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

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Lecture – 03
Overview of New Drugs and Clinical Trials Rules 2019

Hello friends, welcome back to the revised course Current Regulatory Requirement for Conducting Clinical Trials in India for IND and New Drugs. So, these views are presented by me, are my opinions. Now we are going to see lecture III of this course, which is about Overview of the New Drug and Clinical Trial rule 2019.

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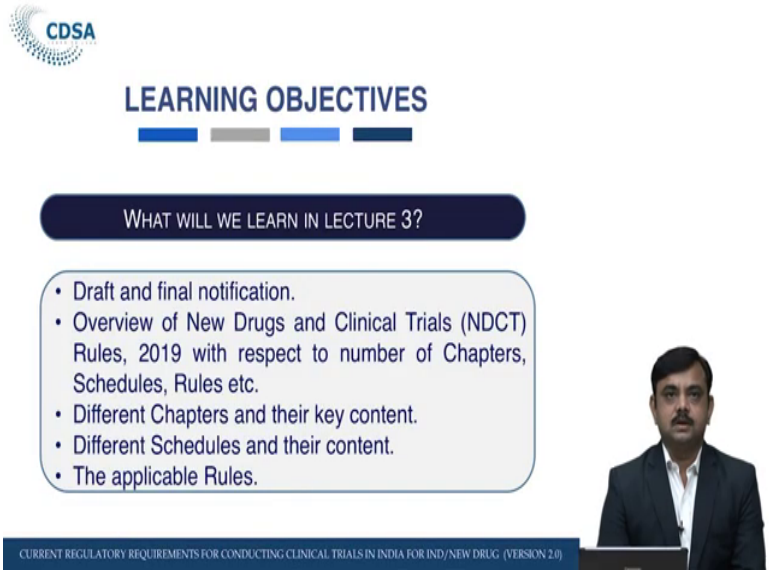

The learning objective of this lecture, the learners will come to know what is a draft notification and final notification of the NDCT Rules 2019. Then overview of new drug and

clinical trials rule with respect to how many chapters are, there how many schedules are there, how many rules are there. Then we are going to see the different chapters and its key content, then different schedules and its content what is given in the schedules, then what are the applicable rules for example, for the chapter one it is from 1 to 5 likewise we are going to see the rules.

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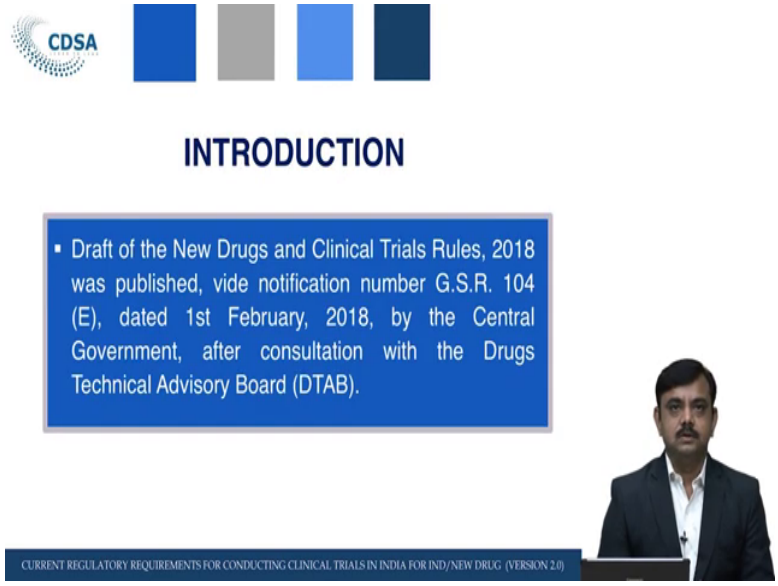

So, in the introduction we will see how we make the rules in brief; so, the CDSCO that is the central drug regulatory authority, which is having a drug technical advisory board. So, whenever there is proposal for the amendment of rule or the addition of any rule, the proposal for this amendment put up into the drug technical advisory board.

These Drug Technical Advisory Board that is a DTAB, then deliberate that proposal and after giving the consensus in majority that is finalize and forwarded to the ministry for its approval.

Then Ministry of Health and Family Welfare, Government of India publishes draft notification in this regard and after receiving the objections, suggestions from the stake holders, then they publishes the final notification which then come into the force.

So, in this regard for the New Drug and Clinical Trial Rule, the draft rule of these NDCT rule 2000 was publish wide notification 104 on 1st February 2018 by the central government after consultation with the drug technical advisory board.

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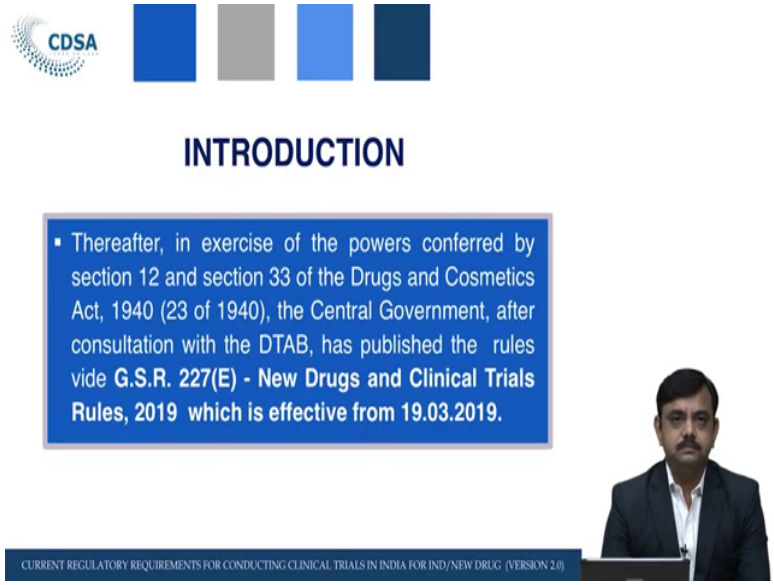

Thereafter, after receiving the objections, suggestions in exercise of the powers confer by section 12 and section 33 of the Drug and Cosmetic Act 1940, the Central Government that is the Ministry of Health and Family welfare.

After consultation with the drug technical advisory board finally, published the new rules that is a New Drug and Clinical Trial Rule vide gazette notification 227 and these rules are called as new drug and clinical trials rule 2019. These rules are effective from 19 3 2019. Now, we will see the overview of these rules.

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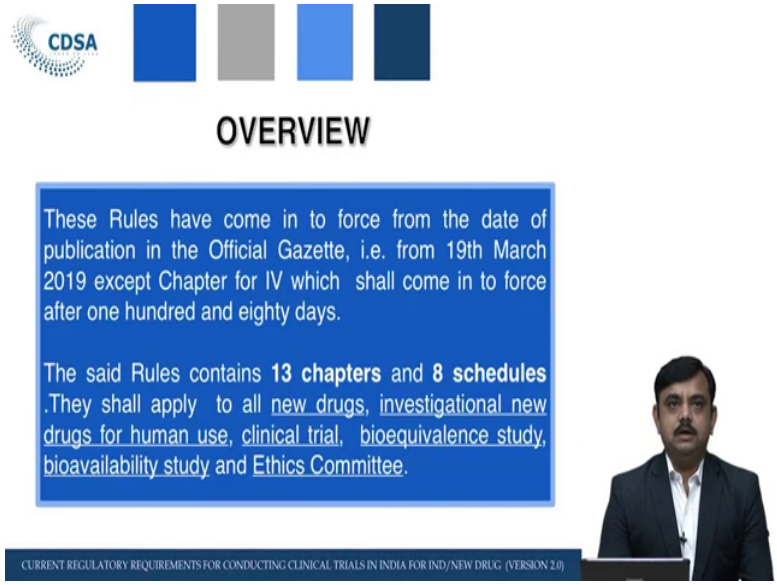

So, as I have mention these rules have come into force from the date of publication in the official gazette, that is from 19 March 2019 except chapter IV which is related to the biomedical and health result, which shall come in to force after 118 days from the publication of these New Drug and Clinical Trial Rule. The said rules that is New Drug and Clinical Trial Rules contain 13 chapters, 8 schedules many of the tables and they shall apply to all new drugs investigational new drug for human use and for clinical trials, for bioequivalence study, bioavailability study and the ethics committee.

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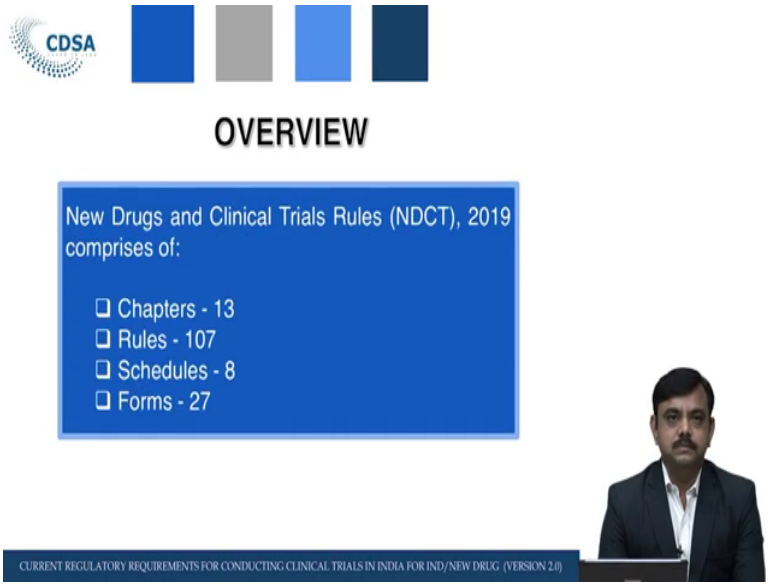

Let us see what are the how many chapters are there and what are these rules. So, in these rules there are 13 chapters, 107 rules and 8 schedules and there are many forms. We have seen if you remember earlier only one form was there for the application of new drug and d that was the form 44. In these New Drug and Clinical Trial Rule there are around 27 forms which are for the different purposes. We will see the chapter one by one and the major content of this chapter.

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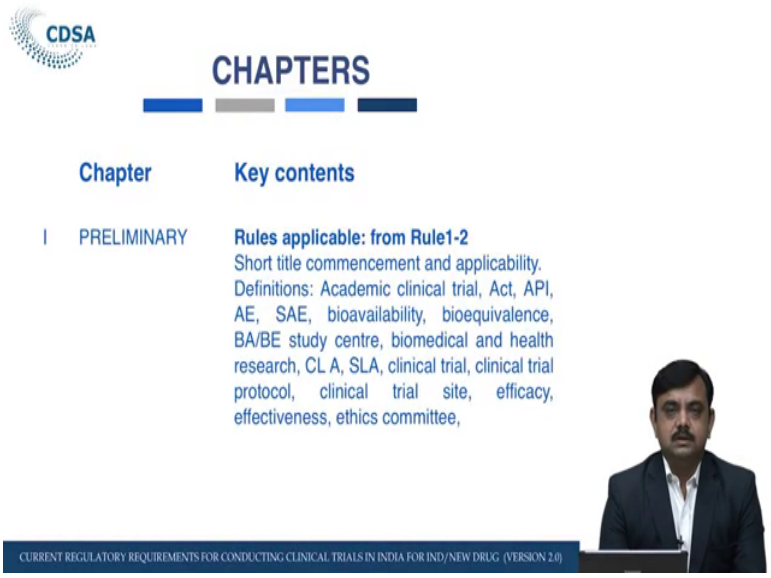

The first chapter is preliminary chapters and the rules applicable for these chapter is from rule first and rule second. In this chapter the short title commencement and applicability has been given as well as the definition with respect to the academic clinical trial, what is academic clinical trial, what is means by act, like a act means the drug and cosmetics act, what is API that is Active Pharmaceutical Ingredients, what is adverse event, what is SAE bioavailability these all the definitions are given.

So, earlier these all definitions were not there in the clinical trial rules and an Cosmetics Act. So, these definitions are with respect to BA BE what is bioavailability, what is bioequivalence, what are the study centers, then what is means by biomedical and health research is biomedical and health research it means that, which are not cover under the clinical trial and the research that research we called it as a bio medical and health research,

where going to see these biomedical and health research another definition in our other lectures.

Then what is means by central licensing authority, state licensing authority, what is means by clinical trial, clinical trial protocol, clinical trial site, efficacy, effectiveness, what is means by ethics committee, then good clinical practice guideline means these are the guideline developed by the Indian regulatory authority.

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Then what is means by the global clinical trial. The trial which is conducted simultaneously over the global and in the different countries, that we call the global clinical trial then what is means by a investigational new drug; the drug which is not approved elsewhere in the world that we call the investigational drug. Similarly the investigational product which is in the

which is in the research, that is we call investigational product investigator, then medical management, new chemical entity, new drug, orphan drug.

So, orphan drug also the definition was not there earlier, now these has been defined that the drug which is use for the population, which is affected population which is not more than 5 lakh for that drug we called as the orphan drug. Then pharmaceutical formulation, pharmacovigilance, phytopharmaceutical drug, post trial access registered pharmacist, similar biologic, post then sponsor trial subject all these definitions are given under the chapter first which is from the rule 1 and 2.

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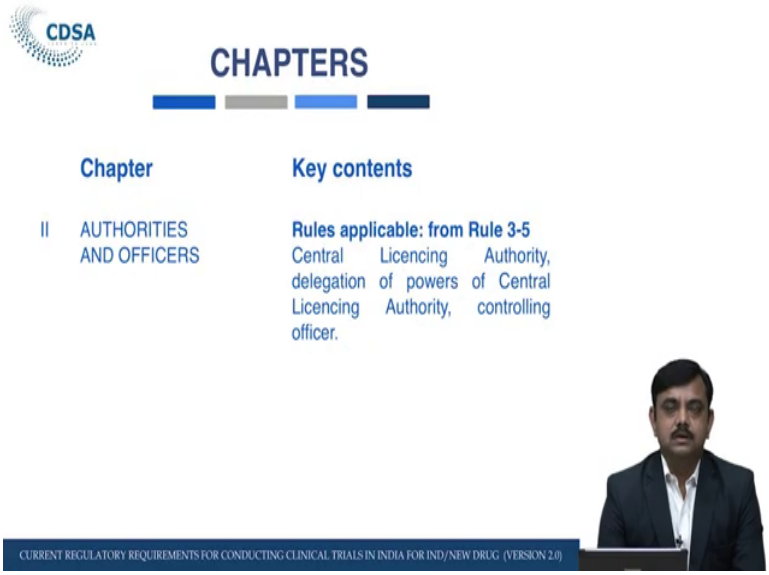

Chapter II it is related to the authorities and the officers. So, what are the authorities where we have to apply that that has been given in this chapter of II, that is authorities and officers. The rules applicable are from rule 3 to rule 5 here it is defined what is central license

licensing authority, what are the delegations of the powers of the central licensing authority, who can we call the controlling officers that has been given in this chapter.

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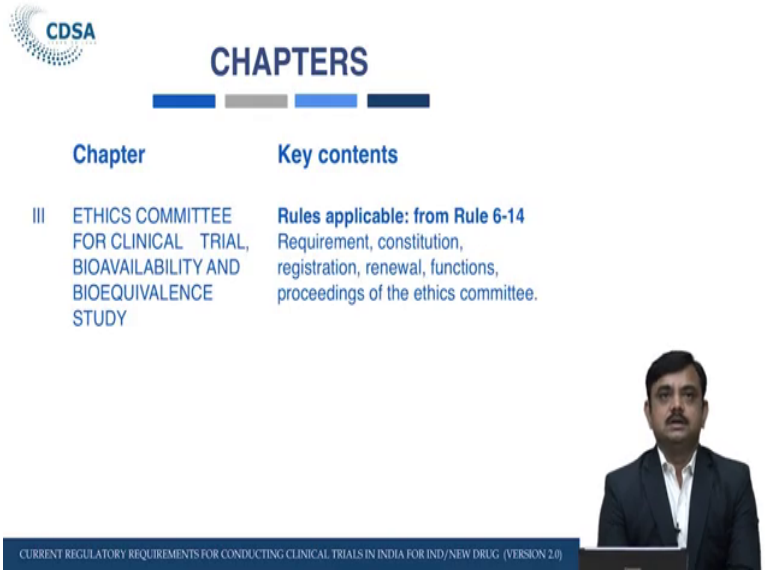

Chapter III is ethic committee for clinical trial, bioavailability and bioequivalence studying and the rules applicable are from rule 6 to rule 14. Here the requirement constitution registration renewal functioning proceeding of the ethics committee. It means the all whatever related with the ethics committee that has been given in this chapter III.

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Chapter IV, as I have mention it is ethics committee for biomedical and ether ethic ethical research that is biomedical and health research the rules applicable for this is rule 15 to rule 18; so, in this chapter all about the biomedical and health research ethic committees given. Details about the constitution how should be the constitution, where to be apply, what is the procedure for registration of the ethics committee for biomedical and health research everything about the biomedical and health research has been given in the chapter IV.

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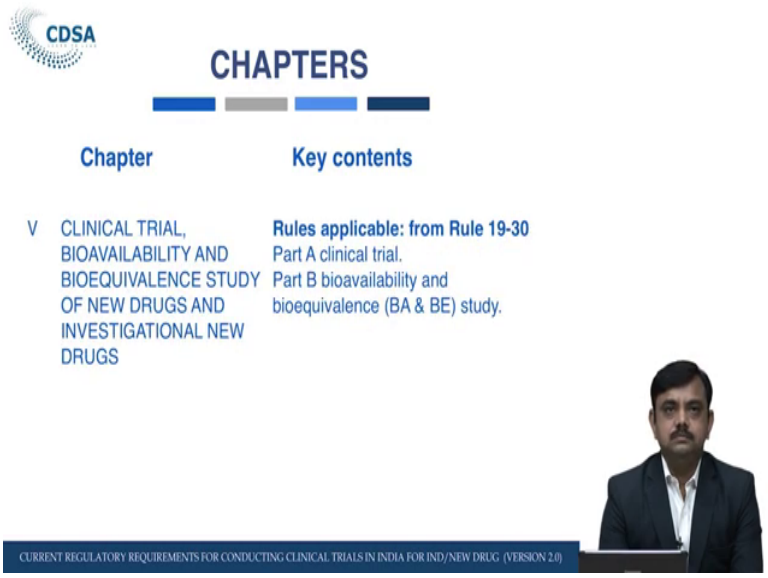

Chapter V is related to the clinical trial, bioavailability and bioequivalence study of new drug and investigational new drug. So, this is very important chapter those who are conducting the clinical trials and the rules applicable for this chapters are rule from 19 to rule 13. So, if you would like to see in detail, then you can refer this rule 19 to rule 13.

This chapter actually it has been divided into the part 2, the part 1 that is a is related to the clinical trial and part B is related to the bioavailability and bioequivalence study. So, these chapter has been divided into the two part for the convenience to the applicant those who are applying for the clinical trial and those who are applying for bioavailability and bioequivalence study.

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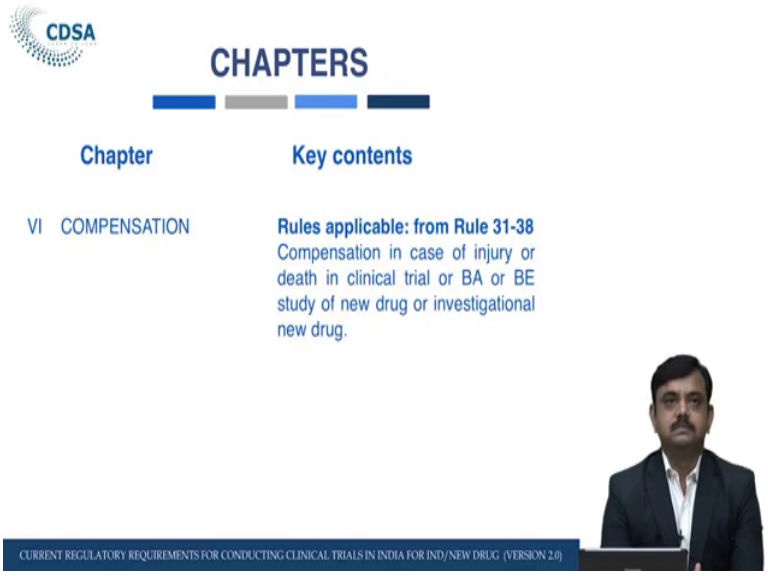

The next chapter that is chapter VI is related to the compensation. In case of injury or in case of the death during the clinical trial or it may be during the bioavailability or bioequivalence study of new drug or investigational new drug, if any injury or death happens then how should be the compensation to be paid, what is the procedure, how to calculate that compensation that has been given in these chapter.

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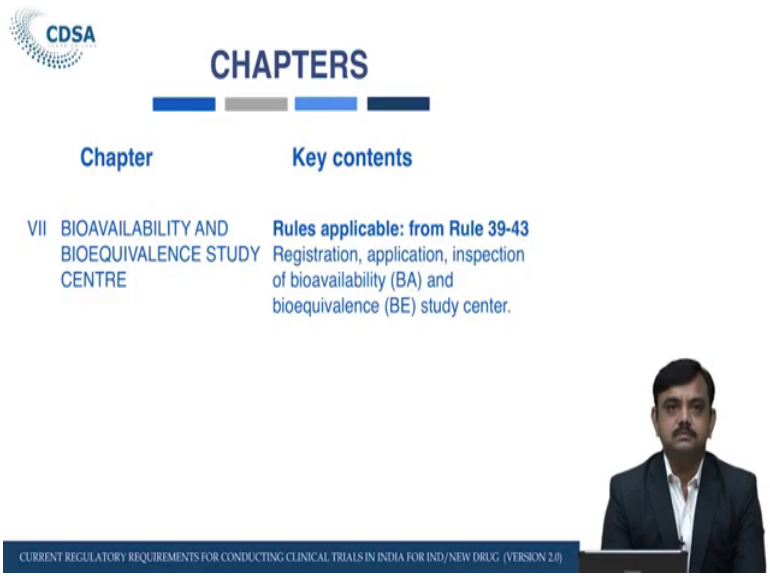

The next chapter that is a chapter VII it is related to the bioavailability and the bioequivalence study center. So, we have seen in the chapter V that is the part B bioavailability and bioequivalence study. And this chapter is about the BA BE study centers ok. So, the rules applicable are from rule 39 to rule 43. Here it is the how to apply for this registration of the study center that has been given, then how to apply, then how to conduct the inspection what are these BA BE study centers, what are the forms everything about the BA BE study center has been given in the chapter VII.

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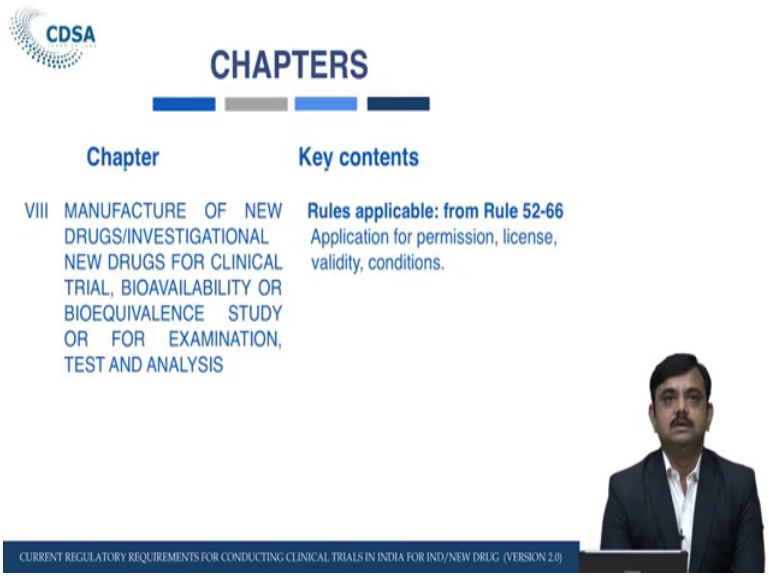

Chapter VIII is related to the manufacture of new drug or investigational new drug for clinical trial bioavailability, bioequivalence study or for examination test and analysis. So, this is about the manufacture of new drug. So, you have seen that before manufacturing a one the applicant requirement to take permission from the state licensing authority and before that if it is a new drug, he has to take a permission from the central licensing authority to conduct a clinical trial.

So, if it is regard related to the manufacture of new drug, then the applicant has to refer to the chapter VIII and the rules in to be refer as from the rule 52 to 62. Here in this chapter, the application for permission how to apply which are the forms, that has been given and in which form the licensing authority will give the permission, what would be the validity, then what are the conditions that has been given. These all in detail what are the condition, what is

the validity period, we will see it in another lecture this is just about the overview of this NDCT rules.

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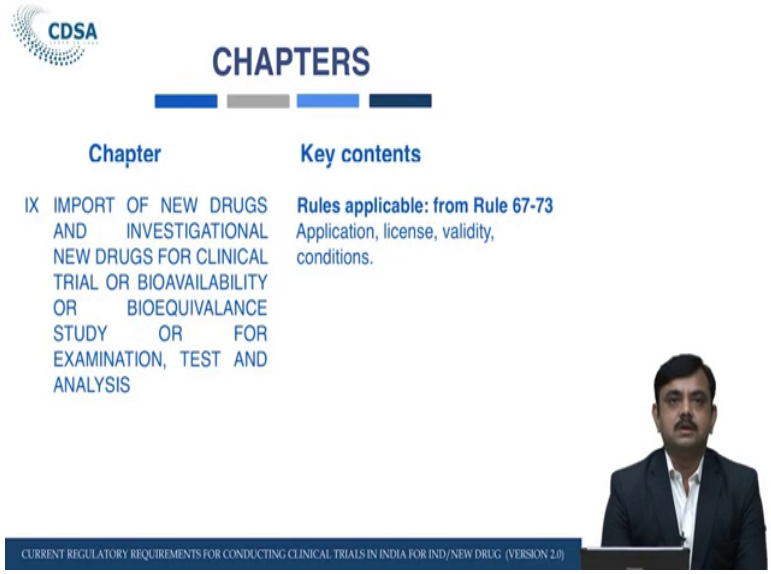

Then next chapter that is chapter IX it is related to the import. We have seen the previous chapter it is related to the manufacture and this chapter is related to the import of the new drug and the IND. And, the rules applicable are from the rule 67 to rule 73. Here in also as we have seen in the chapter for the manufacturer what are the application, what is the procedure in which form the licensing authority issues the license what id the validity period everything has been given, but it is related to the import only. If it is a manufacture then we have to refer the previous chapter that is chapter VIII.

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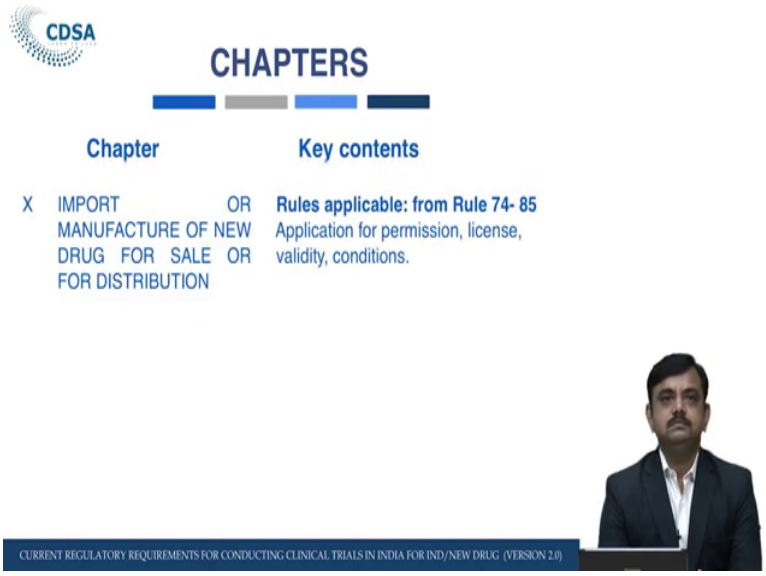

The next chapter, chapter X it is Import or Manufacture of New drug for Sale or for Distribution. So, the rules applicable are rule from 74 to rule 85 here in also the procedure validity condition everything has been given in this chapter.

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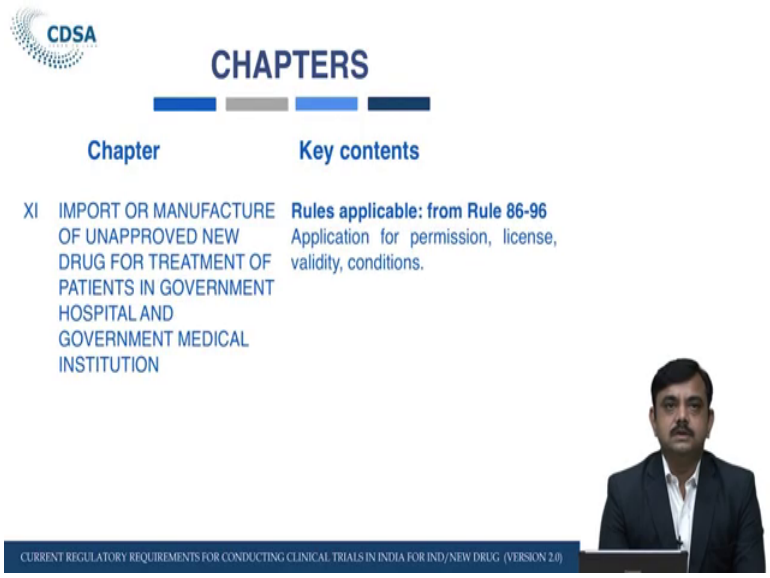

Chapter XI is related to the import or manufacture of unapproved drug for the treatment of patient by government hospital and government medical institution. This chapter we have seen the chapter previous chapter that is related to the manufacture of drug, then we have seen the chapter which is related to the import of that the drug and this chapter is import or manufacture, but it is for particularly for the patient in the limited quantity.

So, if hospital or any organization desires to imports some small quantity drug for the patient, then they can apply according to these chapter and the rules applicable are from the rule 86 to rule 96. So, here also the application for permission, how to apply which forms are require, then in which form the licensing authority will issue the license, till how long it would be valid and what would be the condition if somebody is desires to import or manufacture small quantities that has been given.

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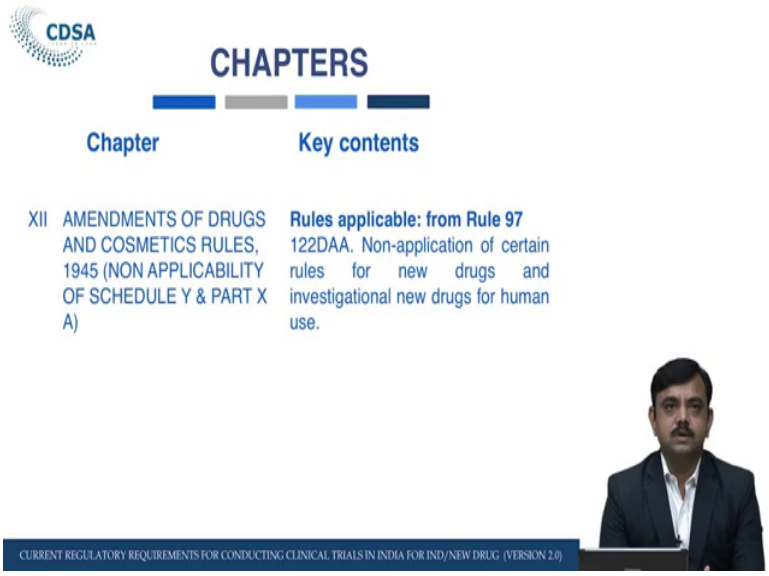

Next chapter is chapter XII which is amendment of drug and cosmetics rule and not applicable of schedule y. We have seen in our previous course those who have attended that course, wherein earlier only the schedule y was there and very few form like form 44 form 46 was there.

So, this schedule y is now no more applicable, that has been given in this chapter according to this chapter. And the rule this is as per the rule 97, here it is also mention that 122DAA the known the non application of the certain rules for new drugs and the investigational drug. So, these earlier previous earlier rules whatever related to the clinical trials like a schedule y and other, these are not applicable now and the applicant has to apply as per the rules given in the New Drug and Clinical Trial Rules that has been mentioned.

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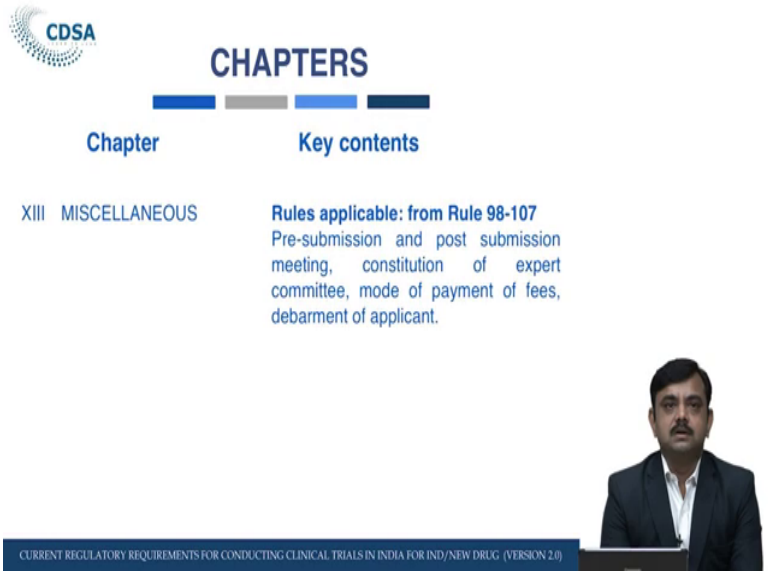

Chapter XII is the miscellaneous chapter, but it is also very important chapter and here the rules applicable are from 98 to 107, the special provision has been made by these chapters. These special provision like to pre submission and post submission meeting, then constitution of expert committee may mode of payment of fees and debarment of application that has been which is not covered in the previous chapter, that has covered in this chapters.

Let us see: what are the schedules, the schedules are like annexure to the rules. As we know the first there is a act, then there is a rules and then there is a schedules and guidelines let us see what are these schedules.

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First schedule it is related to the general principle and practices for the clinical trial and the rules applicables are from 19 to 31. The second schedule the rule applicable are 21 75 80 and 95. This is regarding requirement and guideline for permission to import or manufacture of new drug for sale or to undertake a clinical trial.

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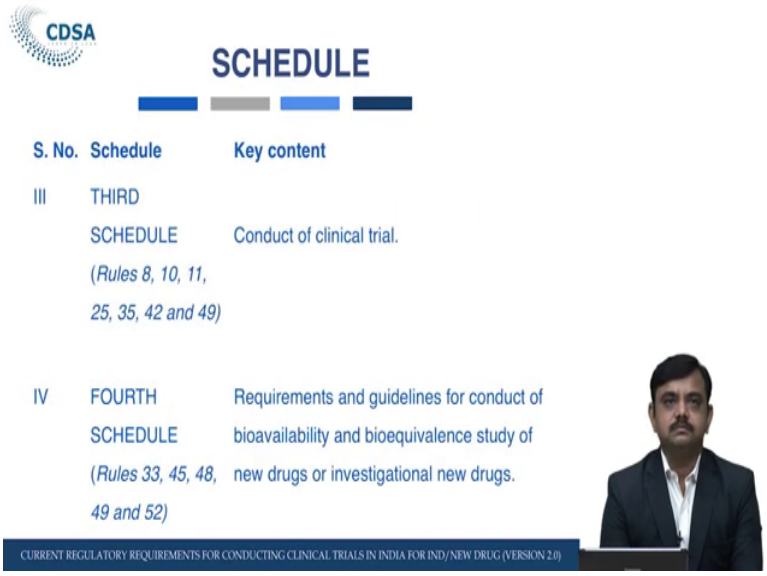

Then the third schedule it is related to the conduct of the clinical trial, how to conduct a clinical trial what are the provisions that has been given in the third schedule. You can see the rules applicable in the bracket rule 8, 10, 11 25, 35, 42 and 49. As we have seen there are so, many rule like rule 1 up to more than hundred rules are there, but we have focused on the rules which are particularly applicable for the clinical trials.

The forth schedule, the rule applicable are 33, 45 48, 49 and other this is related to the requirement and guideline for conduct of bioavailability and bioequivalence study of new drug and the investigational product.

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The next schedule that is the schedules V; the rule applicable are 77 and the 82 and this is related to the post market assessment. We are going to see in detail in the next our chapter what is post market assessment, that is this is after the clinical trial has been completed.

The 6th schedule: wherein it is given the fee payable for license, permission and the registration certificates. So, whatever the fees earlier there were only 50,000 fees for the trials. So, now, the different fees has been given for the test license, for the phase 1, phase 2, for the import manufacture. So, for everything the fees has been separated all these fees has been given in the 6th schedule.

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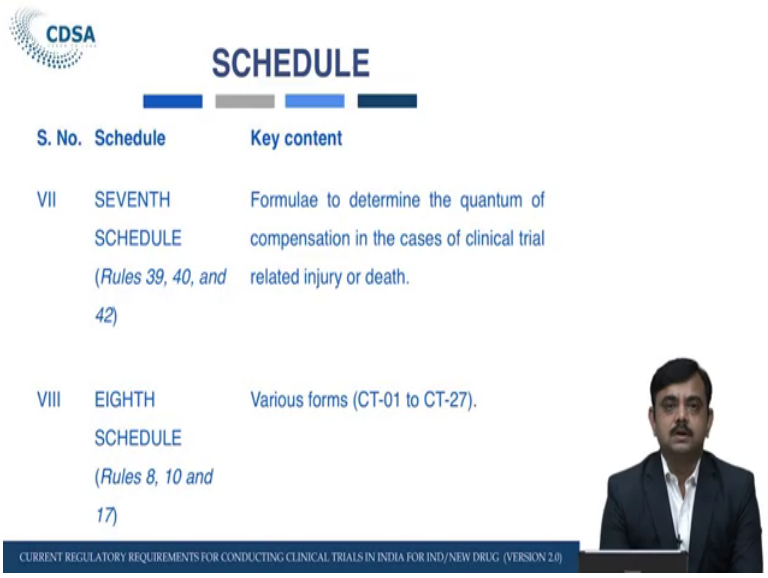

The next schedule that is VII schedule, it is formula to determine the quantum of compensation in case of clinical trial related death or injury. How to calculate the compensation, what is the formula in case of injury, what is the formula in case of the I S A E, in case of the death that formula has been given in the these schedules. The next schedule is schedule VIII and in these schedule the various forms are given. We have seen there more than 27 form.

So, form were the applications of the phase 1, phase 2, phase 3 forms for the manufacturing, for forms for the application of the import and in which form the licensing authority gives the permission for the small quantity for the import, for the manufacture these all forms are given in the chapter that is the chapter VIII and the rules applicable for this schedule is rule 8, 10

and 17. So, this is a short lecture about the overview of new drug and clinical trials we are going to see everything in detail in our subsequent and other lectures.

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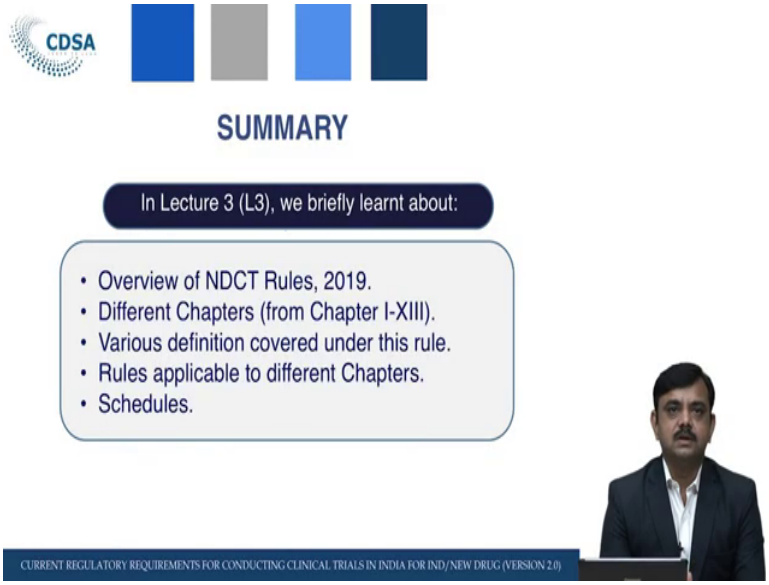

Let us have the quick look at the summery what we have seen in this lecture. So, we have seen in this lecture the overview of New Drug and Clinical Trial Rule 2019 when it has been published, what was the draft notification. Then we have seen the different chapter from chapter I to chapter XIII and the key contents of these chapters. Then we have seen the various definition covered under these rules like orphan drug definition we have covered.

The orphan drug which is the drug required to be treat our population which is not more than 5 lakh. Then rules applicable to different chapters we have seen. So, every after chapter we have seen in the bracket given the which are the rules applicable. Same we have seen for the schedules also different types of schedules that is VIII schedule we have seen and the rules

applicable for that schedules that also we have seen in the bracket. So, this is about the lecture 3.

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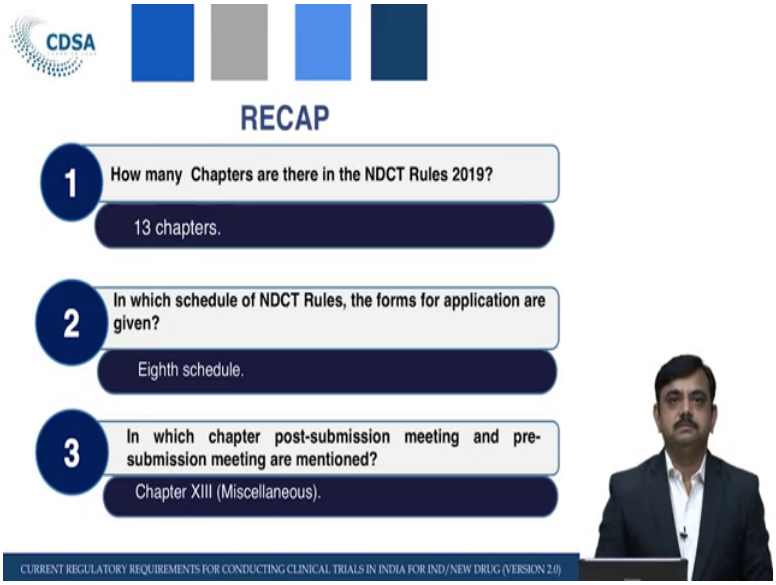

So, do just check your memory, let us have quick view on the questions; the questions for you. The first question, how many chapters are there in New Drug and Clinical Trial Rule 2019? So, you have to answer it quickly. So, there are 13 chapters in the New Drug and Clinical Trial Rules. Similarly how many schedules are there in the New Drug and Clinical Trial Rule? So, there are 8 schedules. The next is in which schedule of NDCT rule the form of application are given? We have seen it is in the eighth schedule. There are 8 schedule also and the forms are given in the eighth schedule.

The next question: in which chapter post submission meeting and pre-submission meetings is given; the provision for post submission and the pre submission meeting? You have to recall

from this lecture, yes it was the last chapter and that is chapter 13; miscellaneous wherein pre-submission post-submission meeting has been given.

So, this is all about the lecture 3 and we will come soon with the next lecture till then you take care bye, bye.

Thank you for your attention.