

Quality Assessment of Off-patent Research Molecules Vs Indian Branded Generic Drugs

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BRIEF HISTORY OF P.D. HINDUJA HOSPITAL & MRC:

Following the partition, Bombay saw a sharp rise in health challenges due to overcrowding and poor sanitation. Understanding the urgent need for quality care, Late Shri Parmanand Hinduja took a remarkable step by founding the 'Seth Deepchand Gangaram Hinduja Health Care' in December 1951. Starting from a small setup with an OPD and dispensary, it expanded over the years with dedication and planning support from international experts, including Massachusetts General Hospital. By 1986, the hospital had grown into a 300-bed tertiary care center. Later, in 2013, Hinduja Surgical at Khar was also launched to further serve the city.

THEORETICAL UNDERSTANDING AND PRACTICAL EXPOSURE:

Theory:

While studying Research Methodology, I learned how to structure findings logically and that helped me to understand my project. The academic focus is usually on analyzing secondary data that's already cleaned and prepared so we work more on interpretation than collection.

Practical:

The data and information were not always readily available. I often had to coordinate with different teams to get details on branded generics. It was only after going through comparison and discussion that I could draw conclusions on quality and provide relevant suggestions for improvement.

SWOT ANALYSIS:

Strength

- Smoothly handling of purchase planning and vendor communication.
- knowledgeable and experienced staff.
- Reliable vendors, which ensures timely availability of important drugs and materials

Weakness

- Some processes still rely on manual registers like internal stock transfers.
- Inventory Gaps Between Buildings, Sometimes one building had excess while another faced a shortage.
- Operations are smooth, during emergencies, delays in transporting materials or samples—due to manual coordination or lack of transport staff.

Opportunity

- Implementing software, the department can speed up workflows, improve accuracy.
- By analyzing past consumption trends, demand forecasting could improve.
- Introducing QR codes for all materials and drugs would help in real-time tracking.

Threat

- Entry of new competitions in area such top hospitals. i.e. Apollo.
- The cost of specialized medical items is increasing.
- Facing competitions from Lilavati Hospital and Kokilaben Dhirubhai Ambaani Hospital etc.

VISION:

To deliver quality healthcare that's affordable, ethical, transparent, and driven by measurable outcomes.

MISSION:

To become a center of medical excellence that not only treats but also teaches. With a strong focus on continuous improvement, the hospital aims to uplift healthcare standards by training doctors, nurses, and allied professionals, while also fostering clinical research. It strives to align high-quality treatment with the real needs of patients across the country, maintaining a perfect balance of service, learning, and innovation.

PROJECT

Aim: To compare the quality aspects of the Off-patent research molecules Vs Indian branded generic drugs.

Objectives:

- To determine quality standards of Branded Generics Drugs.
- To evaluate the safety profile. i.e. ADRs of both type of Drugs.
- To identify similarities between off-patent research molecules and Indian branded generics drugs.

Methodology:

- **Study Area:** P.D. Hinduja Hospital & Medical Research Centre
- **Study Design:** Comparative and Descriptive Study
- **Sample size:** (Meronem- Zaxter, Supacef- Zocel, Zavicefta- Xavitaz, Zosyn- Tazact, Ambisome- Phosome, Eraxis- Andulfa, Magnex Forte- Sulbagate, Augmentin- Advent) 8 pairs injectables antibiotics of off-patent research molecules and Indian branded generics drugs.
- **Data Sources:** Product Monographs and Certificate of Analysis report (COA) of some Indian branded generics drugs.

Findings:

Based on Pharmacological Data:

Research drugs mentioned pharmacokinetic, pharmacodynamics studies and clinical trials studies on product monograph while branded generics drugs include exact same data.

Based on Certificate of Analysis (COA):

Indian branded generic drug's COA report compliance with specifications which considered within Indian Pharmacopoeias.

Based on Adverse Drug Reactions (ADRs):

Clinical trials in research molecules provides ADRs by severity and frequency of reactions. Branded generics drug's post-marketing studies not included in product monograph.

Suggestions:

- 1) Implementing software system to streamline management process of regulatory documents.
- 2) Branded generics drugs, medication procure from companies that can demonstrate bioequivalence and certificate of analysis documents.
- 3) Indian branded generics drugs procure from top 20 brands that ensures quality of medications.

Learning during Internship:

- 1) How to communicate with colleagues, team and other workers.
- 2) Experience of the corporate world.
- 3) Learnt roles and responsibilities of materials department in hospital.
- 4) Real-world data analysis that enhanced MS-Excel skills.

Challenges Faced During Internship:

- 1) Adapting to corporate world
- 2) Limited resources of data

