

Internship Training

at

AKUMS DRUGS AND PHARMACEUTICALS

by

Name: **ABHINAV TYAGI**

Enrollment No: **PG/20/003**

On

**To study the Epidemiology & Treatment of GERD in India And
Introduction with special reference to PPI's DDR Technology**

Under the guidance of

Dr B.S SINGH

PGDM (Hospital and Healthcare Management)

Batch: 2020-2022



International Institute of Health Management Research

New Delhi

Abstract

New DDR (Dual Drug Release) technology is a suitable therapeutic option for moderate to severe GERD patients.

Gastroesophageal Reflux Disease is common, accounting for more than 5.6 million physician visits each year. From 10% to 20% of adults in western countries and nearly 5% of those in Asia experience GERD symptoms at least weekly. GERD is an important health concern as it is associated with decreased quality of life and significant morbidity. GERD symptoms can be typical, such as heartburn and regurgitation, and atypical, such as chest pain, chronic cough, laryngeal burn, globus, and hoarseness.

GERD is a chronic disease instead of an acute illness, it causes a significant economic impact due to the expense of the long-term management of the disease. The Indian society of Gastroenterology (ISG) Task Force (TF) on GERD made a set of consensus statements for the diagnosis and management of GERD in India. According to the Indian Society of Gastroenterology, the prevalence of GERD in India ranges from 7.6% to 30%, being <10% Less than 10% of GERD patients in India have erosive esophagitis. The global prevalence is estimated to be around 15%, with a higher prevalence in North America and European nations.

The report will focus on working with Akums Drugs and Pharmaceuticals and conducting Secondary Research by analyzing the market of Gastro-resistant drugs for the last 3 years and try out to find the gap, opportunities and upcoming challenges for the market establishment of new DDR technology.

**Completion of Dissertation from
Akums Drugs and Pharmaceuticals**

The certificate is awarded to

ABHINAV TYAGI

in recognition of having successfully completed his

Internship in the department of

New Product Development

and has successfully completed his Project on

To study the Epidemiology & Treatment of GERD in India And Introduction

with special reference to PPI's DDR Technology

Date_ 21st March 2022 to 21st June 2022

Organization

Akums Drugs And Pharmaceuticals

He comes across as a committed, sincere & diligent person who has a strong drive & zeal for
learning.

We wish him all the best for future endeavors.



Training & Development

Mr. Aashish Suri (AGM)

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Abhinav Tyagi student of PGDM (Hospital & Health Management) from the International Institute of Health Management Research, New Delhi has undergone internship training at Akums Drugs And Pharmaceuticals, from 21st March 2022 to 21st July 2022.

The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfilment of the course requirements.

I wish him all success in all his future endeavours.



Dr. Sumesh Kumar

Associate Dean, Academic and Student Affairs

IIHMR, New Delhi



Dr B. S. Singh

Mentor Dr B.S Singh

IIHMR, New Delhi

Certificate of Approval

The following dissertation titled “**To study the Epidemiology & Treatment of GERD in India And Introduction with special reference to PPI’s DDR Technology**” is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **PGDM (Hospital & Health Management)** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of the dissertation.

Name	Signature
1) <u>Dr. VIRENDER LAL</u>	<u></u>
2) <u>VINAY</u>	<u></u>
3) <u>ROHINI</u>	<u></u>

Certificate from Dissertation Advisory Committee

This is to certify that **Mr ABHINAV TYAGI**, a graduate student of the **PGDM (Hospital & Health Management)** has worked under our guidance and supervision. He is submitting this dissertation titled “To study the Epidemiology & Treatment of GERD in India And Introduction with special reference to PPI’s DDR Technology” at “Akum Drugs And Pharmaceuticals” in partial fulfilment of the requirements for the award of the **PGDM (Hospital & Health Management)**.

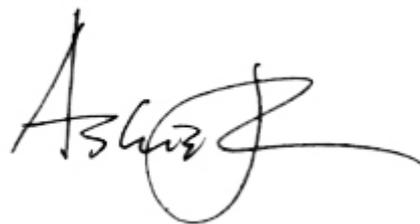
This dissertation has the requisite standard and to the best of our knowledge, no part of it has been reproduced from any other dissertation, monograph, report or book.



Dr B. S. Singh

Dr B.S Singh

IHMR, Delhi



Mr. Ashish Suri

Assistant General Manager

Akums Drugs and Pharmaceutical

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT

RESEARCH,

NEW DELHI

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **“To study the Epidemiology & Treatment of GERD in India And Introduction with special reference to PPI’s DDR Technology”** and submitted by Abhinav Tyagi Enrollment No. PG/20/003 under the supervision of **Dr B.S. Singh** for award of PGDM (Hospital & Health Management) of the Institute carried out during the period from **21st March 2022 to 21st July 2022** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Student Name: Abhinav Tyagi

Signature:



FEEDBACK FORM

Name of the Student: Abhinav Tyagi

Name of the Organization in Which Dissertation Has Been Completed: AKUMS

Area of Dissertation: DDR Technology

Attendance: Perfect for the organisation's norms

Objectives achieved: Launching of a new DDR technology product in the Indian market

Strengths: Sincere, passionate, and dedicated to work.

Suggestions for Improvement: Should be target-oriented and self-motivated.



Date: 21st July 2022

Place: Delhi

**Signature of the Officer-in-Charge/
(Organization Mentor)**

INTRODUCTION

Akums is India's single largest Contract Research and Manufacturing (CRAMS) organization responsible for manufacturing approximately 11-12 % of all drugs consumed in the country. The organization offers a comprehensive range of services starting from formulation development to market launch all en suite.

- Contract Research & Manufacturing Services (CRAMS),
- Formulation & development of Novel Drugs Delivery Systems (N.D.D.S.),
- Loan License,
- New Formulations with DCGI Approvals,
- Institutional business
- Technology Transfer,
- Technical collaboration and Joint venture,

Akums 10 state of the art facilities are equipped to produce all modern dosage forms — tablets, hard gelatin capsules, soft gelatin capsules, powder in sachets, liquid syrups and suspensions, injections, eye/ear drops, ointments, creams, gels, lotions, ayurveda and herbal preparations, nutraceutical and cosmetic preparations and many more. Akums offers significant manufacturing capacities, offering:

- 140.00 Million Tablets,
- 21.00 Million Hard Gelatin Capsules
- 4.50 Soft Gelatin Capsules
- 2.01 Liquid Orals
- 2.07 Sachets
- 1.96 Vials
- 1.07 Ampoules
- 0.75 FFS
- 0.61 Topical Preparations
- 0.30 Million 3-Piece Eye/Nasal Drops.

Akums has emerged as an integrated solution provider for companies seeking specific development and business goals. Along with its core service offering, the company offers advanced solutions for formulation development and testing. Akums total revenue stood at more than INR 21 Billion in the financial year 2019-20, growing at a rate of more than 20% over the past year.

Adhering to its guiding pillars of quality, transparency and innovative excellence, and directive principles of humility and orientation in mission, the esteemed leadership team at Akums, is committed to observing the highest ethical standards and inculcating the premier standards of quality in its products and processes. With industry veterans and stalwarts on board, the major financial, strategic and operational decisions are taken keeping customer satisfaction and partner advancement as the spine of the company's progression.

The leadership with a firm belief in sustainable development and CSR policies of the land vouches to abide by and execute the company practices on the highest ethical standards. following strict regulatory compliance in products processes / parameters as per National and international guidelines and stringent adherence to quality parameters and audits form the backbone of the company's progression.

The Board of Directors at the apex, as trustee of shareholders, carries the responsibility of strategic supervision of the Company. With this structure, the organization is able to rapidly capitalize on opportunities to advance the business. The leadership vision further aims to strengthen future healthcare leaders understanding of complex business, management, and policy issues with a focus on innovation and clinical process improvement.

AKUMS is the most promising contract manufacturer in India. We serve our partners with comprehensive product solutions including regulatory approvals & support , NDDSs , Novel Packaging and much more.

Our 10 state-of-art manufacturing facilities producing formulations in almost all dosage forms and therapeutic segments for most of the leading Pharma companies across the globe. Our world class manufacturing facilities equipped with ultramodern equipment &

machineries for manufacturing formulations in wide range of dosage forms, including ;tablets, hard & soft gelatin capsules , dry & liquid syrups, dry & liquid injectables, prefilled syringes , large volume parenterals, eye & ear drops and herbal, nutraceuticals , dermatological , hormonal & cosmeceutical products.

Akums does not limit it's activities to CMO but has set in the trend of Contract Research and Manufacturing Services (CRAMS) in Indian Pharma industry. The services offered by Akums include, Pre-formulation, formulation development, stabilities studies, method development, and product permissions from Directorate Controller General of India (DCGI). Upon approval Akums offer the products to the clients in its own technology. Akums also arranges Bio-equivalence studies and Clinical trials whenever required.

LITERATURE REVIEW

TITLE: Indian consensus on gastroesophageal reflux disease in adults: A position statement of the Indian Society of Gastroenterology

doi: 10.1007/s12664-019-00979-y

Result: The prevalence of GERD in India ranges from 7.6% to 30%, being < 10% in most population studies, and higher in cohort studies. The dietary factors associated with GERD include use of spices and non-vegetarian food. Helicobacter pylori is thought to have a negative relation with GERD; H.

Global prevalence of, and risk factors for, gastro-oesophageal reflux symptoms: a meta-analysis
Global prevalence of, and risk factors for, gastro-oesophageal reflux symptoms: a meta-analysis

TITLE: Global prevalence of, and risk factors for, gastro-oesophageal reflux symptoms: a meta-analysis

Result: The prevalence of gastro-oesophageal reflux symptoms varied strikingly among countries, even when similar definitions were used to define their presence. Prevalence was significantly higher in subjects ≥ 50 years, smokers, NSAID users and obese individuals, although these associations were modest.

TITLE: The role and limitations of H2-receptor antagonists in the treatment of gastro-oesophageal reflux

DOI: [10.1111/j.1365-2036.1995.tb00778.x](https://doi.org/10.1111/j.1365-2036.1995.tb00778.x)

RESULTS: When treating oesophagitis, the H2RAs suffer from the disadvantage of their relatively short duration of action (compared with PPIs), development of tolerance, and incomplete inhibition of acid secretion in response to a meal. Therefore, it is not easy for the H2RAs to achieve optimum conditions for healing the more severe forms of oesophagitis-- even very high doses may fail. In mild GERD the H2RAs have been shown to be effective in relieving symptoms.

TITLE: Efficacy and tolerability of pantoprazole 40 mg versus 80 mg in patients with reflux oesophagitis.

<https://doi.org/10.1111/j.0953-0673.1996.00397.x>

RESULTS: Endoscopic healing of the reflux esophagitis after 4 weeks' therapy was observed in 78% of the 40 mg group and in 72% of the 80 mg group. The cumulative healing rates after 8 weeks' therapy were 95% and 94%

Objectives

- I. Learn all the aspects of analyzing the market and conducting research at (Akums Drugs and Pharmaceuticals)
- II. Find opportunities by assessing the Gastro segment market of India
- III. Conduct research on current options for treatment and “Why we need this advance technology”
- IV. Launching of a new DDR technology product in the Indian market

METHODOLOGY

Study area and population-

- It is a quantitative research study.
- AIOCD DATA of all India are used to conduct this study.
- Data is taken from the “Akums Data Base” and external sources like Research paper, Articles and Other Publications (Cipla med, PubMed, CDSCO, etc).

Inclusion criteria-

- All genders and castes are taken into consideration.

Exclusion Criteria-

- People not having GERD or any other GIT disease are excluded from the study.

Duration-

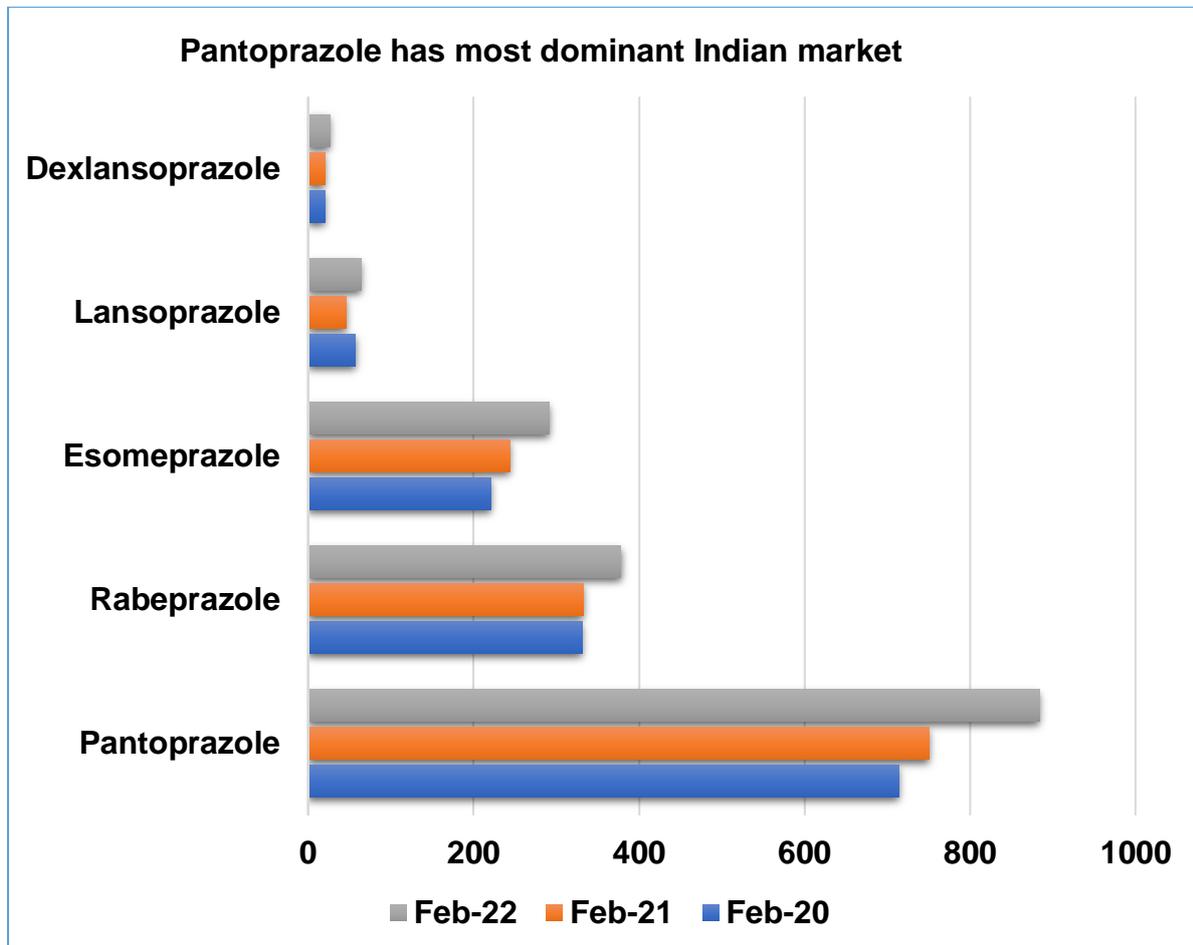
- March 2022 - June 2022

Materials and methods-

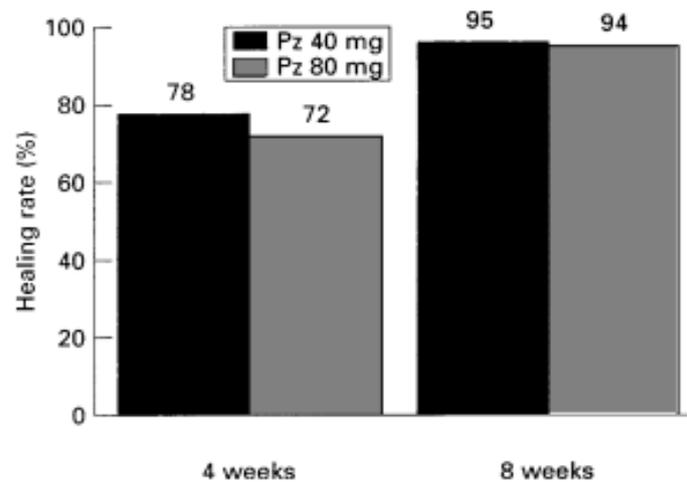
- Approval for using AIOCD data of company.
- Extracting data from the CDSCO AND CTRI portals.
- General tabulation is the format for data analysis.
- Excel are used for the data analysis.

RESULTS

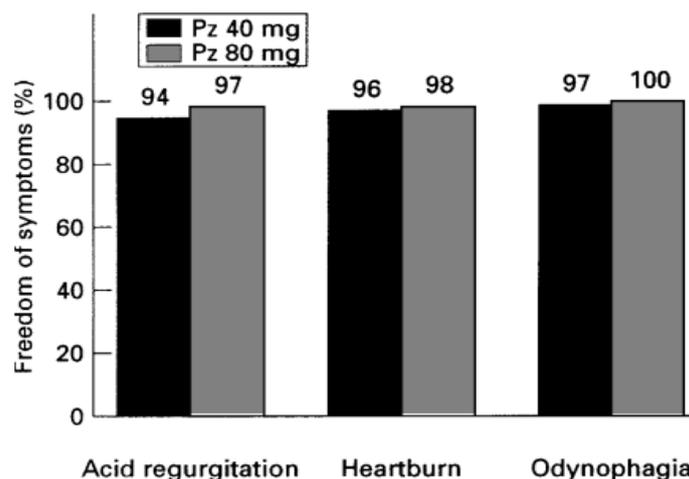
On analysing the Data from AIOCD Data the following observation were taken into consideration



- ✓ Market of Pantoprazole is rising rapidly year by year
- ✓ Market size of pantoprazole is huge in comparison of other PPIs like Esomeprazole and Rabeprazole, Lansoprazole, etc.
- ✓ Pantoprazole have established a dominated market in India



- GERD when treated with Pantoprazole DDR 80 mg experienced a significant benefit in frequency of heartburn, sustained resolution of heartburn, quality of life than those treated with Pantoprazole 40 mg
- Additionally, Pantoprazole DDR 80 mg provided benefit as early as by 14 days. Overall, the drug was found to be safe and well tolerated by the patients.



- Pantoprazole Dual-release gastro-resistant tablet can be considered as suitable therapeutic option in patients suffering from refractory moderate to severe GERD.

DISCUSSION

Despite of wide range of PPI's available, there are limitations with current conventional formulations such as meal dependent anti-secretory effect, Shorter half-life (1-2 h)., Nocturnal breakthrough and lack of sustained acid suppression etc.

That is why we are introducing **Pantoprazole DDR** which is designed to release 25% drug in the duodenum and the rest 75% is designed to dissolve at pH 6.8 (distal part of small intestine) thus providing dual release to maintain pharmacologically effective drug concentrations over a longer period of time (mean residence time of 6 hours) with a single daily dose

LIMITATIONS

- This study only used percentage data rather than actual figures.
- Study was done on the basis of market data (AIOCD) which can change after a certain time.
- Already published research articles and papers are used in this study.

CONCLUSION

The study was conducted in AKUMS DRUGS AND PHARMACEUTICALS at Delhi from March 2022 to June 2022. During study it was observed that Gastroesophageal reflux disease (GERD) is common, accounting for more than 5.6 million physician visits each year. From 10% to 20% of adults in Western countries and nearly 5% of those in Asia experience GERD symptoms at least weekly. According to Indian Society of Gastroenterology, the prevalence of GERD in India ranges **from 7.6% to 30%**. GERD is common in India, both in urban and rural populations, the overall prevalence of GERD was **7.6%: 6.7%** in northern India and **8.4%** in the southern parts. The prevalence in India is almost comparable to that in the West and is higher than in many Asian countries.

The conventional formulations and already existing treatment methods are lacking and have some limitations in the treatment of GERD. That is why new DDR technology is developed for providing 24 hours relief, Dual releasing which provides long lasting acid neutralizing efficacy and Site-specific delivery. These all factors will improve the quality of life of patients.



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CERTIFICATE ON PLAGIARISM CHECK

Name of Student (in block letter)	Abhinav Tyagi		
Enrollment/Roll No.	PG/20/003	Batch Year	2020-2022
Course Specialization (Choose one)	Health Information Technology		
Name of Guide/Supervisor	Dr. B.S Singh		
Title of the Dissertation	"To study the Epidemiology & Treatment of GERD in India And Introduction with special reference to PPT's DDR Technology"		
Plagiarism detect software used	"TURNITIN"		
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Name:

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