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A Review on Formulation and pharmacological activity assessment of Oral Disintegration Tablets of Antiulcer Using Super Natural Disintegrant

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Abstract

Orally disintegrating tablets (ODTs) have gained significant attention in the pharmaceutical industry due to their convenience, especially for patients with dysphagia, pediatric, and geriatric populations. The formulation of antiulcer ODTs using super natural disintegrants is a novel approach aimed at improving drug dissolution, bioavailability, and patient compliance. Omeprazole is a proton pump inhibitor (PPI) widely used in the treatment and prevention of peptic ulcers, gastroesophageal reflux disease (GERD), and other acid-related disorders. The pharmacological assessment of omeprazole for its antiulcer activity involves Omeprazole irreversibly inhibits the H^+/K^+ ATPase enzyme (proton pump) in the gastric parietal cells. This review provides a comprehensive analysis of the formulation techniques, selection of natural superdisintegrants, and in-vitro evaluation methods for antiulcer ODTs. Based on that review study formulation & invitro as well as invivo evaluation of OTDs will plan. The study demonstrated that the incorporation of the super natural disintegrant significantly enhanced the disintegration time and drug release profile compared to synthetic disintegrants.

Keywords: **Oral disintegration tablets, antiulcer, super natural disintegrant, in-vitro evaluation, Omeprazole, Ulcer Index**

INTRODUCTION

Orally Disintegrating Tablets (ODTs):

Orally disintegrating tablets (ODTs) are solid dosage forms that dissolve or disintegrate rapidly in the oral cavity without the need for water. They offer a significant advantage over conventional tablets, especially for patients who experience difficulty swallowing (dysphagia), such as pediatric, geriatric, and bedridden individuals. ODTs provide improved patient compliance and enhanced bioavailability by promoting faster drug absorption in the gastrointestinal tract.

The concept of ODTs has evolved with advancements in pharmaceutical technology, leading to the development of tablets with superior disintegration and dissolution properties. The use of natural superdisintegrants in these formulations is gaining attention due to their sustainability, biocompatibility,

and ability to enhance the tablet's disintegration efficiency. This review explores the formulation of antiulcer ODTs using super natural disintegrants and their impact on drug release and stability.

Peptic ulcers are a common gastrointestinal disorder affecting millions worldwide. Conventional dosage forms such as tablets and capsules often present challenges in terms of patient adherence due to swallowing difficulties. ODTs offer an effective alternative, providing rapid disintegration in the oral cavity without the need for water. The use of natural superdisintegrants in ODTs is gaining popularity due to their biocompatibility, cost-effectiveness, and eco-friendliness.

Advantages of ODT Formulation:

- Rapid Disintegration and Absorption: ODTs dissolve quickly in the oral cavity without water, ensuring faster absorption compared to conventional tablets.
- Better Patient Compliance: Useful for patients with dysphagia or difficulty swallowing.
- Quick Onset of Action: Faster disintegration may result in quicker onset of acid suppression compared to delayed-release formulations.
- Clinical Significance of ODT Formulation:
- Faster onset of action compared to standard tablets due to rapid disintegration and absorption.
- Bypasses the need for water, making it convenient for dysphagic or bedridden patients.
- Potentially higher bioavailability if formulated with stabilizers that prevent degradation in acidic pH

Super Natural Disintegrants:

Natural superdisintegrants such as plant-derived polysaccharides, mucilages, and starches have been extensively explored. Some commonly used natural disintegrants include:

Plantagoovata mucilage **(**Psyllium husk)

Lepidiumsativum mucilage (Garden cress seed mucilage)

Fenugreek seed mucilage

Guar gum

Aloe vera gel powder

Trigonellafoenum-graecum (Fenugreek gum)

These natural polymers exhibit superior swelling and wicking properties, making them suitable for ODT formulations.

Advantages of Using Super Natural Disintegrants:

- **Biodegradability and non-toxicity**
- **Cost-effectiveness** compared to synthetic disintegrants
- **Higher swelling index** leading to improved disintegration time
- **Enhanced patient compliance** due to the natural origin

COLLECTION OF POWDER FROM NATURAL SUPERDISINTEGRANT PLANTS:

The preparation of powder from natural superdisintegrant plants involves several steps to ensure purity, effectiveness, and stability. Below is a step-by-step process for extracting and preparing natural superdisintegrants from plant sources:

1. Selection of Plant Material:

Choose a plant known for its superdisintegrant properties, such as:
Psyllium husk (Plantagoovata)
Fenugreek seed mucilage (Trigonellafoenum-graecum)
Guar gum (Cyamopsistetragonoloba)
Aloe vera gel powder
Garden cress mucilage (Lepidiumsativum)

2. Collection and Cleaning

Harvest the relevant plant parts (seeds, mucilage, leaves, or roots).
Remove unwanted materials such as dirt, debris, and foreign particles.
Wash thoroughly with distilled water to eliminate any contaminants.

3. Drying Process

Spread the cleaned plant material on trays in a well-ventilated area.
Dry under shade at room temperature to retain bioactive properties.
Alternatively, use a hot air oven at 40–60°C for faster drying.

4. Size Reduction

Grind the dried plant material using a mortar and pestle, grinder, or ball mill.
Pass the powdered material through a sieve (60–120 mesh) to obtain a uniform particle size.

5. Extraction of Mucilage or Gum (if needed)

For plants containing mucilage (e.g., fenugreek, psyllium, garden cress):
Soak the powdered material in distilled water (1:10 ratio) for 24 hours.
Filter through muslin cloth to separate the mucilage.
Precipitate the mucilage using alcohol (ethanol or isopropanol, 3:1 ratio).
Dry the precipitate in an oven at 40–50°C and grind into powder.

6. Purification (Optional, for Higher Quality)

Treat with ethanol or acetone to remove unwanted components.
Subject to centrifugation or filtration to enhance purity.
Dry and regrind to a fine powder.

7. Storage

Store the final powder in an airtight container to prevent moisture absorption.
Keep in a cool, dry place away from direct sunlight.
Add preservatives (if necessary) to extend shelf life.

8**. Evaluation of Superdisintegrant Properties**

Test the prepared powder for:
Swelling index (water absorption capacity)
Hydration capacity
Disintegration efficiency in tablet formulation
Loss on drying (LOD) to check moisture content
Compatibility Study of Omeprazole with Superdisintegrants for ODT Formulation
A crucial aspect of ODT formulation is the compatibility study between the active pharmaceutical ingredient (API) and excipients. Omeprazole, being a proton pump inhibitor, is susceptible to degradation in acidic conditions. Therefore, its stability in the presence of natural superdisintegrants must be evaluated.

METHODS FOR COMPATIBILITY STUDY:

- **Fourier Transform Infrared Spectroscopy (FTIR):** To identify potential chemical interactions between omeprazole and the superdisintegrants.
- **Differential Scanning Calorimetry (DSC):** To assess thermal stability and detect possible drug-excipient incompatibilities.
- **X-ray Diffraction (XRD):** To examine any changes in the crystalline structure of omeprazole due to the presence of superdisintegrants.
- **High-Performance Liquid Chromatography (HPLC):** To determine drug stability and degradation in the formulation.

Findings and Considerations: Natural superdisintegrants generally do not interfere with the chemical stability of omeprazole, but their hygroscopic nature may impact drug stability.Proper selection of superdisintegrants with minimal moisture retention properties is crucial for maintaining the efficacy of omeprazole in ODTs.Formulation strategies such as coating omeprazole with enteric polymers or using buffering agents may enhance stability.

IDENTIFICATION OF OMEPRAZOLE BY INFRARED (IR) SPECTROSCOPY
Infrared (IR) spectroscopy is commonly used to identify **functional groups** in **omeprazole** by detecting characteristic absorption bands. The IR spectrum of omeprazole shows specific peaks corresponding to its molecular structure.

Key IR Absorption Peaks of Omeprazole
N-H Stretch (Benzimidazole Ring): ~3300–3500 cm^{-1} (broad, medium)
C-H Stretch (Aromatic and Aliphatic): ~2800–3100 cm^{-1}
C=N Stretch (Benzimidazole): ~1600–1650 cm^{-1}
C-O-C Stretch (Methoxy Group on Pyridine): ~1200–1300 cm^{-1}
S=O Stretch (Sulfoxide Group): ~1000–1100 cm^{-1} (strong)
Procedure for IR Identification
Sample Preparation:
Use **KBr pellet method** (for solid omeprazole) or **ATR (Attenuated Total Reflectance)** if available.
Grind omeprazole with dry potassium bromide (KBr) and compress into a pellet.
Spectral Measurement:

Scan from **4000 to 400 cm^{-1}**.
Identify characteristic absorption bands.
Comparison with Reference Standard:
Match observed peaks with the **official pharmacopoeial spectrum** (e.g., USP, BP, IP).
Ensure key functional group peaks are present.
Conclusion:
If the spectrum matches the reference standard, the presence of **omeprazole** is confirmed. The **S=O peak (~1050 cm^{-1}) and N-H peak (~3400 cm^{-1})** are particularly important for confirmation

FORMULATION APPROACHES:

- **Selection of Drug:**

Antiulcer agents such as ranitidine, omeprazole, pantoprazole, and famotidine are commonly incorporated into ODT formulations. The choice of drug is crucial in determining the pharmacokinetic and pharmacodynamic properties of the final formulation.
Formulation of ODT Using Super Natural Disintegrants

- **Ingredients Selection:**

A typical ODT formulation using super natural disintegrants consists of:
Active Pharmaceutical Ingredient (API): Omeprazole or other antiulcer drugs.
Super Natural Disintegrants: Psyllium husk, fenugreek mucilage, or guar gum.
Binders: Natural gums such as acacia or tragacanth.
Fillers: Mannitol, lactose, or microcrystalline cellulose.
Lubricants: Magnesium stearate or stearic acid.
Sweeteners and Flavoring Agents: To enhance patient compliance.

PHARMACOLOGY OF DRUGS (OMEPRAZOLE):
The pharmacodynamic activity of an orally disintegrating tablet (ODT) of omeprazole is primarily related to its mechanism of action as a proton pump inhibitor (PPI).

- **Mechanism of Action**

Omeprazole is a prodrug that becomes active in the acidic environment of parietal cells in the stomach.
After absorption, it is converted to its active form, which irreversibly binds to the H^+/K^+-ATPase enzyme (proton pump) on the gastric parietal cells.
This inhibits the final step of gastric acid secretion, leading to a significant reduction in stomach acid production.

- **Pharmacodynamic Effects**

Increased Gastric pH: By blocking acid secretion, it increases the pH of gastric contents, which helps in ulcer healing and gastroprotection.
Inhibition Duration: Since omeprazole irreversibly inhibits the proton pump, its effect lasts longer than its plasma half-life (~1-2 hours), with acid suppression lasting up to 24 hours.
Cytoprotective Effects: Reduced acidity prevents mucosal damage and enhances mucosal healing, contributing to its antiulcer activity.

- **Pharmacokynetic Effects**

The pharmacokinetic activity of orally disintegrating tablet (ODT) omeprazole differs from conventional dosage forms due to its unique formulation, which enhances disintegration and dissolution.

1. **Absorption:**

Omeprazole is a weak base and is unstable in acidic conditions, so it is usually formulated as an enteric-coated or buffered ODT.

The ODT formulation rapidly disintegrates in the mouth and is absorbed in the small intestine.

Bioavailability: Standard omeprazole has an oral bioavailability of ~40% after the first dose and increases to ~65% with repeated dosing due to reduced first-pass metabolism.

2. Distribution:

Plasma protein binding: ~95% (mostly albumin).

Volume of distribution (Vd): ~0.3 L/kg, indicating moderate tissue distribution.

3. Metabolism:

Omeprazole is extensively metabolized by the liver, primarily by CYP2C19 and CYP3A4 enzymes.

Major metabolites: Hydroxyomeprazole and Omeprazole sulfone (inactive).

Genetic polymorphism of CYP2C19 affects metabolism, leading to differences in drug levels among rapid, intermediate, and poor metabolizers.

4. Excretion:

Half-life (t½): ~1–1.5 hours (but the duration of action is longer due to irreversible inhibition of proton pumps).

Elimination route: ~80% excreted in urine as metabolites, ~20% via feces.

METHODS OF ODT PREPARATION:

Various techniques are used for preparing ODTs, including:

Direct Compression: The most commonly employed method due to its simplicity and cost-effectiveness.

Wet Granulation: Involves the addition of a binder solution to improve powder cohesiveness.

Freeze-Drying (Lyophilization): Produces porous tablets with faster disintegration but is costly.

Molding: Enhances drug dissolution due to the porous nature of the final product.

IN-VITRO EVALUATION OF ANTIULCER ODTS

- **Drug-excipient compatibility studies** (Fourier-transform infrared spectroscopy, differential scanning calorimetry)
- **Flow properties of powder blend** (Angle of repose, bulk density, tapped density)
- Post-Formulation Studies
- **Disintegration Time:** Should be less than 30 seconds as per pharmacopoeial standards.
- **Wetting Time:** Determines how quickly the tablet absorbs moisture.
- **Water Absorption Ratio:** Assesses the tablet's ability to absorb water and disintegrate.
- **Dissolution Studies:** Conducted using USP dissolution apparatus to evaluate drug release profiles.
- **Friability Test:** Ensures mechanical strength of ODTs (should be <1%).

- **Hardness Test:** To assess tablet compactness and handling strength.
- **Drug Content Uniformity:** Ensures consistent drug distribution within the formulation.

EFFECT OF SUPER NATURAL DISINTEGRANTS ON DRUG RELEASE

The type and concentration of super natural disintegrants play a critical role in the drug release profile of ODTs. Their impact is observed in the following ways:

- **Disintegration Time:** Faster disintegration leads to quicker drug dissolution and absorption.
- **Water Absorption and Swelling Index:** Higher swelling capacity of natural disintegrants enhances tablet breakup and promotes drug release.
- **Dissolution Rate:** Effective superdisintegrants facilitate rapid drug dissolution, improving bioavailability.
- **Tablet Porosity:** Increased porosity due to natural superdisintegrants enhances water penetration and drug diffusion.

Studies have shown that ODTs formulated with psyllium husk and fenugreek mucilage exhibit superior disintegration and drug release profiles compared to synthetic disintegrants. The hydrophilic nature of natural disintegrants contributes to a higher dissolution rate, ensuring better therapeutic efficacy.

IN VIVO EVALUATION STUDY

An **in vivo study** of **Omeprazole Orally Disintegrating Tablets (ODT)** typically involves assessing **pharmacokinetics, bioavailability, and pharmacodynamic efficacy** in animal models or human subjects. Here's how such a study is usually conducted:

1. Objectives of the In Vivo Study:

- **To evaluate the antiulcer activity** of Omeprazole ODT.
- **To assess pharmacokinetics (PK):** Absorption, distribution, metabolism, and excretion (ADME).
- **To compare bioavailability** of ODT with conventional formulations (e.g., capsules, tablets).
- **To determine onset of action** and disintegration time in physiological conditions.

2. Experimental Design:

- **Animal Model Selection:**

Common models: Rats, rabbits, or pigs (closer to human GI physiology).

Induction of ulcers:

Ethanol-induced ulcer model

Pylorus ligation-induced ulcer model

NSAID (Aspirin/Indomethacin)-induced ulcer model

Stress-induced ulcer model

H. pylori-infected models (for chronic studies)

- **B. Grouping and Treatment:**

Control Group: Normal animals without ulcers.

Ulcer Control Group: Induced ulcer, but no treatment.

Standard Treatment Group: Omeprazole conventional formulation (capsules/tablets).

Test Group: Omeprazole ODT.
Dose Selection: Based on human equivalent doses (HED) and previous literature (e.g., 20 mg/kg for rats).

3. Pharmacokinetic (PK) Study:
Parameters: Cmax (peak concentration), Tmax (time to peak), AUC (area under curve), t1/2 (half-life).
Sample Collection: Blood samples at specific intervals (e.g., 0.5, 1, 2, 4, 6, 8 hours).
Analysis: HPLC or LC-MS/MS to quantify plasma omeprazole levels.

4. Pharmacodynamic (PD) Study – Antiulcer Activity
Ulcer Index Calculation:
Number of ulcers
Ulcer size
Ulcer severity score
pH Measurement: Gastric juice pH before and after treatment.
Gastric Mucosal Protection:Histopathological studies to check tissue damage and healing.

5. Statistical Analysis:
Comparing mean values between groups using ANOVA or t-tests.
Significance level: $p < 0.05$.

6. Expected Outcomes
Faster **disintegration** and absorption with ODT.
Higher **bioavailability** compared to standard tablets.
Significant **ulcer healing** and pH increase.
Reduced **gastric mucosal damage** in test groups.

DETERMINATION OF CMAX & TMAX IN AN IN VIVO STUDY
Cmax (Maximum Plasma Concentration) and Tmax (Time to Reach Cmax) are key **pharmacokinetic (PK) parameters** used to evaluate the absorption and bioavailability of a drug in an in vivo study. These are determined through blood sampling and plasma drug concentration analysis over time.

1. Study Design for Determining Cmax&Tmax
A. Animal Model Selection
Species: Wistar rats, rabbits, or other suitable models.
Number of Animals: Usually **6–8 per group**.
Dosing: Omeprazole ODT and **Standard Omeprazole Tablet** (e.g., 20 mg/kg).
Route of Administration: Oral (per os).

2. Blood Sampling Procedure
Time Points: Blood is collected at predetermined intervals **(e.g., 0, 0.5, 1, 2, 4, 6, 8 hours)** post-dose.
Sample Volume: ~0.2–0.5 mL per sample.

Plasma Separation: Blood is centrifuged at **3000 rpm for 10 minutes**, and plasma is stored at **-20°C** until analysis.

3. Plasma Drug Concentration Analysis

Analytical Method: High-Performance Liquid Chromatography (HPLC) or **LC-MS/MS** is used.

Standard Curve: A calibration curve of **Omeprazole concentration vs. plasma levels** is prepared for quantification.

Detection Wavelength: Omeprazole is typically detected at **302 nm (HPLC-UV)**.

4. Determination of Cmax and Tmax

Cmax (Maximum Plasma Concentration): The highest **measured plasma concentration (ng/mL or µg/mL)** of Omeprazole after administration.

Tmax (Time to Reach Cmax): The **time (hours) at which Cmax is observed**.

Graphical Representation:

Plasma concentration-time data is plotted as a **line graph (time vs. concentration)**.

Cmax is the peak of the curve, and **Tmax is the corresponding time**.

Example Data Table

Time (hours)	Plasma Omeprazole (ng/mL)
0.0	0
0.5	50
1.0	120
2.0	180 (Cmax)
4.0	130
6.0	60
8.0	20

From this table:

Cmax = 180 ng/mL

Tmax = 2.0 hours

5. Interpretation

Higher Cmax → Indicates **better absorption**.

Lower Tmax → Suggests **faster onset of action**.

Comparison with Standard Tablets: Omeprazole ODT should ideally show **higher Cmax and lower Tmax**, indicating **improved bioavailability and rapid absorption**.

CALCULATION OF MUCUS SECRETION IN AN IN VIVO STUDY

Mucus secretion plays a crucial role in gastric protection against ulcers. In an **in vivo antiulcer study**, **gastric mucus secretion** is measured **quantitatively** using the **weighing method** or **colorimetric analysis**.

1. Weighing Method (Mucus Content Measurement)

This is a **gravimetric method** where the mucus adhered to the gastric mucosa is **collected and weighed**.

Procedure:

Sacrifice the Animal

After treatment, animals are euthanized **(e.g., cervical dislocation under anesthesia).**

Stomach Collection

The stomach is **dissected**, opened along the greater curvature, and rinsed with cold saline.

Mucus Collection

The **gastric surface mucus is gently scraped** with a glass slide or spatula.

Weighing the Mucus

The mucus is collected into a **pre-weighed petri dish**.

The dish with mucus is weighed again.

Mucus Weight (mg) = (Final Weight – Initial Weight).

Calculation Example:

Petri Dish	Weight (mg)
Empty Dish (Initial)	10.5 mg
Dish + Mucus (Final)	15.8 mg
Mucus Secretion	5.3 mg

2. Colorimetric Estimation of Mucus (Alcian Blue Binding Method)

This **quantifies mucus secretion** by **binding Alcian Blue dye** to acidic mucopolysaccharides.

Procedure:

Alcian Blue Dye Administration

Inject **1% Alcian Blue dye (1 mL per 100 g body weight)**intragastrically.

Stomach Collection

After 1 hour, the stomach is removed and washed.

Mucus Extraction

The stomach is placed in **10 mL of 0.1M $MgCl_2$ solution** for **2 hours** to extract the bound dye.

Quantification (Spectrophotometry)

The solution is centrifuged, and the absorbance is measured at **605 nm (UV-Vis Spectrophotometer)**.

A standard curve of Alcian Blue is used to determine mucus concentration.

Calculation Example:

Absorbance (Sample) = 0.45

Standard Curve Equation: Mucus Concentration(µg/mL)=100×Absorbance\text{Mucus Concentration} (\mu g/mL) = 100 \times \text{Absorbance}Mucus Concentration(µg/mL)=100×Absorbance

Mucus Secretion = 45 µg/mL of Alcian Blue bound mucus.

3. Interpretation of Results

Higher mucus secretion → Stronger gastric protection.

Comparison of Groups:

Ulcer Control: Lowest mucus secretion.
Omeprazole Standard Treatment: Moderate increase.
Omeprazole ODT Test Group:Highest mucus secretion (indicating better gastroprotection).

DETERMINATION OF GASTRIC PH IN AN IN VIVO STUDY

Gastric pH is a key parameter in **antiulcer studies**, as it helps evaluate the **acid suppression effect** of a drug like **Omeprazole ODT**. The measurement is done by collecting **gastric juice** and determining its **pH using a digital pH meter** or **titration method**.

1. Materials Needed

Animal model (e.g., Wistar rats, rabbits)
Omeprazole ODT and control formulations
Centrifuge
Digital pH meter
0.1N NaOH (for titration)
Gastric juice collection tubes

2. Procedure for Gastric pH Measurement

A. Collection of Gastric Juice

Animal Sacrifice or Gastric Cannulation:

After the experimental period, animals are euthanized under anesthesia.
Alternatively, gastric contents can be aspirated in live animals using a **gastric cannula**.
Stomach Isolation & Rinse:
The stomach is dissected and opened along the greater curvature.
The contents are **collected in a pre-weighed tube**.
Centrifugation of Gastric Juice:
The gastric fluid is centrifuged at **3000 rpm for 10 minutes** to remove debris.
The **supernatant (clear gastric juice) is used for pH measurement**.

B. Measurement of Gastric pH

Method 1: Using a Digital pH Meter (Recommended)
Calibrate the pH meter using standard buffers (pH 4.0 and pH 7.0).
Dip the electrode into the gastric juice sample.
Record the pH value displayed on the meter.
Method 2: Titration Method (Alternative)
Take 1 mL of gastric juice in a beaker.
Titrate with 0.1N NaOH until the color changes (using phenolphthalein indicator).
Calculate acidity using the
formula: Gastric Acidity (mEq/L)=(V×N×1000)/Volume of Gastric Juice (mLWhere:
V = Volume of NaOH used (mL)
N = Normality of NaOH

3. Expected Results

Group	Gastric pH
Normal Control	3.5 – 4.0
Ulcer Control (Ethanol-induced)	1.8 – 2.5 (Highly acidic)
Omeprazole Tablet (20 mg/kg)	4.5 – 5.5
Omeprazole ODT (20 mg/kg)	5.5 – 6.5 (Higher pH = Better acid suppression)

4. Interpretation

Lower pH (<3.0): High acidity, more ulcer risk.
Higher pH (>5.0): Omeprazole effectively **reduces acid secretion**, promoting ulcer healing.
Omeprazole ODT is expected to increase pH faster than conventional tablets due to quicker absorption.

CALCULATION OF ULCER INDEX (%) IN AN IN VIVO TEST

The **Ulcer Index (UI)** is used to quantify **gastric mucosal damage** in animal models of ulcers. It is calculated based on **ulcer severity, total ulcerated area, and number of ulcers** observed in the stomach.

1. Methods for Ulcer Index Calculation

There are **three common approaches** to determine the ulcer index:
Ulcer Severity Score Method (Grading System)
Ulcerated Area Measurement Method
Gastric Lesion Count Method

2. Ulcer Severity Score Method (Grading System)

A. Procedure

Dissect and isolate the stomach after euthanizing the animal.
Open along the greater curvature and rinse with normal saline.
Examine the gastric mucosa under a magnifying lens.
Score each ulcer based on severity:

Ulcer Severity Grade	Description
0	Normal (No ulcers)
1	Slight mucosal damage (red coloration)

Ulcer Severity Grade	Description
2	Severe ulcers (longer than 2 mm)
3	Deep ulcers (penetrating into muscle layer)
4	Perforated ulcers (hole in the stomach wall)

Calculate the Ulcer Index using the formula:
Ulcer Index=Total Ulcer ScoreNumber of Animals in Group\text{Ulcer Index} = \frac{\text{Total Ulcer Score}}{\text{Number of Animals in Group}}Ulcer Index=Number of Animals in GroupTotal Ulcer Score

3. Ulcerated Area Measurement Method
This method calculates **ulcer index (%) based on the ratio of the ulcerated area to the total stomach mucosal area**.
A. Procedure
Capture an image of the stomach using a digital camera.
Analyze the ulcerated area using ImageJ software or manual graph paper measurement.
Calculate the ulcer percentage using the formula:
Ulcer Index(%)=(Total Ulcerated Area (mm2)/Total Gastric Mucosal Area (mm2))×100**Example Calculation**
Total gastric mucosal area = 100 mm²
Ulcerated area = 25 mm²
Ulcer Index (%) = (25/100)×100=25%(25/100) \times 100 = 25\%(25/100)×100=25%

4. Gastric Lesion Count Method
This method assigns a **score based on the number of ulcers per stomach**.
A. Ulcer Index Formula
Ulcer Index=Total Number of Ulcers in Group/Total Number of Animals in Group
Example Calculation

Animal	Number of Ulcers
Rat 1	3
Rat 2	2
Rat 3	4
Rat 4	3
Rat 5	2
Total Ulcers	14

Ulcer Index = 145=2.8\frac{14}{5} = 2.8514=2.8

5. Interpretation of Results

Group	Ulcer Index (%)	Interpretation
Normal Control	0.0%	No ulcers
Ulcer Control (Ethanol-induced)	80–90%	Severe ulceration
Omeprazole Tablet (20 mg/kg)	40–50%	Moderate protection
Omeprazole ODT (20 mg/kg)	15–25%	Significant ulcer protection

6. Statistical Analysis

Data Analysis: One-way ANOVA followed by Tukey's post hoc test.

Significance Level:$p<0.05p < 0.05p<0.05$ indicates **statistically significant protection**.

ONE-WAY ANOVA FOLLOWED BY TUKEY'S POST HOC TEST FOR ULCER INDEX ANALYSIS

To compare the **ulcer index (%)** among different treatment groups in an in vivo antiulcer study, we use **One-Way ANOVA (Analysis of Variance)** followed by **Tukey's post hoc test**. This helps determine whether there are **statistically significant differences** between groups.

1. Steps for Statistical Analysis

A. One-Way ANOVA Test

Used to check if **at least one group** differs significantly from the others.

Null Hypothesis (H_0): There is no significant difference between the groups.

Alternative Hypothesis (H_1): At least one group differs significantly.

B. Tukey's Post Hoc Test

If ANOVA shows a significant difference (**$p < 0.05$**), Tukey's test is performed.

This test identifies **which specific groups** differ from each other.

2. Example Data (Ulcer Index %)

Group	Ulcer Index (%) (Mean ± SD)
Normal Control	0.0 ± 0.0
Ulcer Control	85.0 ± 5.2
Omeprazole Tablet (20 mg/kg)	40.0 ± 4.8
Omeprazole ODT (20	20.0 ± 3.5

Group	Ulcer Index (%) (Mean ± SD)
mg/kg)	

3. Python Code for One-Way ANOVA &Tukey's Test

Using **Python (SciPy&Statsmodels)** to calculate ANOVA and Tukey's test:

FUTURE ASPECTS OF SUPER NATURAL DISINTEGRANTS

The application of super natural disintegrants in pharmaceutical formulations is expected to expand due to their numerous advantages. Future research may focus on:

- **Development of Novel Natural Polymers:** Exploration of untapped plant-based disintegrants with enhanced efficiency.
- **Optimization of Formulation Techniques:** Improving processing methods to maximize the benefits of natural disintegrants.
- **Enhanced Stability Studies:** Investigating strategies to improve the stability of drugs formulated with natural disintegrants.
- **Sustainability and Commercialization:** Large-scale production and commercialization of eco-friendly natural disintegrants for various drug delivery systems.
- **Combination Strategies:** Exploring synergistic effects by combining multiple natural superdisintegrants to achieve superior drug release profiles.

CONCLUSION

The incorporation of super natural disintegrants in the formulation of antiulcer ODTs presents a promising approach for improving drug dissolution and patient adherence. These natural excipients offer an eco-friendly and effective alternative to synthetic counterparts while maintaining high pharmaceutical performance. Future research should focus on optimizing formulations, conducting stability studies, and exploring novel natural polymers for enhanced drug delivery.

Omeprazole, a proton pump inhibitor, has proven to be an effective antiulcer agent due to its potent ability to suppress gastric acid secretion, promoting ulcer healing and symptom relief. When formulated into an oral tablet using natural superdisintegrants—such as plant-based materials like Plantago ovata husk, Lepidium sativum (garden cress), or Mucilage of Hibiscus—the disintegration time and drug release profile can be significantly improved. Natural superdisintegrants offer advantages such as biocompatibility, low toxicity, cost-effectiveness, and eco-friendlines

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