, which is called as FDA or the commissioner drug control authority that we have seen in our first lecture. Let us see the objective of the Drug and Cosmetic Act.

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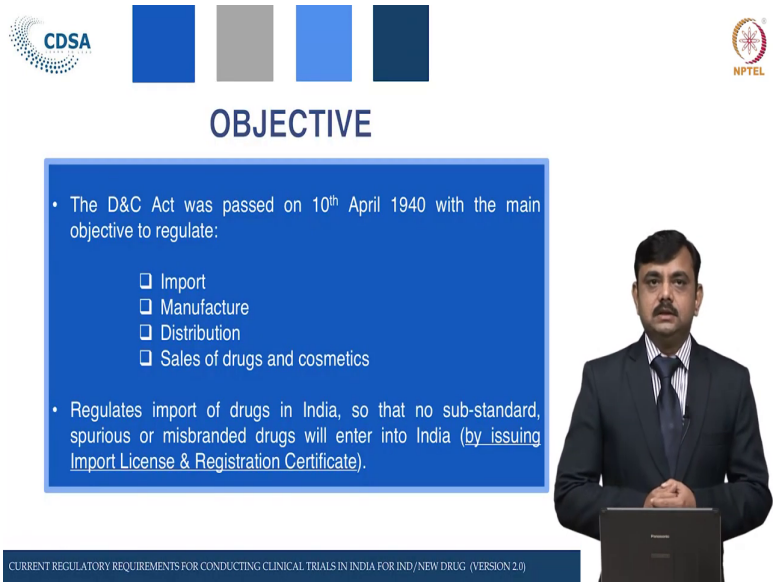

The Drug and Cosmetic Act was passed on 10th April 1940 with the main objective to regulate the import, manufacture, sale and distribution of the drug and cosmetic. The import of the drug is regulated by issuing the import license and registration certificate, to avoid the substandard or the not of standard quality drug in the market.

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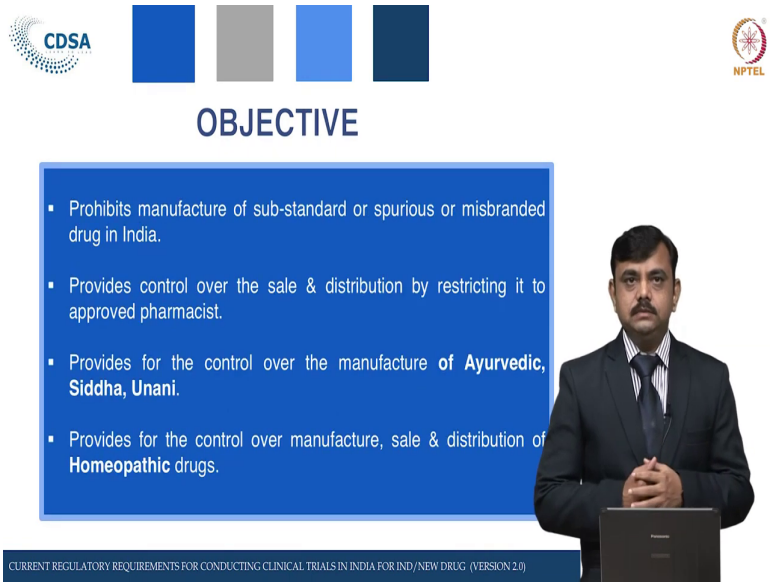

The act prohibits manufacture of sub standard spurious or misbranded drug. If anybody is manufacturing the sub standard drug, it is the violations of the conditions and under the act he can be punished with fine and imprisonment. The act provides control over the sale and distribution of the drug and cosmetic and also the medical devices by restricting the sale of this drug and the medical devices and cosmetic with the pharmacist. It means the pharmacist only has to sale the drugs, so, that only the right drug can reaches to the patients.

The act provides for the control over manufacture of the our traditional systems; drugs that is Ayurveda then homeopathic and Unani also. It provides for the control over manufacture sale and distribution of homeopathic drugs as well. How the quality of the drug which are available in the market is regulated by the regulator. So, for that as I have said there are two

things; the first is the regular inspection and giving them the manufacturing licenses in case of the import giving them the import license.

The second thing is the sampling of the drugs. The drug inspector are responsible to pick up the samples and they are sending these sample to the laboratories, the laboratories take this sample and evaluate for its quality of the drugs. The act also prescribes the manner and requirement of labeling and packing of the various classes of drug and the cosmetics. Let us have look on the various chapters of the act.

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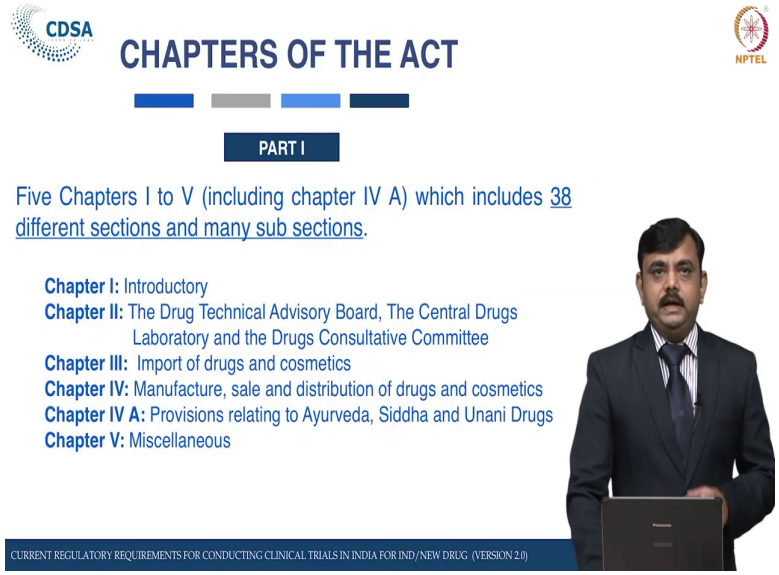

In fact, in the Drug and Cosmetic Act there are 6 chapters, but it is up to a fifth that is one to fifth and one more chapter it is having that is a IV A, hence these are the 6 chapters. The act is provided with a 38 different sections and it is having many sub sections.

The first chapter is the introductory chapter where in the extent an application of the act has been given. The second chapter is provided with the drug technical advisory board we call it as a DTAB and the DCC committee. This committees are mainly responsible to give the advise to the government, mainly the matters, technical matters arising out of this act such as banning of the drug, prohibition of the drug. Recently we have prohibited the manufacturing the of the oxytocin, we have prohibited the import of the oxytocin, that is after the consultation with this DTAB committee.

We are having the another committee we call it as a drug consultative committee this committee is mainly responsible for unifying the implementation of the rules and regulation across the country by various state licensing authorities. Chapter III is exclusively for import of drug and cosmetics. So, whatever the procedure to import the drug and cosmetic in India what is means by import, what are the applications, in what form the import license and registration certificate is being issued by central licensing authority, that is given in this act and in case of the violation of these conditions, what are the punishment and what are the offenses that is also given in this act in this chapter.

Chapter IV is related to the manufacture sale and distribution of drug and cosmetics. Similar for the what we have seen in case of the import it is for the manufacture. To prohibit the manufacture of sub standard not of standard quality drug, misbranded drug, the act provides the procedure, how to apply for the manufacturing in what form the applicant has to apply in what form he will take the manufacturing license, what forms are require, what licenses are require for its sale and distribution, what are the condition stipulated there in the licenses issued that has been given in the chapter IV.

Chapter IV A it is provisions relating to the Ayuevedic Sidda and Unani system. Similarly what we have seen for the import manufacture of the drug the same things are apply for the Ayurveda Sidda and Unani system the applicant has to take the license for its manufacturing and for its sale. In case of Ayuveda, the sale license is not require;however, in case of the homeopathy the sale license is required. So, whatever the procedure and provisions that that have been provided in this chapter.

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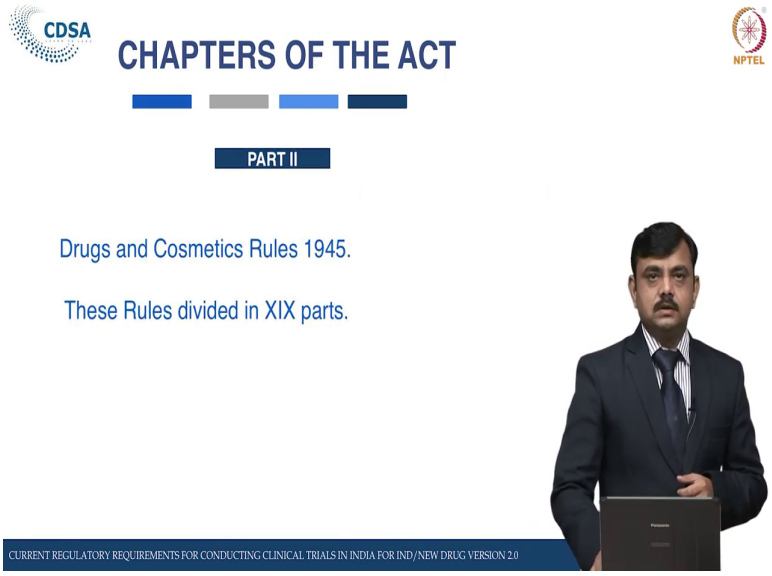

Chapter V is a miscellaneous chapter. So, the part II we can divide this Drug and Cosmetic Act and rules as a part I and part II. Part I is about all the chapter what we have seen and the part II is drug and cosmetic rules 1945. These rule for the sake of convenience has been divided into the 19 parts. Each part deals with the different activities now let us see what are the schedules available in the act.

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So, there are two schedule in the act; the first schedule it gives the list of Ayurvedic Sidda and Unani books. To manufacture the Ayurvedic Sidda and Unani preparation, what are the procedure and which are the drugs which are available in the books. So, the list of the books to be use has been provided in the first schedule.

The second schedule is related to the standard to be complied with by imported drugs and drugs manufacture for sale and distribution. This whatever the drugs which are coming into the India through the import or the drug which are available in the market through the manufacturer, what are the specification, what are the standard the applicant or the manufacturer or the importer has to specify that has been given in the second schedule and it has been maintain in the schedule that they should comply with the pharmacopoeia of India.

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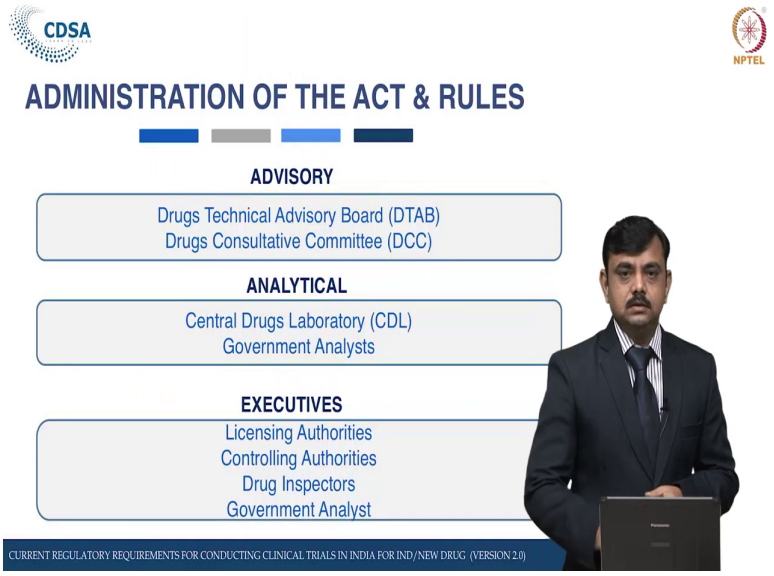

Moving to the administration of the Drug and Cosmetic Act and rules; so, the act is provided with the three types of the committee that is advisory, analytical committee and the executive body. Advisory committee we have seen that it consist of the drug technical advisory board and the drug consultative committee. Then we are having the analytical laboratories these are for the testing of the drug and cosmetics since by the regulator, these are called the central drug laboratory and the government analyst is the responsible for giving the result. Then the executive body is also there. So, in the in the act the licensing authority, controlling authority and drugs drug inspector has been defined.

Let us see what is import manufacture and sale of drug.

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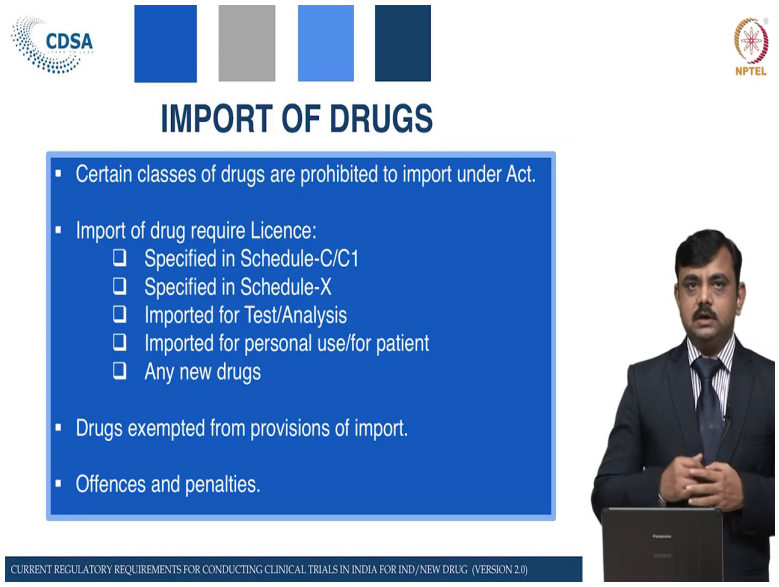

So, under the act certain classes of drug provided to import and this classes of drug which are the drug which are removed from that country, the drug which are suspended in that country or the drug which are prohibited in the India, this drugs are prohibited to import into the India. Certain drugs which are allowed and but these drugs require the license from the Indian regulator. These drugs are specified in schedule C and C 1; the special these are special biological products schedule C and C 1.

The drugs which are specified in schedule X, which is related to the narcotic and the psychotropic drug. So, this type of drug also require a license imported for test and analysis. So, the drug if it is not available in the India and if the applicant likes to import that drug in the small quantity for iron d purpose or test and licensing purpose then also it require to take a test license either from state government or either from the central licensing authority.

Import for personal use or for the patient use. If the drug is not available in India and somebody would like to import for the personal purpose, then he has to apply to the central licensing authority and accordingly the central licensing authority can give him the permit to import the limited quantity of the drug for the personal use. Same is for if the government institution or any of the institution, if they desire to bring certain kind of drug for their patient, then they can apply to the central licensing authority and after verifying the physicians prescription and the patients data, the central licensing authority can give them permit to bring such drug.

Any new drugs if the drug is not available India and the new drug if it require to import then the proper procedure is there, that procedure the applicant has to conduct clinical trial. If it is not available in the India and then he has to take the import license and the registration certificate and then he can import the drug to the country. Certain drugs exempted from the provisions of import; the drug such as mannitol and other which are having the dual purpose, some drug which are not for the medicinal use that that are exempted from the taking the import license in the registration certificate with certain conditions. So, violation of the import license conditions or not complying with the conditions what are the penalties, what are the offences that has also been given in the act. So, this is all about the import.

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In case of the manufacturer to avoid the sub standard drugs in the market, the certain drugs prohibited to manufacture such as the drug which are misbranded, the drug which are spurious or the drug which are having not having the standard quality or the drug which have been prohibited restricted by the central licensing authority by giving notification, these drugs cannot be manufactured by the manufacturer. The drugs which are require license are the manufacture of other than in schedule CC C and C 1. So, the drug which are available in schedule C and C 1 mostly it is a parenteral non parenteral biologicals. So, to manufacture these it require a license. The manufacture of those in schedule C and C 1. So, both the drug which are in schedule C and C 1 and which are not in C and C 1 both it require the manufacturing license.

The manufacture of schedule X drug; it means the drug which are for the narcotic and psychotropic purposes, but which are having the medicinal use and if somebody want to

manufacture, he has to applying certain form to the state licensing authority or to the central licensing authority then he will be issued the manufacturing license.

Loan license in case of the applicant is not having his own manufacturing facility, but who desire to manufacture drug for the Indian market then he can avail the others facility, but before that he has to inform to the central licensing authority or state licensing authority and accordingly he has to apply for the loan license after taking the loan license from the state licensing authority, he can manufacture the drug in others facility. Provided that this facility should be complied with the schedule M that is good manufacturing practices and if it is for medical device then the quality management assisting.

So, violation of the condition of these manufacturing licenses then manufacture of the prohibited drug, manufacture of misbranded drug, the violation that has been given in the offenses and the penalties has also been given in the Drug and Cosmetic Act.

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After the import and manufacture, there is a sale of the drug. Certain classes of drug prohibited to be sold in the market. Those drug which are sub standard, those drug which are prohibited by the central licensing authority by giving a notification this type of drugs are prohibited to be sold.

Other category of drug what we have seen in schedule C C 1, then schedule X drug, these drugs require to take a drug license even if they are sold out by the retail or wholesale, then it has to take the license from the state licensing authority. Let us see what are the different schedules in the rules.

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We have seen there are two schedule in the act. Now these are the schedules starting from A to schedule Y, these are schedule to the rules. So, the schedule A is regarding the proforma of forms. So, in this schedules all the forms from starting from 1 to form 50 has been given, there are different sub sections; so, that form A form B.

So, these forms provides the applicant to apply in the particular format if somebody would like to apply for the retail sale or wholesale sale, then he has to apply in a particular format the format has been given in the schedule A. Then the schedule B it is a rate of fees for test analysis by the CDL. So, different rates have been already given in the drug and cosmetic rules. So, what are the fees to be charged by the central drug licensing central drug laboratory that has been prescribed in the schedule B. For example, for bioassay of antibiotic it require to charge the 400 rupees or for (Refer Time: 17:28) 150 rupees or for the UV it is 100 rupees the

different type of test that is chemical test, physical test, then the pharmacological test the test and their charges have been mentioned in this schedule B.

Schedule C is list of biological and special products. So, this special product are related to the injectable product that is parenteral and what are the provision applicable that has been given in the schedule C this special product like sera, vixen, antigen and antitoxin. C 1 is related to the list of biological and special product and this is specially for the non-parenteral. Those the product which are not to be administrate by the injections these products such as fish liver oil, then in vitro diagnostics or the (Refer Time: 18:22) diagnostics preparation these are in the schedule C 1.

Schedule D is related to the list of drug that are exempted from the provision of the import; is those the category of the drug or devices which are exempted from the import which do not require the import license such are the those drug which are not for medicinal use or the those drug which are imported into the India manufactured and again to be exported in the SCZ. So, these are also exempted from the import and registration license.

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The schedule D is again having a three sub part that is schedule D 1 schedule D 2 and D 3 where in the documents require to be submitted for the import and registration of the formulation and API has been given.

Schedule F is related to the blood bank. So, whatever the provisions applicable or the procedure applicable to run a blood bank and the blood product that has been given in the schedule F. Schedule F 1 is a special provision applicable to biological and special products for example, bacterial, viral vaccines which are used for the animal purposes such as anthrax spore vaccine or the fowl cholera vaccines. So, what are the provision or what are the specification to be applied for these has been given in the schedule F 1.

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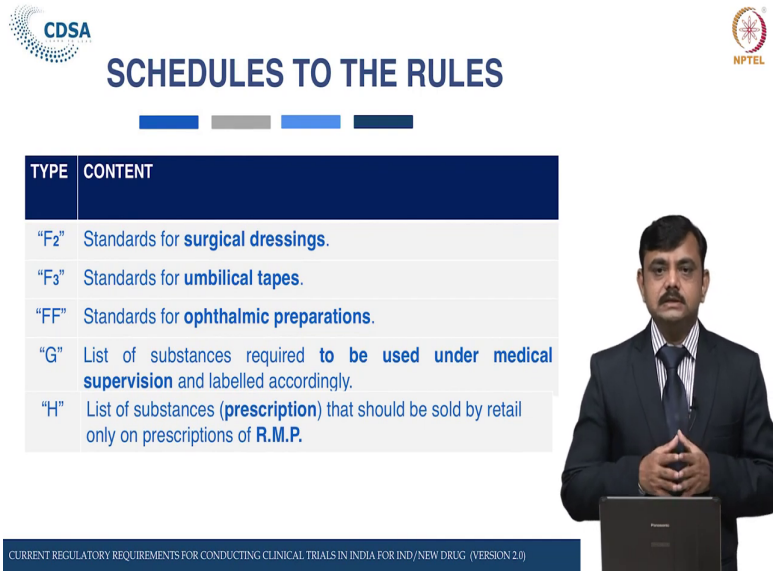

F 2 is related to the standard for surgical dressing such as bandages cloth and bandages gauze. So, what should be the dimension and what should be the length, what should the diameter everything has been given the schedule F 2. Schedule F 3 is related to the standards for the umbilical tapes. Schedule FF is for standard for ophthalmic preparation. The preparation like ophthalmic solution, ophthalmic suspension, what are the provision, what are the standards applicable to this preparation that have been given in the schedule FF.

Schedule G is a list of substances required to be used under medical supervision and labeled accordingly. So, the schedule G is provided with the list of substances to be use under medical supervision only if the doctor prescribe then only that has to be gives. Then schedule H is a list of substances that is we call it as prescription drug that that should be sold by retail only on the prescription of the physician. So, without the prescription of the physician, the retailer should not have to sell these drugs. The drugs like antibiotic, the drugs like narcotic

psychotropic these are require to be sold by the retailer only on the prescriptions. So, the list of such drug has been given in the schedule H.

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Schedule J is the list of diseases and ailment that drug should not claim to cure. The diseases like AIDS, then if it is a blindness, the fairness, the insanity, diabetic this cannot the drug cannot claim to be cure by the drug. So, the list of such devices has been given for which the manufacturer import cannot claim to cure these diseases. Schedule K is list of drug that are exempted from the provision regarding to manufacture what we have seen the product which are not use for the medical purposes or the condensed milk. So, the certain presumption has been given under the schedule K.

Schedule L 1 is the good laboratory practices. So, the animal toxicity testing or what are the animal toxicity testing there conducted in the laboratory that should be comply with the good

laboratory practices according to the schedule L 1. Schedule M 1 and M 3 these are as we know these are related to the good manufacturing practices for the drug, for the medical devices, for the cosmetics. Now with the recent publication of the medical device rule so, this schedule M 3 which is exclusively for medical devices is no more in existence.

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Schedule N is provided with the list of equipment to run a pharmacy. So, if somebody would like to run a pharmacy, then what are the minimum equipments require to run the pharmacy that list has been given in this schedule. Schedule O is for the standard for disinfectant fluids. So, whatever the standards required to be complied by the manufacturer that has been given in schedule O. Schedule P is provided with the life period of a drug. So, what should be the pack size, what should be the shelf life of the drug that has been given in the schedule P?

Schedule Q is related to the coal tar color permitted to be used in the cosmetic. So, how much should be the quantity to be permitted in the cosmetic regarding the coal tar color, what should be the specification standard that has been given in the schedule Q. Schedule R standard for medical devices as I have said medical device this is no more now because the separate medical device rule is in effective since 2017.

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This schedule is requirement of factory premises for Ayuevedic Sidda and Unani.

Then schedule U is manufacturing and analytical record of a drug. So, what are the record to be kept by the manufacturer that has been given in schedule U, Schedule U 1 is manufacturing and analytical record of the cosmetics? So, the U is for the drug and the U 1 is for the cosmetic the record to be kept by the manufacturer. Schedule V is provided with the standard for patent and proprietary medicines. So, those the medicine which are not in

market, those which are the standard specification not available in the pharmacopeia and if it is a patent and proprietary drug, then what the standard they should follow so, that is maintained in the schedule V.

Schedule W is list of drugs marketed under generic names. Again this schedule was there, but now it has been omitted. Schedule X is list of narcotic drug and psychotropic substances. So, which are the narcotic and psychotropic substances that has been given in this schedule; earlier schedule Y was there. So, with the new drug and clinical trial 2019 this schedule Y is no more.

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Recently the government has published some new rules that is we know the medical device rule 2017, then new drug and clinical trial rules 2019, new cosmetic rules are also in pipeline.

So, this course is about the new drug and clinical trial rule 2019. So, in this course we are going to see in detail what are these new rules and since when it has been effective.

So, we will have a glimpse of the medical device rule, although it cover in our course II that is current requirement for the medical devices.

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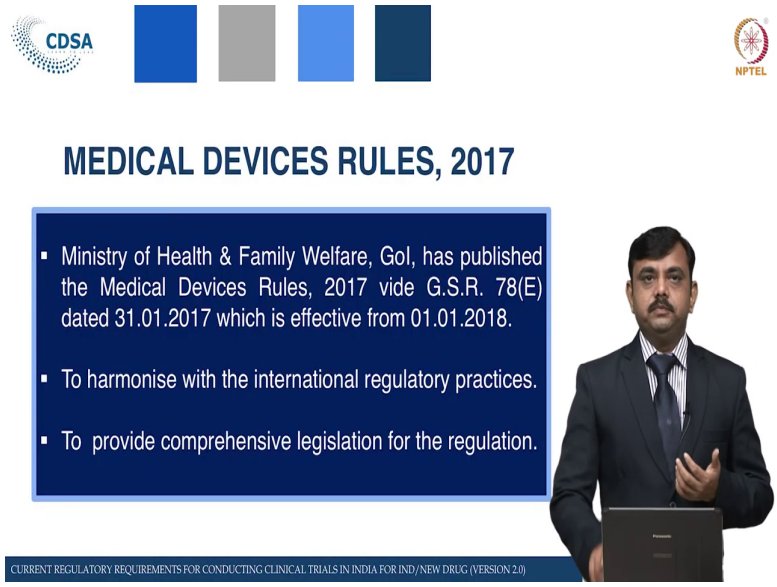

So, the Ministry of Health and Family Welfare has publish the medical device rule 2017. Vide does it notification 78E dated 31st January 2017 which is effective from 1st January 2018. So, this medical device rule is effective from 1st January 2018 this rules have been made to harmonize the practices that is Indian practices with the international regulatory practices to provide the comprehensive legislation for the regulation. Earlier there were no separate definition of the medical device, there were no procedure separate procedure of the

medical device for manufacture and for the import and the medical device is had been consider as a drug and the procedure whatever the applicable for drug that was implemented.

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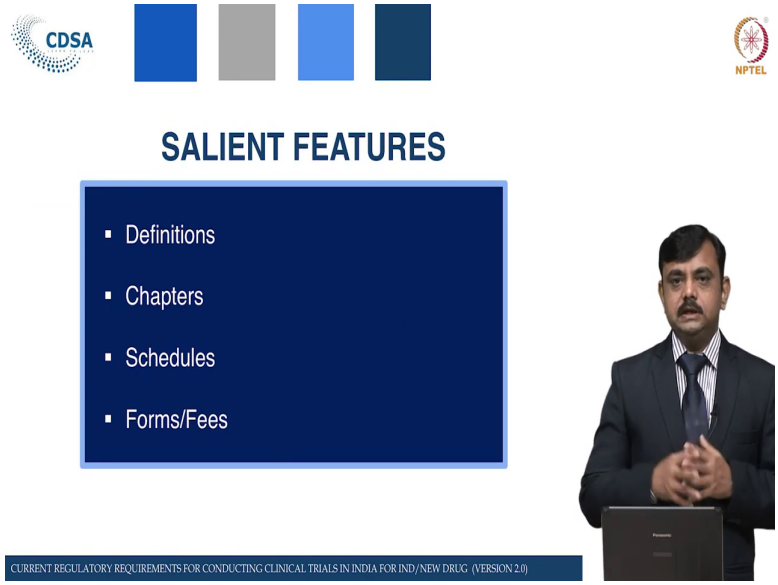

So, in this medical device rule the around 50 definitions have been given what is medical device, what is active medical device, what is clinical investigation, clinical performers, what is in vitro diagnostic likewise all the definition has been given in this medical device rule, then there are different chapters like the for the chapter for the introductory chapter, then chapter for manufacturing of the medical devices, medical device import, then clinical investigation the separate chapter is there, clinical performer separate chapter is there, what are the different forms fees that also has been given in the chapters and to be more elaborative the schedules have also been provided.

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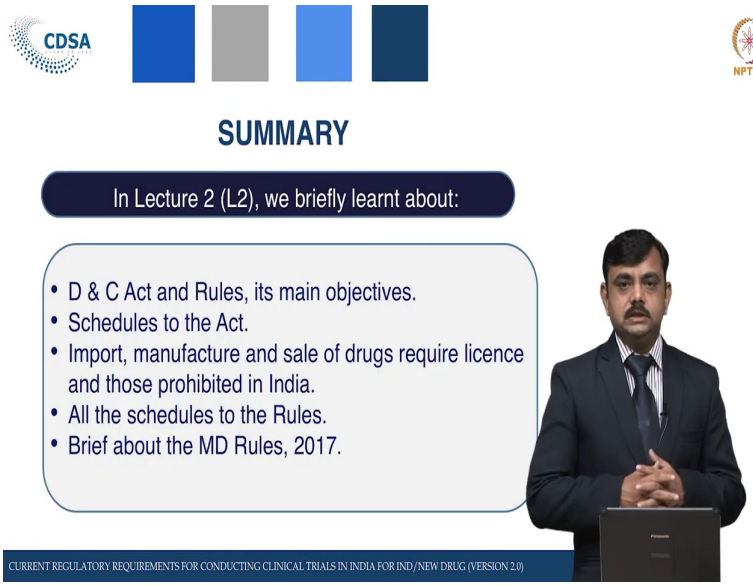

Then there are forms and fees separate forms and fees also has been provided in this medical device rules. So, this is the overview of the Drug and Cosmetic Act and rules thereunder 1945. So, let us have quick recap of this lecture. So, in this lecture we have seen what is Drug and Cosmetic Act, what is its objective, then schedule to the act that is there are two schedules schedule first regarding the list of books for Ayuevedic Sidda Unani and the schedule two that is with related to the standard to be complied by the applicant for the manufacturing for the import of the drugs.

Then we have seen the different schedules available in the rules from the A to schedule X. We have seen which type of drug are prohibited which type of drug are drug are permitted to be imported to be manufactured in the country, then we have seen the which type of drug which is require license to be sale into the India.

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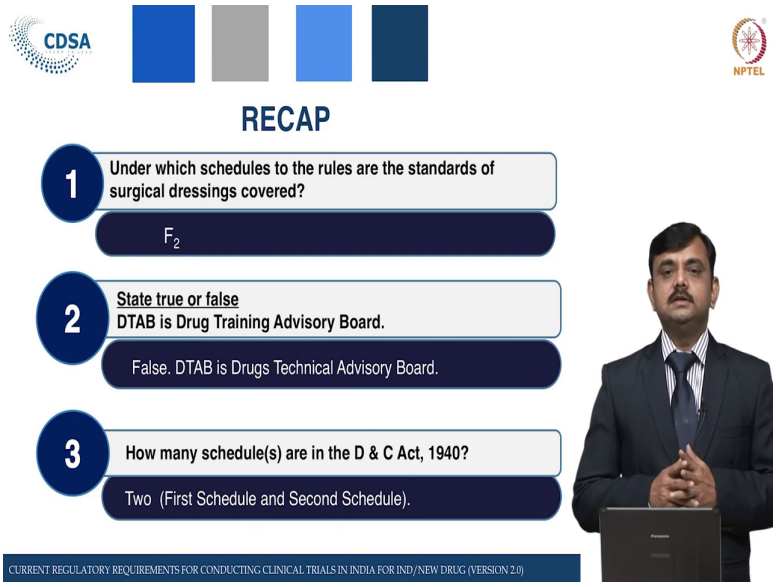

So, now the time for the question. So, first question for you under which schedules to the rules are the standard of surgical dressings cover? I have mention all the schedules that is schedule A to schedule X. So, this is the schedule F 2; under the schedule F 2 rules are given for the standard surgical dressings.

The second question you have to you have to state the what is a true whether it is true or false. So, DTAB is a Drug Testing Advisory Board. So, it is false the DTAB is we have seen drug technical advisory board to advise the for the technical matter arise thereof. Then the last questions how many schedules are there in the Drug and Cosmetic Act? Yes there are two schedules given in the Drug and Cosmetic Act do not confuse with the schedules given in drug and cosmetic rules.

So, this is all about drug and cosmetic act and rules thereunder will be back soon for the lecture 3 till then bye take care and all the best.

Thank you.