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A Review on Fast Dissolving Tablet of Famotidine

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ABSTRACT: Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms. The reason that the oral route achieved such popularity may be in part attributed to its ease of administration as well as the traditional belief that by oral administration the drug is as well absorbed as the food stuffs that are ingested daily.

In fact, the development of pharmaceutical products for oral delivery, irrespective of physical form involves varying extents of optimization of dosage form characteristics within the inherent constraints of GI physiology.

Therefore, a fundamental understanding of various disciplines, including GI physiology, Pharmacokinetics, Pharmacodynamic and formulation design are essential to achieve a systemic approach to the successful development of an oral pharmaceutical dosage form. In any case, the scientific frame work required for the successful development of an oral drug delivery system consists of a basic understanding of the following three aspects: Physicochemical, pharmacokinetic and Pharmacodynamic characteristics of the drug.

KeywordGI physiology, Pharmacokinetic, Physiochemical, Pharmacodynamic characteristic.

FAST DISSOLVING TABLETS:

A fast-dissolving tablet can be defined as a solid dosage form that can disintegrates into smaller granules which slowly dissolve in the mouth. The disintegration time for fast dissolving tablet varies from a few seconds to more than a minute depending on the formulation and the size of the tablet.

A fast disintegrating or dissolving system or tablet can be defined as a solid dosage form that can disintegrate or dissolve within 30 seconds, in the oral cavity resulting in a solution or suspension without administration of water.

The fast-disintegrating tablets are synonymous with fast dissolving tablets; melt in mouth tablets, rapimelts, porous tablets, Orodispersible, quick dissolving or rapidly disintegrating tablets.

ADVANTAGES OF FAST DISSOLVING TABLETS:

- Rapid onset of drug therapy.
- Achieve increased bioavailability/rapid absorption through GIT.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.
- Convenient for administration and shows better patient compliance. The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.
- Fast onset of action.
- No need to swallow tablet.
- Good stomach and intestinal tolerance.
- More portability.
- Improved palatability.
- Superior stability.
- More consistent response.
- Incorporation of large amounts of active ingredients.
- Accurate Dosing.
- Improved Therapeutic Effect.
- In remote areas, especially where parenteral forms are not available due to prohibitive cost, lack of qualified medical staff, effervescent tablets could become an alternative.

Property Of Fast Dissolving Tablet:

- They should require no water for oral administration but it should disintegrate or dissolve in the mouth usually within fraction of seconds.
- Theses dosage forms must have a pleasant mouth feel.
- Must be compatible with taste masking and other Excipient.

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- It should have sufficient strength to withstand the strain of the manufacturing process and post manufacturing handling.
- It should leave negligible or no residue in mouth after oral administration.
- Exhibit low sensitivity to environmental conditions such as temperature and humidity.
- Should be adaptable and amenable to current processing and packaging machinery.
- Allow high drug loading.

Ingredients used in FDT formulation:

Excipient balance the properties of the actives in fast-melting tablets. This demands a thorough understanding of the chemistry of this Excipient to prevent interaction with the actives. Determining the cost of these ingredients is another issue that needs to be addressed by formulators. The role of excipient is important in the formulation of fast-melting tablets. These inactive food-grade ingredients, when incorporated in the formulation, impart the desired organoleptic properties and product efficacy. Excipient are general and can be used for a broad range of actives, except some actives that require masking agents.

BULKING MATERIALS:

Bulking materials are significant in the formulation of fast-melting tablets. The material contributes functions of a diluents, filler and cost reducer. Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, besides; adding bulk also reduces the concentration of the active in the composition. The recommended bulking agents for this delivery system should be more sugar-based such as Mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch hydrolystate for higher aqueous solubility and good sensory perception. Mannitol in particular has high aqueous solubility and good sensory perception. Bulking agents are added in the range of 10 percent toabout 90 percent by weight of the final composition.

EMULSIFYING AGENTS:

Emulsifying agents are important excipient for formulating fast-melting tablets they aid in rapid disintegration and drug release without chewing, swallowing or drinking water. In addition, incorporating emulsifying agents is useful in stabilizing the immiscible blends and enhancing bioavailability. A wide range of emulsifiers is recommended for fast-tablet formulation, including alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agents can be incorporated in the range of 0.05 percent to about 15 percent by weight of the final composition.

LUBRICANTS:

Lubricants, though not essential excipient, can further assist in making these tablets more palatable after they disintegrate in the mouth. Lubricants remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach.

FLAVOURS AND SWEETENERS:

Flavours and taste-masking agents make the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. Both natural and synthetic flavours can be used to improve the Organoleptic characteristic of fast-melting tablets. Formulators can choose from a wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose. The addition of sweeteners contributes a pleasant taste as well as bulk to the composition.

SUPER DISINTEGRANTS:

A disintegrants is an excipient, which is added to a tablet or capsule blend to aid in the breakup of the compacted mass when it is put into a fluid environment.

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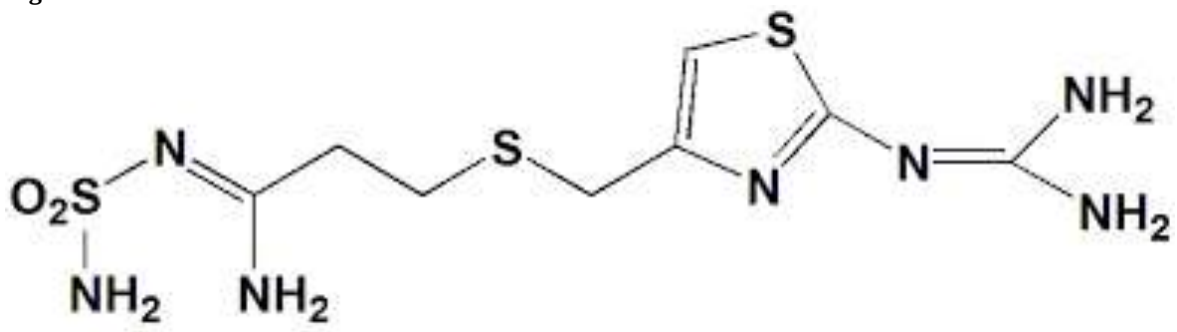
Drug Profile:



Famotidine

Synonyms3-[[2-(diaminomethylideneamino)-1,3-thiazol-4-yl]methylsulfanyl]-N'-methylsulfonylpropanimidamide

Formula: - $C_8H_{15}N_7O_2S_3$
Molecular Mass: - 337.45 g/mol
Density:1.8±0.1 g cm^3
Melting Point: - 163–164 ºC
Colour: - White
Odour: - Faint
Routes of Administration: - oral
Bioavailability 40-50 %
Protein Biding: - 15-20 %
Metabolism: - Cytochrome P450,
Onset of Action: -30–60 minutes
Excretion: - Renal
Half-life: -3 hours
Solubility: -0.1% w/v
Storage condition: - Recommended storage temperature -20-30 °C

Mechanism of Action:

Histamine acts as a local hormone that stimulates the acid output by parietal cells via a paracrine mechanism. Neuroendocrine cells called enterochromaffin-like (ECL) cells lie close to the parietal cells and regulate the basal secretion of histamine. Histamine release is also promoted from stimulation by acetylcholine and gastrin, a peptide hormone. Gastrin (G) cells release gastrin, which works on CCK_2 receptors on ECL cells. This action promotes the release of histamine from ECL cells. Upon release, histamine acts on H_2 receptors expressed on the basolateral membrane of parietal cells, leading to increased intracellular cAMP levels and activated proton pumps on parietal cells. Proton pump releases more protons into thestomach, thereby increasing the secretion of acid. [4] In conditions that are associated with acid hypersecretion such as ulcers, there is a loss of regulation of acid secretion. Famotidine works on H_2 receptors and blocks the actions of histamine.

Assay:

Dissolve 0.120 g of famotidine in 60 ml of anhydrous acetic acid R. Titrate with 0.1 M perchloric acid, determining the end-point potentiometrically. 1 ml of 0.1M perchloric acid is equivalent to 16.87 mg of C8H15N7O2S3.

Potentiometric Method:

Two potentiometric methods for the determination of famotidine in pure form and in its pharmaceutical tablet form were developed by Ayad et 15 al. In the first method, the construction of plasticized poly vinyl chloride (PVC) matrix-type famotidine ion-selective membrane electrode and its use in the potentiometric determination of the drug in the pharmaceutical preparations are described. It is based on the use of ion-associated species, formed by famotidine cation and tetra phenyl borate (TPB) counterion. The electrode exhibited a linear response for 1 x 10-3–1 x 10-5 M of famotidine solutions over the pH range 1–5 with an average recovery of 99.26% and mean standard deviation of 1.12%. Common organic and inorganic cations showed negligible interference. In the second method, the conditions for the oxidimetric titration of the thioether contained in Famotidine have been studied. The method depends on using Pb (IV) acetate for oxidation of the thioether contained in famotidine. The titration takes place in the presence of catalytic quantities of potassium bromide (KBr). Direct potentiometric determination of 1.75 x 10-2 M Famotidine solution showed an average recovery of 100.51% with a mean standard deviation of 1.26%. The two methods have been applied successfully to commercial tablet.

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POLYMERS PROFILE

Introduction of polymer Used (seed mucilage of plantago ovata):

Plantago seed, psyllium seed or plantain seed which is cleaned, dried, ripe seed of Plantago psyllium or Plantago indica, belongs to family Plantaginaceae. The genus Plantago contains over 200 species. P. ovata and P. psyllium and P. indica are three important species.

These are produced commercially in several European countries, the former Soviet Union, Pakistan, and India. Isabgul, the common name in India for P. ovata, comes from the Persian words ìisapî and ìgholî that mean horse ear, which describes the shape of the seed. India dominates the world market in the production and export of psyllium.

Plantago seeds contain 10 to 30% of hydrocolloid in the outer seed coat which can be separated into acidic and neutral polysaccharides and upon hydrolysis L-arabinose, D-galactose, D-galacturonic acid; L-rhamnose and D-xylose are obtained.

Solution of Plantago gum is thixotropic where as its mucilage has super disintegrant property. The husk is the rosy-white membranous covering of the seed, which constitutes the drug, mainly given as a safe laxative, particularly beneficial in habitual constipation, chronic diarrhea and dysentery. It is a 100% natural product, a soluble fiber and forms gel in water. The usual dose of Plantago ovata is 7.5 g.

The underlying study was conducted with the aim of giving a brief overview of factors affecting cultivation, growth of Plantago ovata, and its pharmaceutical and pharmacological aspects to reveal its uses in various medical fields.

Properties of polymer Used (seed mucilage of plantago ovata):

Various studies have been conducted in the past to study both physical and chemical properties of Plantago ovata.

Study of Fisher exhibited that it possesses 22.6% arabinose and 74.6% xylose with small amount of other sugars. Likewise, Guo also investigated physicochemical properties of Psyllium gum. Different series of Psyllium gum fractions were formulated by extracting Psyllium husk with hot water (80OC) and 0.5 M NaOH, 1.2 M NaOH and 2.0 M NaOH solutions, respectively.

These series of Psyllium gum fractions were labeled as water extractable (WE), 0.5 M alkali extractable (AES0.5), 1.2 M alkali extractable (AES1.2), and 2.0 M alkali extractable fractions. Moreover, to formulate soluble fraction (AES0.5) and a gel fraction (AEG0.5), the alkali extracted solutions were further neutralized with 0.5 M HCl and centrifuged. Monosaccharide analysis and methylation analysis was carried out to study chemical constituents of different fractions.

The monosaccharide analysis revealed that WE, AEG and AES fractions of Psyllium gum contained xylose and arabinose as major constituents whereas uronic acid was found in WE and AES0.5 fractions in comparison with AEG 0.5, which only have some neutral sugars.

Methylation analysis also showed that WE and AEG 0.5 mainly contain 1 fi 4) and 1 fi 3) linked β-D-xylopyranosyl residues in the key chain while side-chains comprise of arabinose and xylose connected to the main chain by O-3 and/ or O-2 linkage. The nutritional value and trace element content of Plantago ovata was studied by Buksh and they revealed that both Plantago ovata leaves and seeds possess bundle of crude fibers, proteins fats and carbohydrates.

Properties of Plantago ovata seed Mucilage:

Mucilage are most frequently used adjuvant in different pharmaceutical preparations due to their binding, disintegrating, emulsifying, film forming, suspending and thickening properties.The mucilages were obtained by simple maceration technique and were further subjected to granule and tablet formation at different concentrations.That Plantago ovata possess similar binding properties as that of starch and 8% to 9% concentration showed good binding characteristics in uncoated tablets.

Disintegrants:

Superdisintegrants are substances added to tablets to assist the breakup of compacted mass into particles, so as to facilitate the discharge of active ingredient and drug dissolution, when it approaches the fluid surroundingsPlantago ovata is used as a superdisintegrant owing to swelling characteristics of its mucilage.

Disintegrants were used in concentration of 5% w/w Plantago ovata. The tablets formulated by using Plantago ovata mucilage presented amended drug dissolution and bioavailability as discovered by the results disintegration time and Plantago ovata mucilage, seed and husk powder, respectively

The study divulged better disintegration properties of Plantago ovata mucilage due to highest swelling index. The tablets formulated with

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Plantago ovata showed shorter disintegration time as compared to tablets prepared by sodium starch glycolate and croscarmelose sodium. Just as, FDTs of famotidine were formulated in order to check out the effects of different natural and synthetic superdisintegrants and concluded that Plantago ovata husk powder presented superior flow properties, water retention and disintegration time than maize starch.

Gelling agent:

Sahay (1999) further elaborated the use of mucilage husk of Plantago ovata as an alternative jelling agent. According to him, 4% w/v of ground husk was used in combination with 0.5% w/v of agar media to promote microbial growth; however he had already removed undesirable properties of Psyllium-gelled media by providing UV treatment, oven sterilization and autoclaving.

Suspending agent:

Different studies have been conducted to evaluate use of Plantago ovata as a suspending agent, due to its mucilage forming property.According to Rajamanickam mucilages of different plants can be used to suspend particles in thermodynamically unstablesystems, which aid in preventing sedimentation of particles and promote easy dispersion of settled particles due to their viscous and colloidal nature.

Bashir have isolated arabinoxylan from Plantago ovata seed husk by alkali extraction and compared its properties as suspending agent with betonies by formulating 1% zinc oxide suspension. Arabinoxylan produced stable, highly flocculated suspension, which fulfilled all particle size specifications and microbiological properties; therefore, it appreciated the use of arabinoxylan as effective suspending agent in ZnO suspension.

Plantagoovata Seed Mucilage:

Ispaghula mucilage consists of Epidermis of the dried seeds of Plantagoovata contains mucilage. Plantagoovata seed mucilage is obtained by grinding off the husk. Mucilage of Plantagoovata has characteristics like binding, disintegrating, and sustaining properties. Fast disintegrating tablets of prochlorperazine maleate were formulated with use of PlantagoOvata (2-8% w/w) as superdisintegrant by direct compression method to improve the patient compliance.

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