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"Simplified Overview of Pantoprazole Dissolution"

Tasneem Ara*
**DTL, Dalgate Srinagar Kashmir*

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I. INTRODUCTION:

Pantoprazole is a proton pump inhibitor (PPI) commonly prescribed for conditions such as gastroesophageal reflux disease (GERD), peptic ulcers, and Zollinger–Ellison syndrome. It works by irreversibly inhibiting the H^+/K^+ ATPase enzyme system (the proton pump) in the gastric parietal cells, thereby reducing acid secretion.However,Pantoprazole is highly sensitive to acidic conditions, meaning it can degrade rapidly when exposed to stomach acid. To overcome this, the drug is formulated with an enteric/gastroresistant coating, which protects it from acidic degradation and allows it to be absorbed in the small intestine, where the environment is less acidic.

II. IMPORTANCE OF DISSOLUTION TESTING:

Dissolution testing is an essential quality control tool in pharmaceutical development and manufacturing. It assesses the rate and extent to which the active drug is released from the dosage form in a simulated gastrointestinal environment.For Pantoprazole, proper dissolution ensures:

- That the drug reaches the absorption site (intestine) intact.
- That it releases at the appropriate time (after passing the stomach).
- Therapeutic effectiveness is achieved consistently.
- Batch-to-batch uniformity of the product is maintained.

III. DISSOLUTION TEST PROCEDURE FOR PANTOPRAZOLE

The dissolution test for Pantoprazole typically involves a two-stage process that mimics the conditions of the gastrointestinal tract.

Stage 1: Acid Stage (Simulating Stomach Conditions)
Medium: 0.1 N Hydrochloric Acid (HCl)
pH: ~1.2 (similar to gastric pH)
Duration: 2 hours
Apparatus: USP Apparatus 2 (paddle) or Apparatus 1 (basket) Speed: Commonly 100 rpm

Purpose: To test the integrity of the enteric coating. Pantoprazole should not be released in this acidic stage.
Limit/Acceptance Criteria: Typically, not more than 10% of the drug should dissolve.
Note: If more than 10% is released here, the enteric coating may be compromised, reducing drug efficacy.
Stage 2: Buffer Stage (Simulating Intestinal Conditions)
Medium: Phosphate buffer (commonly pH 6.8)
Duration: 45 minutes to 1 hour (depending on the respective monograph in respective official pharmacopoeia)
Purpose: To simulate the small intestine where the enteric coating dissolves and the drug is released for absorption.
Limit/Acceptance Criteria: Generally, not less than 75% of the drug should be released within 45 minutes.
This stage confirms that the drug is available for absorption at the intended site.

IV. MECHANISM OF RELEASE FROM ENTERIC-COATED TABLETS

A. In the Stomach (Acidic Medium):

The enteric coating remains intact.

Protects the drug from acid degradation.

No significant drug release.

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B. In the Intestine (Basic Medium):
The enteric polymer coating dissolves at higher pH.

The core tablet disintegrates.

Pantoprazole dissolves and becomes available for absorption.

Simplified Schematic View can be shown as follows:-
[STOMACH (pH ~1.2) - 2 Hours]
→ No drug release
→ Enteric coating intact

[INTESTINE (pH ~6.8) - 45 mins]
→ Enteric coating dissolves
→ Drug is released and absorbed.

V. CHALLENGES IN PANTOPRAZOLE DISSOLUTION TESTING

- ✓ pH sensitivity: Pantoprazole is highly pH-dependent and requires precise conditions.
- ✓ Degradation: Exposure to acid or incorrect handling can cause degradation.
- ✓ Analytical method: Often measured by UV spectroscopy or HPLC in buffer medium.
- ✓ Stability: Needs to be protected from light, moisture, and heat.

VI. CONCLUSION

Pantoprazole's effectiveness depends on its controlled release in the intestine. Dissolution testing ensures that:The enteric coating protects the drug in the stomach and the drug releases efficiently in the intestine thus meeting quality and therapeutic standards.Understanding the dissolution profile of Pantoprazole is essential for pharmacists, formulators, and analysts working in both development and quality assurance.Failure to meet dissolution criteria may result in reduced bioavailability, therapeutic failure, or adverse effects. Therefore, dissolution testing serves not only as a regulatory requirement but also as a critical quality control measure for the performance of enteric-coated dosage forms.