Report On Guest Lecture on "Bioequivalence Trials in Healthy Volunteers"

Date: 06.02.2025

Organized by: Department of Pharmaceutics, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV), Tarnaka, Secunderabad.

Time: 11:00 AM

Venue: Auditorium, SNVPMV.

Speaker: Mr.M.Rambabu, Managing Director, Glogen Clinical Reasearch Pvt Ltd., Hyderabad, Telangana.

Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV) hosted a guest lecture titled "Bioequivalence Trials in Healthy Volunteers", designed to provide insights into personal happiness and well-being. The event was coordinated by Department of Pharmaceutics (Dr.B.Haarika, Dr.Ch.Shanthi Priya, Mrs. CH. Bhargavi, Mrs.G.Srilalitha and Mrs. A. Jyothi) and anchored by Salma Sultana and L. Prashanthi Reddy, M.Pharm I Sem (Pharmaceutics) students. Dignitaries were welcomed to the dais with eco-friendly floral greetings, including: Dr. T. Mamatha Principal, SNVPMV. Dr. B.HaarikaProfessor & HOD, Dept. of Pharmaceutics, SNVPMV and Mr. Maddela Rambabu, Managing Director, Glogen Clinical Reasearch Pvt Ltd.

The program opened with a welcome address, followed by Ms. N.Pravallika introducedtheguest of speaker, Mr. Maddela Rambabu, Managing Director, Glogen Clinical Reasearch Pvt Ltd.He captivated attendees with an interactive and his talk began with introduction of Bioequivalence trials in healthy volunteers.

Introduction

Bioequivalence (BE) trials are conducted to compare the pharmacokinetic properties of a test drug with a reference drug. These studies are essential in the development of generic drugs to ensure therapeutic equivalence to the innovator drug. Healthy volunteers are often recruited for these trials to minimize variability and provide reliable data.

Objectives of Bioequivalence Trials

1. To compare the **rate** and **extent** of drug absorption between test and reference formulations.
2. To establish that both formulations have similar pharmacokinetic profiles within an acceptable range.
3. To ensure the **safety** and **efficacy** of the test formulation before regulatory approval.

Study Design

BE trials typically follow a **randomized, open-label, crossover** design, where participants receive both the test and reference formulations with a **washout period** in between.

Key Study Components:

1. **Selection of Healthy Volunteers**
    - Inclusion criteria: Age (18–55 years), BMI within a normal range, no chronic illnesses, and non-smokers.
    - Exclusion criteria: History of drug allergies, significant medical conditions, or concurrent medications.
2. **Dosing and Sample Collection**
    - Volunteers receive a single dose of the test and reference formulations in separate periods.
    - Blood samples are collected at predefined intervals to measure drug concentrations.
3. **Pharmacokinetic Analysis**

- Primary parameters assessed: **Cmax** (maximum plasma concentration), **Tmax** (time to reach Cmax), and **AUC** (area under the plasma concentration-time curve).
- The 90% confidence interval (CI) of the test/reference ratio for Cmax and AUC should fall within the regulatory acceptance range (typically 80–125%).

Ethical Considerations

- **Informed Consent**: Volunteers must be fully informed about the study objectives, procedures, risks, and benefits before participation.
- **Ethical Approval**: The study must be reviewed and approved by an Institutional Review Board (IRB) or Ethics Committee.
- **Safety Monitoring**: Adverse events (AEs) are closely monitored, and appropriate medical care is provided if needed.

Clinical part of BA/BE studies

- Defining Study Objectives
- Selecting CROs
- Protocol Development
- Ethical Considerations
- Assessing Clinical and
- Safety Laboratory Facilities
- Selecting Subjects
- Adhering to Guidelines

Regulatory Guidelines

Different regulatory agencies have specific guidelines for conducting BE studies:

- **US FDA**: Guidelines for conducting BE studies in humans.
- **EMA**: Requirements for bioequivalence assessment of generic medicines in Europe.
- **ICH**: Harmonized guidelines applicable in multiple regions.

Conclusion

Bioequivalence studies are performed to compare the bioavailability of the generic drug product to the brand name product.

Bioequivalence trials in healthy volunteers play a crucial role in the approval of generic drugs by ensuring comparable pharmacokinetic profiles with the innovator drug. Adherence to strict ethical, scientific, and regulatory standards ensures the validity and reliability of these studies.

After his thought-provoking talk, he participated in a Q&A session. Following his insightful lecture, engaged with question and answer session Mr. Maddela Rambabu was felicitated by the dignitaries. Dr. B. Haarika, Vice-Principal, expressed gratitude in the vote of thanks, acknowledging everyone who contributed to the event's success.


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BA/BE Center Consists of:
• Management, HR & Admin, Finance, Purchase
• Business Development
• Medical Writing – Developing Study Protocols
• Clinical – Volunteer recruitment, dosing, blood sample collection and sepration
• Bioanalytical – MD, MV and SA
• Pharmacokinetics and Statistical – PK & Statistical analysis
• Data Management – Compilation and preparation CSR
• Quality Assurance – Overall Compliance of data generated
• Regulatory – Coordinating with regulatory agencies
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