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"A Review: Oro-dispersible Tablets Containing Different Antacids."

Authors- Amit Sharma*[1], Mr. Anup Akarte[2], Dr. Pankaj Chaudhari[3], Mr. Kalpesh Wagh[4], Dr. Prakash Patil[5]

[1,2,4] Department of Pharmaceutics, Kisan Vidya Prasarak Sanstha's, Institute of Pharmaceutical Education, Boradi, Shirpur, Dist.- Dhule 425428.

[3,5] Department of Pharmacology, Kisan Vidya Prasarak Sanstha's, Institute of Pharmaceutical Education, Boradi, Shirpur, Dist.- Dhule 425428.

Abstract:

Pantoprazole sodium, lansoprazole & rabeprazole are potent drug, which is in class of proton pump inhibitor, PPIs are the most potent suppressors of gastric acid secretion are inhibitors of the gastric, category of Above drugs are Peptic ulcers, Gastro-oesophageal reflux disease, similar pharmacological property, It relief symptoms up to 80-90% of Ulcer patients within one hour of treatment. Recent advances technique in new drug delivery systems are aim at increasing the safety and efficacy of drug molecules by creating dosage forms that are easy to administer and improve patient compliance. Oro-dispersible tablets releases a drug that breaks down quickly when it gets on the tongue and dissolves in saliva. In these cases, the observed bioavailability of the drug is higher than that of conventional tablet dosage forms. This is because the medicine taken from the mouth travels upward with the saliva. This article focuses on oral disintegrating tablets; super disintegrate agents, mechanism of action, patented technology and ODTS rating.

Keywords: Oro-dispersible Tablet, Super-disintegrate, Proton Pump Inhibitors, Pantoprazole Sodium.

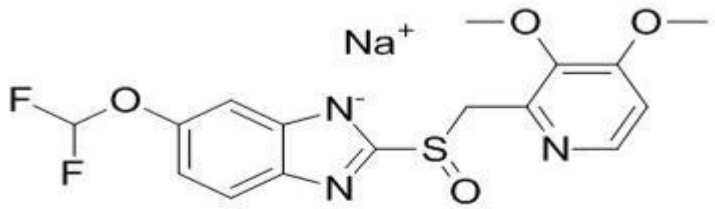
Introduction: The oral route is most of 70 % used as route of administration. Although other modes of administration are used to administer drugs, oral administration is recommended due to flexibility in dosage design and patient compliance. The popularity of oral routes of administration is explained by the ease of administration, administration to the patient, accurate dosing, cheap manufacturing process, and generally increased shelf life of the product. There are several existing technologies for drug delivery systems in which tablets, capsules, and liquids are used as drug carriers. Sterile conditions don't require to solid formulation & Solid formulation less expensive to manufacture than parental formulation. Oral Drug delivery system: It is a targeted drug delivery system deliver of drug to gastrointestinal GI transit.

Oro-dispersible tablets are solid dosage form it contains active pharmaceutical ingredients and excipients that usually disintegrates rapidly within 3 minutes. ODT latency typically ranges from a few seconds to

about a 3 minute Oro- dispersible tablets better patient's compliance those who are not able to swallow tablets ease for that's patients. Such as Paediatric, Psychiatric & Geriatric patients.

Tablets are solid unit dosage form it contain API (Active Pharmaceutical Ingredients) and Excipients API is Active Pharmaceutical Ingredients Which is have biological effect API is also called drug. Excipient is used to improve tablets characteristics such as bulk property, flow property etc. In dosage form tablets are most widely used because of ease manufacturing, patients compliance and easy administration, tablets are most popular dosage form 65 % medicine dispense in the form of tablet

Drug Profile :



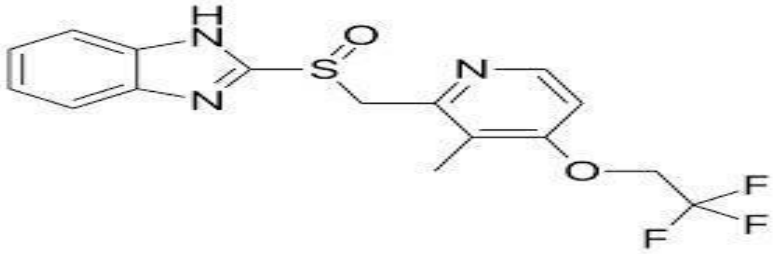
1) Pantoprazole Sodium :

IUPACName:5-(difluromethoxy)-2-[[(3,4-dimethoxy-pyridin-2-yl)methyl] sulphinyl]benzimidazol-1-ide, sesquihydrate.

Empirical Formula: C16H15F2N3O4S

Molecular weight: 432.4.

Category: Gastroesophageal reflux disease (Acid reflux) and peptic ulcer disease.



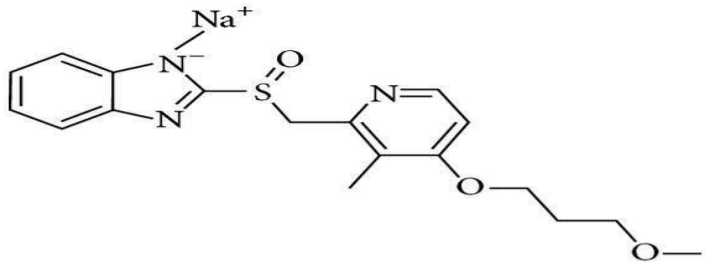
2) Lansoprazole :

IUPACName:2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methylsulfinyl]-1H-benzimidazole.

Empirical Formula : C16H14F3N3O2S.

Molecular Weight : 369.4

Category : Gastroesophageal reflux disease (Acid reflux) and peptic ulcer disease.



3) Rabeprazole Sodium:

IUPACName:2-[[4-(3-methoxypropoxy)-3-methylpyridin-2-yl]methylsulfinyl]-1*H*-benzimidazole.

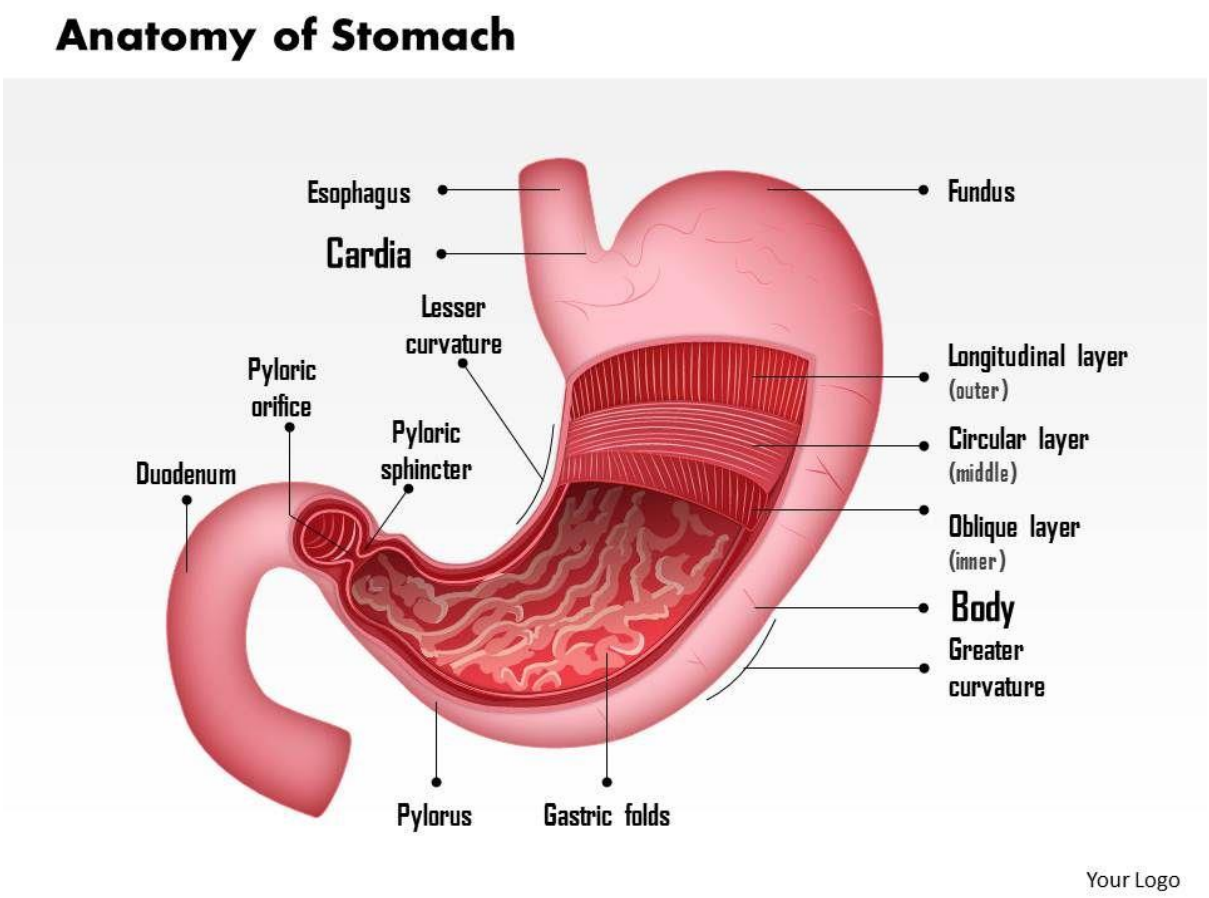
Empirical Formula : C18H21N3O3S

Molecular Weight : 359.4

Category : Gastro-oesophageal reflux disease (Acid reflux) and peptic ulcer disease.

Anatomy of Stomach:

The stomach is a J-shaped extension of the digestive tract that directly inferior the stomach diaphragm. The stomach consists of esophagus, cardia, fundus, cardia, pyloric part. Small intestine is first part stomach, the four main part of stomach is following Food is passes into stomach by cardia & cardia near is esophagus. Fundus have rounded portion it's top part of stomach and left side cardia. Shape of fundus is Dome - Shaped. large and central portion below the fundus called body of stomach. Pyloric part which is divided in three part, The wider area of funnel and first region which is connects to the body of stomach called pyloric antrum. The narrower end and second region which is lead to third region called as pyloric canal. Pylorus is the main and important part of stomach as third region, shape of pylorus is funnel shaped which is connect stomach to duodenum. Mucosa and submucosa fall lies in large fold when stomach is empty called rugae. The pyloric sphincter is located at this last junction and controls gastric emptying. Muscle sphincter called the pyloric sphincter. The bulging side of the abdomen is called the greater curvature. A concave middle edge is a lesser curvature.



Function of Stomach :

- It mixes saliva, food and gastric juice with chyme.
- It serves as a repository for food before it is passes to the small intestine.
- secretes gastric juice, HCl (kills bacteria and converts protein)
- Mixing and breakdown of food
- Absorption of water and lipid soluble substance
- Temporary food storage and non specific storage against microbes.

Advantage of Oro-dispersible Tablets:

Prescribing to patients who cannot swallow, such as the elderly, stroke patients, bedridden patients, etc. Patients who cannot swallow, such as patients with renal in-sufficiency, and patients who refuse to swallow, such as children, elderly and psychiatric patients

Cost effective manufacturing

If you are traveling or do not have direct access to water due to the possibility of swallowing without water

ODT drug have rapid dissolution and absorption of drug

Convenience of administration and accurate dosing compare liquid dossage form.

Reduce dose & Improve Bioavailability.

Rapid onset of action as children, elderly and psychiatric patients

Cost effective manufacturing

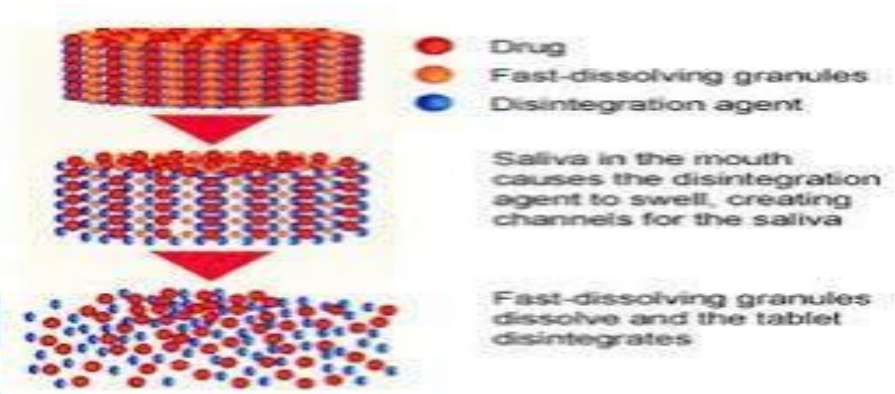
Disadvantage of Oro-dispersible Tablets:

ODT formulation that they are fragile and brittle.
ODT must stored in a dry place.

Occasional taste in the mouth • ODT requires special packaging for proper stabilization and consistent product safety.
Uniformity of dosage is a technical problem.
Carefully handling is required because tablets have insufficient mechanical strength

Super-disintegrate: The use of explosives is the main approach in ODT development. Super-disintegrate play an important role in the breakdown and degradation of ODT. It is important to select the appropriate disintegrate at the optimum concentration to ensure rapid disintegration and high dissolution. The Super Crusher provides rapid dissolution due to the combined swelling and water absorption of the composition. Super-degradable expansion increases the wetting of the carrier surface, which improves the wettability and dispersion of the system.

Mechanism OF Super-disintegrates



TECHNIQUES FOR PREPARING ORODISPERSIBLE TABLETS:

Direct compression : This technique is very important for manufacturing of tablets and ease way Multiple processing steps using existing equipment, publicly available tools and direct compression. Oral dispersed ondansetron HCl tablets were obtained by direct compression using a super-disintegrate and they reported that the in vitro dispersion time of these tablets was 5 minutes, while the usual tablets were 30-35 minutes as usual. Example: pantoprazole manufacturing by direct compression method.

Sublimation: To create a porous matrix, volatile components are introduced into the composition, followed by a sublimation process. Volatiles such as, benzoic acid, ammonium carbonate, bicarbonate, urea, camphor, naphthalene and phthalic anhydride can be compressed into tablets with other excipients.. Example: Ravi Kumar et al. Using camphor as the sublimation and sodium starch glycolate together with croscarmellose sodium as the super diluent, the aceclofenac tablets were made to dissolve rapidly by the sublimation process.

Spray drying: Spray drying: Hydrolysed and non-hydrolysed gelatin, bulk mannitol, sodium starch or croscarmellose sodium glycolate are spray dried as a disintegrant and citric acid and / or alkali (eg sodium bicarbonate) to improve nutrition. Manufactured tablets disintegrate in 20 seconds when dip in an aqueous solution.

Super-disintegrate: Many dissolution / Disintegration methods for oral tablets are based on direct compression and the addition of super-disintegrate mainly affects the disintegration and dissolution rate. The presence of other active ingredients such as water-soluble additives further enhances the degradation process and combination of super-disintegrate method for oro dispersible tablets.

Mass-Extrusion: In this method, a soluble mixture of water-soluble polyethylene glycol and methanol is used to soften the active mixture, and then the softened mass is extruded through an extruder or syringe to produce cylinders with a homogeneous segmented product using a heated tablet-forming knife. Dry cylinders can also be used to cover the bitterness of the granules, thus masking the taste

Sugar Based Excipients: Direct Compression of Oro-dispersible tablets is another technique Or approach of sugar based excipients. The use of sugar-based excipients, especially fillers such as is malt, manitol, starch hydrolyzate fructose, maltirlol, lactylol, dextrose, sorbitol, polydextrose, xylitol and Maltose to achieve high solubility and sweetness in water, resulting in a unique taste. It tastes good in the mouth. Sugar-based bulking agents are classified into two types based on their rate of formation and dissolution.

Type 1 sugars (mannitol and lactose) had a low tendency to mold but a high dissolution rate.

Type 2 sugars (maltilol and maltose) have a high formability and a slow dissolution rate.

Sublimation: To create a porous matrix, volatile components are introduced into the composition, which are then subjected to a sublimation process. Highly volatile materials such as , benzoic acid, naphthalene, camphor, , ammonium bicarbonate, ammonium carbonate urea, urethane and phthalic anhydride can be pressed together with other additives to form tablets. Eg. made aceclofenac tablets to dissolve quickly using a sublimation process, using camphor as the sublime and sodium starch glycolate together with crosscarmellose sodium as a super-disintegrants

Freeze Drying: This is a low temperature dehydration process in which the product freezes, the pressure is released and ice sublimes. The result of this process is a rapidly dissolving amorphous porous structure. Here we describe how these Oro dispersion tablets are prepared by lyophilization. In aqueous solution drug is dissolve The mixture is made by weight and poured along the walls of pre-formed blister packs. The blister goes through a liquid nitrogen tunnel to freeze the medicinal solution. or scattered. The frozen blister packs are stored in the refrigerator to continue freeze drying.

Tablet moulding: Water-soluble substances with water-alcohol solvents are used, which are formed into tablets at a lower pressure than those used for conventional tablet compression, by air drying solvent is remove

Characteristics: Molded tablets are much more compact than compressed tablets with a porous structure that improves disintegration / dissolution and ultimately absorption.

PATENTED TECHNOLOGIES FOR ORODISPERSIBLE TABLETS:

Zydus Technology

Durasolv Technology

Orasolv Technology

Flash Dose Technology

Wow tab Technology

Flash tab Technology

Oroquick technology:

Flash dose technology

Ziplet technology

Pre compression Parameters:

Angle Of Repose: funnel method is used to determine of angle of repose Place a properly weighed powder mixture into the funnel. The mixture can flow freely through the funnel on the surface. Measure the diameter of the powder cone and calculate the angle of repose calculate using below formula

tan θ = h/r

Where h" Means Height

r" Mean radius of powder cone

Bulk Density : Take accurate 25 gm weight of drug , which is already passed from 20# sieve and transfer to graduated cylinder which is have 100 ml volume then calculate bulk density using this formula

Bulk Density = Mass / Volume of Powder

Tapped Density: It is determined by placing cylinder weighing a mixture of drug and additive. The cylinder falls under its own weight onto a hard surface 10 cm high with an interval of 2 seconds. Tap process continues until the change in volume is no longer observed. Tapped density formula below and calculate.

Tapped Density = (Wt of the powder / Final vol. of tapped powder)

Housner's Ratio: coefficient is related to the flow ability, flow ability is similar index of a powder or granule.

Formula, Housner's Ratio: TD / BD

TD= Tapped Density .

BD= Bulk Density.

Carr's Index: This is one of the most important parameters for the characterization of powders and granules. The compressibility index of a powder mixture is determined by the Carr's compressibility index. This is a simple test for evaluating bulk density and tapped density, It can be calculated using the following formula:

Carr's Index = [(TD-BD)×100]/ TD

TD = Tapped Density, BD = Bulk Density

Post Compression Parameters:

General Appearance: To check of tablets colour, odour, physical defect, shape, size & physical description.

Friability: Roche friabilator apparatus used to measure friability, if unit mass of tablet is less than 650 mg to take sample 6.5 g, If unit mass of tablet is more than 650 mg to take sample 10 tablets, first wt of tab called initial weight record then 25 rmp set 100 rpm for 4 min after that calculate friability using below formula.

F = Initial Wt - Final Wt / Initial Wt × 100

Hardness: Tablets require a certain degree of strength or hardness and resistance to brittleness in order to withstand mechanical stress during manufacturing, packaging and shipping operations. Monsanto hardness tester used to measure hardness that's unit kg / cm2

Weight Variations: 20 tablets select randomly and Wt of each 1 tab to 20 time then calculate average that calculate to the as per Indian pharmacopeia.

Limit of weight Variations as per IP

80 mg or less ±10 , More than 80 mg but less than 250 mg ±7.5 , 250 mg or more ±5.

Drug Content Uniformity: Active pharmaceutical ingredients API is determine by this method. Weight of 20 tablet and powdered it then 20 mg of drug dissolve in 0.1 N Hcl the solution filter by Whatman filter paper and dilute with 0.1 HCL, assay at 255nm or after dissolution solution determine Api by using UV Spectrophotometer.

Thickness and Diameter: Thickness and diameter of tablets is measure by vernier-caliper, unit is expressed in millimetre (mm)

In-Vitro Dispersion Time: In- Vitro dispersion time measure, drop the tablet in beaker contain 60 ml 6.8 PH phosphate buffer three tablet from each formulation which is selected randomly.

Wetting Time: To determine the wetting time of the tablets, folded paper (12 cm x 10.75 cm) was placed in a very small plate (inner diameter = 6.5 cm) with 6 ml of Sorenson's buffer (pH 6.8). Place the tablet on a piece of paper and measure the time it takes for the tablet to become completely wet. 3 additional samples for each batch.

Disintegration Test: Time is required to breakdown of drug into small particles called as disintegration time. Disintegration apparatus used to determine DT of tablets as procedure follow as per IP. Each batch consisted of six tablets, and 1 litre of distilled water was used as the disintegrating medium. We recorded the time it took for all 6 tablets to disintegrate completely

Dissolution Test: It is important quality control procedure here is paddle & basket type apparatus use set at 50 rpm. The release profile of the drug was investigated in 900 ml of phosphate buffer at pH 6.8 while maintaining a temperature of 37 ± 0.5 ° C. Periodically, aliquots of the soluble medium were taken, filtered, and the amount of released active ingredient was determined. Then sample to determine active ingredient present in dissolution solution by UV spectroscopy.

Conclusion: article focuses on oral disintegrating tablets, super disintegrate agents, mechanism of action, patented technology and ODTS rating.

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