
**“OMEPRAZOLE: AN OVERVIEW AND DEVELOPMENT OF IT'S
DOSAGE FORM”**

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INTRODUCTION OF PEPTIC ULCER

Ulcers are sores or lesions that develop in the mucosal membrane and extend below epithelium of stomach or duodenum. Ulcers formed in the stomach are called gastric ulcers, while those in the duodenum are called duodenal ulcers. Both types are referred to as peptic ulcers. Peptic ulcer occurs in that part of the gastrointestinal tract (g.i.t.) which is exposed to gastric acid and pepsin, i.e., the stomach and duodenum. The etiology of peptic ulcer is not clearly known. It results probably due to an imbalance between the aggressive (acid, pepsin, bile and H. pylori) and the defensive (gastric mucus, bicarbonate secretion, prostaglandins, nitric oxide, high mucosal blood flow and innate resistance of the mucosal cells) factors.

CAUSES

- Helicobacter pylori infection
- Long term use of painkillers (NSAIDs)

Examples: Aspirin, Ibuprofen, Diclofenac

- Excess stomach acid
- Smoking and alcohol
- Severe physical stress
- Certain medications

Example: - Corticosteroids (especially with NSAIDs), Anticoagulants

- Genetic factors (family history increases risk)

PATHOPHYSIOLOGY

The peptic ulcer disease (PUD) mechanism results from an imbalance between gastric mucosal protective and destructive factors. With peptic ulcers, there is usually a defect in the

mucosa that extends to the muscularis mucosa. Once the protective superficial mucosal layer is damaged, the inner layers are susceptible to acidity. Further, the ability of the mucosal cells to secrete bicarbonate is compromised. *H. pylori* is known to colonize the gastric mucosa and cause inflammation. *H. pylori* also impair the secretion of bicarbonate, promoting the development of acidity and gastric metaplasia.

SIGNS AND SYMPTOMS

- Pain or discomfort in the upper part of your abdomen, anywhere between your belly button and breastbone.
- Feeling full too soon while eating a meal.
- Feeling uncomfortably full after eating a meal.
- Nausea and vomiting.
- Bloating and Belching
- Black or tarry stool, or red or maroon blood mixed with your stool.
- Red blood in your vomit or vomit that looks like coffee grounds.
- Sudden, sharp, or severe abdominal pain.
- Feeling dizzy or fainting.

CLASSIFICATION OF PEPTIC ULCER DRUGS

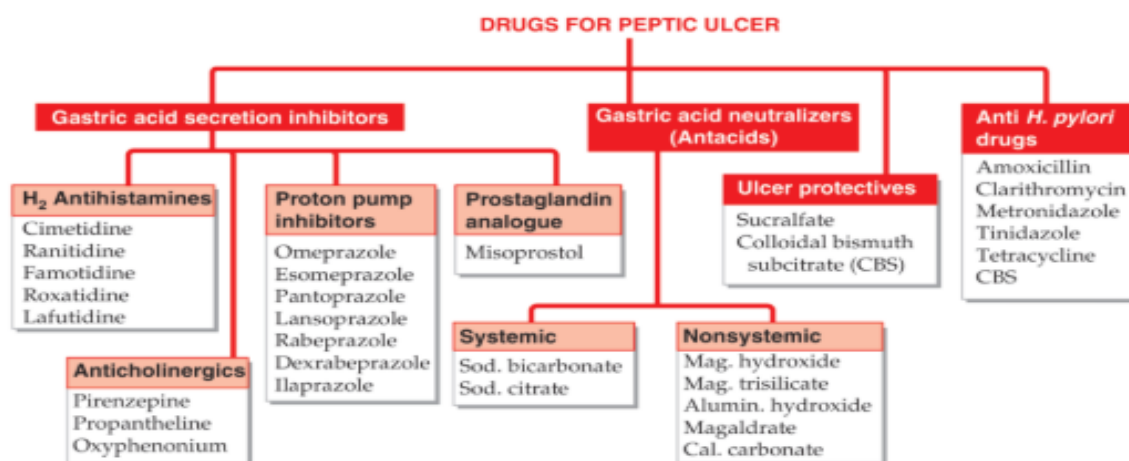


Fig 1: Classification of peptic ulcer drugs.

PROTON PUMP INHIBITORS

PPIs are the most widely used drugs for peptic ulcer and related disorders. The drugs in this category are Omeprazole, Esomeprazole, Lansoprazole, Pantoprazole and Rabeprazole. Since

these drugs are acid labile and can be destroyed by gastric acid, they are available in enteric coated formulations. The PPIs have overtaken H₂ blockers for acid-peptic disorders.

OVERVIEW OF OMEPRAZOLE

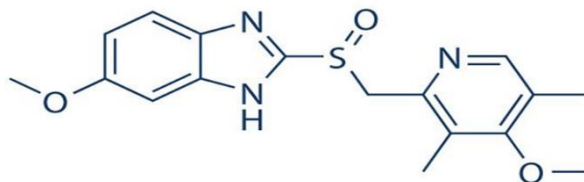
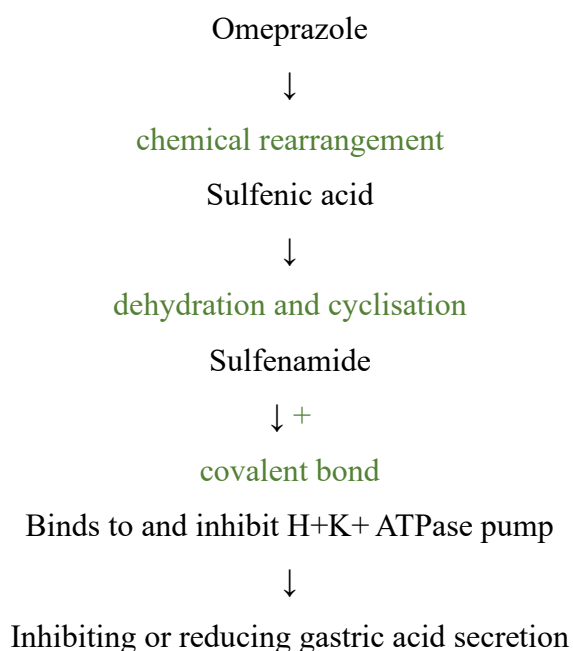


Fig2: Structure of omeprazole.

Omeprazole is a proton pump inhibitor; it is used to treat gastric acid –related disorders. It acts by reducing stomach acid production. It is the prototype member of substituted benzimidazoles which inhibit the final common step in gastric acid secretion. The only significant pharmacological action of omeprazole is dose dependent suppression of gastric acid secretion; without anticholinergic or H₂ blocking action.

MECHANISM OF ACTION

It is a member of class of anti-secretory compounds, the substituted benzimidazole, that stops gastric acid secretion by selective inhibition of the H⁺/K⁺ ATPase enzyme system. As a weak base, it concentrates in acidic canaliculi of parietal cells, becomes activated into sulphenamide form and covalently binds to cysteine residue via disulfide bridges on the alpha subunit of H⁺/K⁺ ATPase pump, thus inhibiting gastric acid secretion.



PHARMACOKINETICS:

- It is acid labile.
- Food interferes absorption of drug, hence it is administered one hour before meals.
- Rapid absorption.
- Distributed widely.
- The half-life of Omeprazole is short, 0.5-1 hour.
- About 95% of drug bound to plasma proteins.
- About 77% of an orally given dose is excreted as metabolites in the urine and the remainder is found in the feces.

ADVERSE DRUG REACTIONS:

- **Common short term side effects;**
- Headache and Dizziness
- Abdominal pain
- Nausea and Vomiting
- Diarrhea
- Flatulence (gas)
- Upper respiratory tract infection
- **Serious long-term effects;**
- Leucopenia (reduction in the number of white cells in the blood)
- Heart failure
- Osteoporosis

DRUG INTERACTIONS:

- As Omeprazole can inhibit the cytochrome P-450 enzyme system, Omeprazole may decrease the hepatic clearance of diazepam, phenytoin or warfarin, thereby enhancing their effects and causing potential toxicity.
- Because Omeprazole can increase gastric pH, drugs that require low gastric pH for optimal absorption (e.g., ketoconazole, ampicillin esters or iron salts) may have their absorption reduced.
- PPIs are metabolized to varying degrees by the hepatic cytochrome P-450 enzymatic system and may alter drug metabolism by induction or inhibition of the cytochrome P enzymes. This is an important consideration in patients taking medications with a narrow therapeutic window, such as diazepam, phenytoin, and warfarin.

USES:

- To treat GERD and other condition caused by excessive stomach acid.
- To promote healing of erosive esophagitis (damage caused by stomach acid to esophagus) and to prevent esophageal cancer.
- To relieve heartburn.
- To treat active benign gastric and duodenal ulcer in adults.
- To treat gastric ulcer caused by *Helicobacter pylori*, along with antibiotics.

PRE-FORMULATION STUDIES

Pre-formulation testing is the first step in the rational development of dosage form of a drug substance. It can be defined as an investigation of physical and chemical properties of a drug substance alone and when combined with excipients.

1. ORGANOLEPTIC PROPERTIES**Table no. 1 Organoleptic parameters.**

Property	Description
Appearance	White to off-white crystalline powder
Odor	Odorless
Taste	Bitter
Texture	Smooth and glossy

2. PHYSICOCHEMICAL PROPERTIES**A) Molecular formula and molecular weight**

- $C_{17}H_{19}N_3O_3S$
- 345.42 g/mol

B) pH

Omeprazole is inactive at neutral pH, but at $pH < 5$ it rearranges to two charged cationic forms (a sulphenic acid and a sulphenamide configurations).

C) Hygroscopicity

It is a hygroscopic substance, meaning it readily absorbs moisture from the air, which can lead to degradation.

D) Solubility

The solubility is the maximum quantity of a solute that can be dissolved in certain quantity of a solvent at a specified temperature. Omeprazole is highly soluble in DMSO (Dimethyl sulfoxide). Freely soluble in organic solvents like ethanol and methanol. Slightly to very

slightly soluble in water at room temperature. Solubility in water and organic solvents can be enhanced by increasing temperature.

E) Stability

Highly unstable in acidic environment (acid labile), but is relatively stable under alkaline conditions. As omeprazole is acid labile, means it degrades rapidly in acidic environment, thus it is always formulated as enteric coated granules or delayed release capsules to prevent its degradation before absorption.

F) pKa (acid dissociation constant)

It is a quantitative measure used to determine strength of acid in a solution. When a weakly acidic or basic drug partially ionizes in GI fluid, generally, the unionized molecules are absorbed quickly. Omeprazole is an amphoteric (can act as both acid and base) substance. Omeprazole contains nitrogen group that allows it to behave as a weak base or weak acid under specific conditions.

G) Melting point

- 150⁰C to 158⁰C (often accompanied by decomposition)

H) Logarithmic Partition coefficient (Log P)

It indicates whether a compound is more soluble in fat (lipophilic) or water (hydrophilic). Partition coefficient is defined, as the ratio of unionized drug concentrations between the organic and aqueous phase at equilibrium. Log P of omeprazole is approximately 2.23. The value indicates that the drug is relatively lipophilic, which is a key characteristic for absorption and distribution within the body.

3. MICROMERITIC PROPERTIES

Pre-formulation studies, which include micromeritic evaluations, almost always focus on the drug mixture (API+ stabilizer) rather than the API alone, as the flow and compression properties change entirely when blended with necessary excipients.

A) Particle Size

Sieve analysis shows omeprazole is moderately fine, with D50 values around 100 μ m, which is within the range of 90 to 125 μ m.

B) Angle of Repose

The angle of repose for raw omeprazole to be around 38.57°, indicating fair to passable flow. The flow characteristics are measured by angle of repose. Angle of repose is defined as maximum angle possible between surface of a pile of the powder and the horizontal plane. Method used is Fixed Funnel Method.

$$\theta = \tan^{-1}(h/r)$$

where, h = height of pile

r = radius of the base of the pile

θ = angle of repose

C) Bulk Density

Bulk density is approximately 0.63 ± 0.07 g/cm³ for omeprazole. Bulk density is the ratio of mass of powder to the bulk volume of powder (including void spaces between particles). It is expressed in g/ml or g/cm³. The bulk density depends on particle size distribution, shape and cohesiveness of particles.

$$\text{Bulk density} = \frac{\text{Mass of powder}}{\text{Bulk volume}}$$

D) Tapped Density

Tapped density is approximately 0.79 ± 0.06 g/cm³ for omeprazole. Tapped density is the ratio of mass of powder to the tapped volume. Tapped volume is the volume occupied by the same mass of powder after a standard tapping. It is expressed in g/ml or g/cm³. The tapped density depends on particle size, size distribution and interparticle friction

$$\text{Tapped density} = \frac{\text{Mass of powder}}{\text{Tapped volume}}$$

E) Carr's Index

Carr's index of omeprazole is reported as 20.25%, which falls within the range of fair flow characteristics. This property is also known as compressibility. It is simple, fast and popular method of predicting powder flow characteristics. It is determined by measuring a powder's bulk density and tapped density using a graduated cylinder and a tapping apparatus. It is expressed in %.

$$\text{Carr's index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

F) Hausner's Ratio

Hausner's ratio of omeprazole is around 1.25, further confirming that the powder has intermediate flow properties. Often requiring the addition of lubricants (e.g., magnesium stearate) or glidants (e.g., talc) for formulation. Hausner ratio is a dimensionless number used

to characterize flow properties of powders and granules. It is the ratio of materials tapped density to its bulk density.

$$\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

4. DRUG EXCEPIENT COMPATIBILTY STUDIES

Drug excipient compatibility studies were carried out by mixing drug with potential excipient. The ratio of formulation excipients to active substances was maintained at a ratio of 1:1. The mixtures were filled in closed vials and placed in stability chambers in the conditions as prescribed in US Pharmacopeia. The possible interactions between omeprazole magnesium and excipients were evaluated by examining the pure drug and drug excipient powder mixtures which were stored under specific conditions for a period of 90 days.

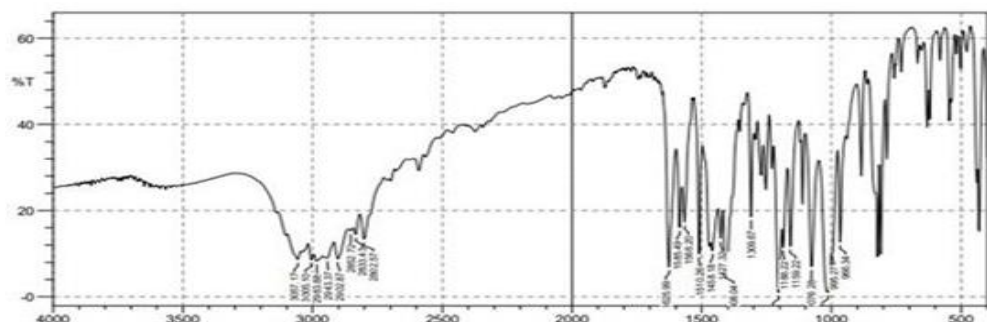


Fig 3: FTIR of omeprazole.

FORMULATION CONSIDERATION

Omeprazole is a benzimidazole derivative that irreversibly inhibits the H⁺/K⁺ ATPase enzyme system of gastric parietal cells. Its poor stability in acidic pH necessitates the use of a multi-particulate dosage form with enteric coating.

1. COMPOSITION AND FORMULATION

The formulation of omeprazole presents unique challenges due to its acid-labile nature and limited solubility, necessitating innovative pharmaceutical strategies to ensure stability, bioavailability, and therapeutic efficacy. The most commonly employed method is the enteric-coated pellet formulation, which allows omeprazole to bypass the acidic environment of the stomach and be released in the intestine where it remains stable and bioavailable.

A) PELLETT CORE

SI.NO.	INGREDIENTS	QUANTITY
1.	Microcrystalline cellulose (MCC)	131.78g

B) ACTIVE DRUG LAYER

SI.NO.	INGREDIENTS	QUANTITY
1.	Omeprazole	23.78g
2.	Lactose monohydrate	20.23g
3.	Sodium lauryl sulfate	0.72g
4.	Sodium pyrophosphate	3.10g
5.	Hydroxypropyl cellulose	4.75g
6.	Purified water	Q. s

C) SEAL COAT

SI.NO.	INGREDIENTS	QUANTITY
1.	Hydroxypropyl methylcellulose	17.38g
2.	Talc	0.22g
3.	Purified water	Q. S

D) ENTERIC COAT

SI.NO.	INGREDIENTS	QUANTITY
1.	Eudragit L30-D55	12.56g
2.	Polyethylene glycol	3.49g
3.	Titanium dioxide	1.01g
4.	Talc	0.22g
5.	Purified water	Q. S

F) GELATIN SHELL**Table no. 2 Composition of delayed release omeprazole capsule.**

SI.NO.	INGREDIENTS	QUANTITY
1.	Gelatin	19.6g
2.	Titanium dioxide	0.4g
3.	Purified water	Q. S

2. MANUFACTURING TECHNIQUE

The production of omeprazole pellets involves sophisticated pharmaceutical processes aimed at achieving high stability, controlled release, and batch-to-batch uniformity. The following are the most commonly employed manufacturing techniques in the development of omeprazole capsule formulations:

A) Extrusion–Spheronization

Extrusion–Spheronization is one of the most widely used techniques for producing uniform, spherical pellets with excellent flow properties and surface smoothness. The process typically

involves; Mixing the drug with binders, fillers (e.g., microcrystalline cellulose), and other excipients to form a wet mass, extruding the wet mass through a die to form cylindrical extrudates and spheronizing the extrudates in a spheronizer to form near-perfect spheres.

B) Fluid Bed Coating

Fluid bed coating is the most preferred method for applying functional coats (e.g., seal coating, enteric coating) to omeprazole pellets. This technique involves suspending pellets in an upward flow of air and spraying coating solutions or dispersions onto them in a controlled environment. Fluidized bed systems are used to apply both the acid-resistant enteric layer and protective subcoats, which are critical for protecting omeprazole from degradation.

C) Production of Hard gelatin capsule shell

The mechanism involved for production of hard gelatin capsule shell are,

- Dipping • Spinning • Drying • Stripping & Trimming • Joining

Dipping: Capsule shells are manufactured under strict climatic conditions by dipping pairs (body and cap) of standardized steel pins arranged in rows on metal bars into an aqueous gelatin solution (25 – 30% w/w) maintained at about 50 ° C in a jacketed heating pan.

Spinning of the dip-coated pins: After adsorption of the gelatin solution on to the surface of the pins, the bar containing the pins is rotated more times to evenly distribute the gelatin solution around the pins, as uniform gelatin distribution being critical for correct and precise capsule wall thickness.

Drying of the gelatin-coated pins: Once the gelatin is evenly distributed on the mould, a blast of cool air is used to set the gelatin on the mould. At this point, the gelatin is dried, and the pins are then passed through several drying stages to achieve the target moisture content.

Stripping & Trimming: After the gelatin is dried, the capsule is stripped off the mould and trimmed to the proper length. **Joining of the trimmed capsule shell:** Once trimmed, the two halves (the cap and body) are joined to the pre-closed position using a pre lock mechanism. At this point, printing is done if needed before packing in cartons for shipping.

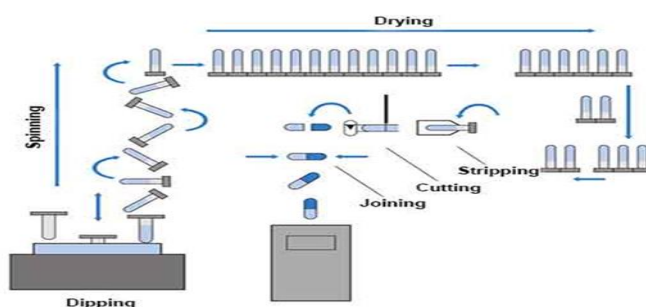


Fig 4: Formulation of capsule shell.

D) Filling of Hard Gelatin capsule

To prepare omeprazole capsules 20mg equivalent, omeprazole enteric coated pellets were taken from pellet formulation. Size 2 capsules were selected for capsule formulation. Dispense omeprazole enteric coated pellets from previous formulation. Load these pellets in hard gelatin capsules No-2 with capsule filling machine. Transfer enteric coated pellets in to capsules by spreading it into equal quantities equivalent to 20mg of omeprazole. Close the capsules by using caps.

3. FINISHING OF CAPSULE

In order to make capsule more elegant, they undergo the process of finishing. The commonly used step for producing finished capsule are as follows:

- 1.Cloth dusting:** It is manual method in which small number of capsules are rubbed with a cloth or gauze which may or may not contain inert oil.
- 2.Polishing:** Special pan may be used for polishing the filled capsule. These pans lined with cheese or polyurethane cloth which remove the dust or other powder adhere to capsule
- 3.Brushing:** In this method capsule are projected under soft rotating brushes which remove the dust from capsule shell. This process is assisted under vacuum.
- 4.Sorting:** This operation is needed to separate the imperfect & damaged capsule. Although in large scale it done manually, some automatic equipment's are available e.g-Rotosort.

EVALUATION PARAMETERS

The quality and performance of omeprazole formulations are determined by a series of evaluation parameters that ensure the final product meets pharmacopeial and regulatory standards. According to the Indian Pharmacopoeia (IP) and other global guidelines, these evaluations are crucial for confirming controlled release behavior, stability, and acid resistance, which are essential for omeprazole's therapeutic efficacy.

EVALUATION OF OMEPRAZOLE PELLETS

1. Particle Size Distribution

Uniform particle size is critical for consistent drug release, coating uniformity, and flow properties during capsule filling or compression. The distribution is typically measured using sieve analysis or laser diffraction techniques.

2. Drug Content and Assay

This test confirms that each batch of pellets contains the labeled amount of omeprazole. It is typically performed using High-Performance Liquid Chromatography (HPLC) as per IP or USP methods. Acceptance criteria often allow $\pm 5\%$ variation from the label claim. Uniform drug content ensures dose consistency and therapeutic reliability.

3. Enteric Coating Integrity

The integrity of the enteric coating is evaluated through acid resistance testing, scanning electron microscopy (SEM), or visual inspection of coating defects. An intact enteric coating is essential for; Protection of omeprazole from gastric degradation.

4. Stability Studies

Omeprazole is sensitive to moisture, heat, and light. Stability testing is performed under ICH guidelines to assess: Shelf-life, Degradation products and Appearance and potency over time
Typical conditions include: **Accelerated testing:** $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \text{ RH} \pm 5\%$ for 6 months
Long-term testing: $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \text{ RH} \pm 5\%$ for 12 months

EVALUATION OF OMEPRAZOLE CAPSULE

1. Appearance

Capsules produced on a small or a large scale should be uniform in appearance. Visual or electronic inspection should be undertaken to detect any flaws in the integrity and appearance of the capsule.

2. Disintegration test

Use disintegration apparatus, place one capsule in each tube. Operate the apparatus for 2 hours without the discs in 0.1 M hydrochloric acid. No capsule shows signs of disintegration or of rupture permitting the escape of the contents. Replace the medium in the vessel with mixed phosphate buffer pH 6.8, add a disc to each tube and operate the apparatus for a further 60 minutes. Remove the apparatus from the medium and examine the capsules. They pass the test if no residue remains on the No. 10 mesh screen.



Fig 5: Disintegration apparatus.

3. Dissolution test

The dissolution test is carried out using the dissolution apparatus as per U.S.P. The capsule is placed in a basket, and the basket is immersed in the dissolution medium and caused to rotate at a specified speed. The dissolution medium is held in a covered 1000ml glass vessel and maintained at $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ by means of a constant temperature suitable water bath. The stirrer speed and type of dissolution medium are specified in the individual monograph.

Number of capsules tested is 6, Acceptance criteria; Each unit is not less than $Q + 5\%$. The quantity Q , is the specified amount of dissolved active substance, expressed as a percentage of the labeled content.



Fig 6: Dissolution apparatus.

4. Weight variation test

20 capsules are taken at random and weighed. Their average weight is calculated; then each capsule passes the test if the weight of individual capsules falls within 85-115% of the average weight. If it is not met, then the weight of the contents for each individual capsule is determined and compared with the average weight of contents. Weigh an intact capsule. Open the capsule without losing any part of the shell and remove the contents as completely as possible. Weigh the shell. The weight of the contents is the difference between the weighing's. Repeat the procedure with a further 19 capsules. Determine the average weight. Not more than two of the individual weights deviate from the average weight by more than

the percentage deviation shown in below and none deviates by more than twice that percentage.



Fig 7: Weighing balance.

5.Content uniformity test

30 capsules are taken, 10 are assayed. Nine tablets should contain not less than 85% and not more than 115% of the labelled drug content. The 10th tablet can contain not less than 75% and not more than 125%.

6.Moisture permeation test

By packing the dosage unit together with a colour-revealing desiccant pellet; exposing the packaged unit to known relative humidity over a specified time, observing the desiccant pellet for colour change (indicating absorption of moisture) and comparing the pre and post weight of the packaged unit, moisture permeation can be determined.

PACKAGING

Capsule packaging refers to how pharmaceutical capsules (hard-shell or soft gel) are enclosed for distribution and use. It includes primary packaging (the immediate container in contact with the capsules, e.g., blister cavities or bottles) and secondary packaging (outer cartons, boxes, and labels that further protect and identify the product). Good capsule packaging must protect the drug from moisture, light, and contamination, ensure stability through shelf-life, and meet regulatory requirements.

PRIMARY PACKAGING

1.Blister packaging

Blisters provide excellent barrier properties: they can be made with materials like PVC/PVDC or foil (Alu-PVC, Alu-Alu) to block moisture, oxygen and light.

2.Strip packaging

Strip packs are another form of unit-dose primary pack. Strip packs often use aluminum foil which is impermeable to moisture and oxygen. This makes them ideal for moisture-sensitive capsules or pediatric meds where long shelf life is needed. They are lighter and flatter than blisters, saving space.

3.Bottle packaging

Bottles are the classic multi-dose container. Capsules are filled into bottles (plastic or glass) which are then capped. They are usually made from HDPE or PET plastic, or glass (for strong chemical inertness).

SECONDARY PACKAGING

After choosing a primary pack, capsules are usually placed into secondary packaging like carton boxes or shrink-wrapped cases. Cartons provide extra protection during shipping.

Cartons & Inserts: Medical cartons must include product inserts (Leaflets with dosage instructions, batch number, expiry, manufacturer info, etc.). These are often paper leaflets inserted into the box.

Tamper Seals: Secondary packaging commonly has tamper-evident seals (e.g., security tapes, shrink bands) to show if the box has been opened.

LABELLING

- **Product Name:** Omeprazole Delayed-Release Capsules, USP
- **Strength:** 20 mg
- **Dosage Form:** Delayed-Release Capsule
- **Active Ingredient:** Each capsule contains 20 mg of omeprazole (USP grade).
- **Purpose:** Acid Reducer.
- **Indications:** Treats frequent heartburn (2 or more days a week).
- **Directions for Use:**
 - Swallow capsule whole with water before eating in the morning.
 - Take daily for the duration of the treatment course, as directed by a healthcare professional.
 - Do not chew, crush, or open capsules.
 - May take 1 to 4 days for full effect.
- **Warnings:**
 - Do not use if allergic to omeprazole.

- Do not use with alcohol.
- Stop use if severe skin reactions occur.
- Ask a doctor if you have difficulty swallowing, vomiting with blood, or black stools.
- **Storage:** Store at 20°C to 25°C. Protect from moisture.



Fig 8: Label of omeprazole capsule.

STORAGE

Storage of hard gelatin capsule shell for long time period require proper maintenance of temperature & humidity.

Table no.3 Storage of omeprazole.

STORAGE CONDITION	RELATIVE HUMIDITY (%)	TEMPERATURE (°C)
Minimum	35	15
Best possible	50	20
Maximum	65	25

SUMMARY

This report is a comprehensive review of the pharmaceutical and clinical aspects of omeprazole, a drug widely used in the treatment of peptic ulcers and gastroesophageal reflux disease (GERD). It begins with an overview of peptic ulcers and introduces omeprazole as a proton pump inhibitor that works by blocking gastric acid secretion. The pre-formulation studies examined omeprazole's organoleptic properties, physicochemical properties, micromeritic properties and compatibility with excipients using FTIR analysis.

The oral formulation of omeprazole was typically prepared as an enteric-coated system (such as pellets, capsules) to protect the drug from degradation in stomach acid. The final product

was evaluated for several critical quality control (QC) parameters like weight variation, drug assay, disintegration, dissolution and stability. The report also discusses packaging, labelling and storage conditions for omeprazole formulations, ensuring the product is safe, effective, and stable for patient use.

REFERENCE

1. Saxena M. Pharmacology III. 1st ed. Lucknow: Thakur Publication Pvt. Ltd; 2020. p. 48.
2. Srivastav Y, Kumar V, Srivastava Y, Kumar M. Peptic Ulcer Disease (PUD), Diagnosis, and Current Medication-Based Management Options: Schematic Overview. *J Adv Med Pharm Sci.* 2023;25(11). p. 14-27.
3. Vakil N. Peptic ulcer disease: a review. *JAMA.* 2024;332(21). p. 1832-1842.
4. Mayo Clinic. Peptic ulcer: Symptoms & causes. Rochester (MN): Mayo Foundation for Medical Education and Research; 2024 Aug 16.
5. Malik TF, Gnanapandithan K, Singh K. Peptic Ulcer Disease. [Updated 2023 Jun 5]. In: StatPearls. Treasure Island (FL): StatPearls Publishing; 2026 Jan.
6. Laine L. Peptic Ulcer Disease. In: Loscalzo J, Fauci A, Kasper D, Hauser S, Longo D, Jameson J, editors. *Harrison's Principles of Internal Medicine.* 21st ed. New York: McGraw-Hill Education; 2022.
7. Rasheed SH. Pharmacology III. 4th ed. Hyderabad: SIA Publishers & Distributors Pvt. Ltd.; 2020. p. 1.20.
8. Tripathi KD. Essentials of medical pharmacology. 6th ed. New Delhi: Jaypee Brothers Medical Publishers; 2019. p. 631-3.
9. Rasheed SH. Pharmacology III. 4th ed. Hyderabad: SIA Publishers & Distributors Pvt. Ltd.; 2020. p. 1.22-3.
10. CIMS Medica India. Current Index of Medical Specialties. 104th ed. Bangalore: CIMS Medica India Pvt Ltd; 2013. Omeprazole; p .38.
11. Ganesan V. Drug profile: Omeprazole. Department of pharmaceutics. Erode: The Erode College of Pharmacy and Research Institute. Chapter 5. p. 25-8.
12. Ganesan V. Pre-formulation studies. Department of pharmaceutics. Erode: The Erode College of Pharmacy and Research Institute. Chapter 7. p. 49-55.
13. Al-Badr AA. Omeprazole Profile. Profiles of Drug Substances, Excipients and Related Methodology. Vol. 35. Academic Press; 2010. p. 151-262.
14. Subrahmanyam CVS. Textbook of Physical Pharmaceutics. 3rd ed. Delhi: Vallabh Prakashan; 2015. p. 215, 222-4, 226.

15. Archi D, Pooja K, Shital F. Fourier transform infrared spectrophotometry: An eco-friendly green tool for quantification of omeprazole in pharmaceutical formulation. *Res J Pharm Technol.* 2022;15(8):3431-6.
16. Mishra K, Sharma V. Preformulation evaluation of omeprazole for pharmaceutical dosage form development. *International Journal of Health Advancement and Clinical Research.* 2026;4(1). p. 24-30.
17. Bansal A, Jain N. Formulation and evaluation of omeprazole raft forming system for the treatment of gastro esophageal reflux disease. *Int J Pharm Res Appl.* 2022 Nov-Dec;7(6). p. 230-237.
18. Bhaskaran S. *Pharmaceutical Dosage Form.* 1st ed. Delhi: Birla Publications Pvt. Ltd; 2009-2010. p. 45.
19. Sahoo L. Capsule (Unit-III). *Industrial Pharmacy-I (BP502T).* Berhampur: Roland Institute of Pharmaceutical Sciences.
20. Thapa P, Thapa R, Woo KT, Choi DH, Jeong SH, Kim MS, et al. Factors contributing to drug release from enteric-coated omeprazole pellets. *AAPS PharmSciTech.* 2020 Jan;21(1):41.
21. Kumisbek G, Vetchý D, Kadyrbay A. Development of a new bioequivalent omeprazole product. *Medicina.* 2024 Mar 2;60(3):427. p. 1-15.
22. Muthuprasanna P, Lathaeaswari R, Suriaprabha K, Roosewelt C, Gopinath M, Sreedhar V, Satish Babu A. Formulation of delayed release oral dosage forms for omeprazole and it's in vitro evaluation. *Materials Science: An Indian Journal.* 2007 Dec;3(4):255-260.
23. Adhikari A, Chaudhary A, Khan A. Formulation, evaluation, and applications of omeprazole pellets IP: a brief review. *Int J Pharm Sci.* 2025;3(5). p. 2503-2508.
24. Bhaskaran S. *Pharmaceutical Dosage Form.* 1st ed. Delhi: Birla Publications Pvt. Ltd; 2009-2010. p. 63-64.
25. Mohan SD, Gupta VRM, Yasam H, Jampani Y, Yalamanchili M. Nonaqueous enteric coating application of HPMC and Eudragit L100 on hard gelatin capsules: designed to achieve intestinal delivery. *J Appl Pharm Sci.* 2015 May;5(Suppl 1). p. 001-006.
26. Bhadane SS. Formulation and evaluation of omeprazole pellets by using fluidized bed processor. *Int J Adv Res Innov Ideas Educ.* 2024;10(2). p. 5110-51121.
27. Jinlu Packing. *Complete Guide to Capsule Packaging Options: Types, Materials, and Machines for Pharmaceutical Packaging.* Guangdong, China: Jinlu Packing; 2026 Apr 25.
28. Daily Med. Label: OMEPRAZOLE capsule, delayed release [Internet]. Bethesda (MD): U.S. National Library of Medicine; 2025 Aug 10.