

SHREE NARANJIBHAI LALBHAI PATEL COLLEGE OF PHARMACY, UMRAXH
Webinar on “An Overview of Bioequivalence Studies- USFDA submission perspective”

Date: 20th January, 2023

Time: 10.30 am to 12.00 pm

Resource Person: Mr. Shailesh Pedhadiya, M.Pharm, Group Leader at Alembic Research Center in Clinical Affairs department.

Title: “An Overview of Bioequivalence Studies- USFDA submission perspective”

No. of Participants: 59

Summary of webinar:

IIC and IQAC of Shree Naranjibhai Lalbhai Patel College of Pharmacy, Umrakh, has organized A webinar on “An Overview of Bioequivalence Studies- USFDA submission perspective” for the final year. B. Pharm and M. Pharm students on 20th January 2023. A webinar was started at 10:30 am with a welcome speech by Dr. Vipulkumar Gajera, Associate Professor, SNLPCP and Co-ordinator of this webinar. He has welcomed the speaker of the webinar Mr. Shailesh Pedhadiya, Group Leader at Alembic Research Center in Clinical Affairs department.

The speaker Mr. Shailesh Pedhadiya, has explained about What is Bioavailability and Bioequivalence? Why bioequivalence study (BE study) is conducted? Drug Development and approval pathway- IND, NDA and ANDA, Permission require for BE study, How BE studies are conducted? And Acceptance Criteria for Passing BE study.

There was Question answer session also, in which student’s queries and questions were answered by Mr. Shailesh Pedhadiya.

Under the guidance of Dr. Ketan Shah, Principal, SNLPCP the event was successfully completed. All Faculty members have actively supported for the event. Students of 7th B.Pharm, M.Pharm and faculty members have attended the webinar. To conclude the session, Dr. Vipulkumar Gajera, Associate Professor, SNLPCP, UMRAXH, showed his gratitude and appreciation to Mr. Shailesh Pedhadiya for his informative session. SNLPCP is thankful to Mr. Shailesh Pedhadiya for his valuable time.



**IIIC AND IQAC OF
SHREE NARANJIBHAI LALBHAI PATEL COLLEGE OF PHARMACY.**

(Vidyabharti Trust Institution, Umrakh)

Accredited by NBA, New Delhi (B. Pharm course upto June 2024)

Approved by AICTE & Pharmacy Council of India - New Delhi, Affiliated to GTU, Ahmedabad.



**Organized
Webinar on**

AN OVERVIEW OF BIOEQUIVALENCE STUDIES – USFDA SUBMISSION PERSPECTIVE



Speaker

MR. SHAILESH PEDHADIYA

Group Leader at Alembic Research Center

Date and Time

20 Jan 2023, Friday

10.00 am

Online Platform : Google Meet

Convener

Dr. Ketan Shah
Principal

Co-ordinator

Dr. Vipulkumar Gajera
Asso. Professor

Vidyabharti Campus, At & Po Baben, Ta: Bardoli, Di. Surat, Pin: 394601.

10:50 HD 4G

jmk-afzy-ktg

What is IND, NDA and ANDA?

Pranshu is presenting

Participants: Heny, Pranshu, You, Dr. 44 others

10:44 HD 4G

jmk-afzy-ktg

Drug Development and approval pathway (Generic drug)

Pranshu is presenting

Participants: Heny, Pranshu, You, Dr. 44 others

10:32 HD 4G

jmk-afzy-ktg

Bioequivalence

- "absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study"
- significant difference? BE acceptance criteria
- rate and extent to which active ingredient becomes available? C_{max} and AUC
- pharmaceutical equivalent (same active ingredient, dosage form and strength but may differ in shape, color, excipients, release mechanism, packaging, labeling and expiration date)
- pharmaceutical alternative (same active ingredient but may differ in salt, ester, dosage form or strength)
- site of drug action? Systemic Circulation, i.e. Blood
- same dose and similar condition? Same strength and uniformity during study conduct
- appropriately designed study? As per regulatory requirements

Pranshu is presenting

Participants: Heny, Pranshu, You, Dr. 42 others

11:18 HD 4G

jmk-afzy-ktg

Bioequivalence study*- Clinical Phase

Check-in day:

Pranshu is presenting

Participants: Heny, Pranshu, You, Dr. 41 others