

JSS Academy of Higher Education & Research
JSS College of Pharmacy,
Sri Shivarathreswara Nagara, Mysuru

Date: 19th April 2023

REPORT ON WEBINAR

“Fixed Dose Combinations and need for FDC’s in Patients Health Care”.

Speakers:

1. Mr. K Narendran, Assistant Drug Controller (ADC), Chennai, Tamil Nadu.
2. Mr. Sridhar, Joint Director of Drugs Control, Chennai, Tamil Nadu.
3. Mr. J. Jayaseelan, Founder & Director of Delvin Formulations Private Limited.

Faculty of Program:

- Dr. K Bangarurajan, Professor, Regulatory Affairs Group, Department of Pharmaceutics
- Dr. Balamuralidhara.V, Associate Professor & Head, Regulatory Affairs Group, Department of Pharmaceutics
- Dr. M P Venkatesh, Associate Professor, Regulatory Affairs Group, Department of Pharmaceutics

Students of Program:

1st year and 2nd year M. Pharm (Pharmaceutical Regulatory Affairs) and Ph.D. scholars of JSS College of Pharmacy, Mysuru.

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Discussion:

Dr. K Bangarurajan, Professor, Regulatory Affairs Group, Department of Pharmaceutics introduced the speakers to the students and delivered opening remarks.

Speaker 1: Mr. K Narendran

Mr. K Narendran, Assistant Drug Controller (ADC), was the first speaker of the webinar. He started his talk by giving an overview of “Regulations on Fixed-dose combinations in India”. He discussed about the categories of FDCs, fees payable for review of FDC application and approval process of FDCs. Further he elaborated on various regulatory aspects including submission requirements and the committees for approval process of new FDCs.

Speaker 2: Mr. Sridhar

Mr. Sridhar, Joint Director of Drugs Control, was the second speaker of the webinar. His talk was focussed on the “Manufacturing approval process of FDCs in India”. He discussed rational and irrational FDCs along with their manufacturing license approval process. A detailed review on the need and importance was given to the participants. Various approval and documentation required was discussed. At the end of the session, Mr. Sridhar attended to the queries/ questions raised by the participants.

Speaker 3: Mr. J. Jayaseelan

Mr. J. Jayaseelan, Founder & Director of Delvin Formulations Pvt. Ltd was the final speaker of the webinar. His speech was focused on “The need for FDCs in patient healthcare”. He discussed the importance and the challenges faced in developing FDCs in India and the United States. He also emphasized the need for further research to optimize FDCs and make them safer and more effective.

In conclusion, the webinar on Fixed-Dose Combinations was informative and provided valuable insights into the regulatory aspects of FDCs. The session was interactive, the speakers answered all the questions and clarified the doubts of the students and faculty. The session was concluded by addressing a vote of thanks by Dr. K Bangarurajan.



