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Review

Floating Drug Delivery System: An Updated Review

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Abstract:

The purpose of writing this review on floating drug delivery systems (FDDS) was to compile the recent literature with special focus on the principal mechanism of floatation to achieve gastric retention. The recent developments of FDDS including the physiological and formulation variables affecting gastric retention, approaches to design single-unit and multiple-unit floating systems, and their classification and formulation aspects are covered in detail. Including floating drug delivery systems (FDDS), swelling and expanding systems, polymeric bio-adhesive systems, high-density systems, modified-shape systems and other delayed gastric emptying devices. In this review, current & recently developments of Stomach Specific FDDS are discussed that helps to overcome physiological adversities like short gastric residence times and unpredictable gastric emptying times.

Keywords: *floating drug delivery systems, FDDS, gastric emptying devices, gastric residence times.*

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Introduction:

Oral drug delivery is the most desirable and preferred method of administering therapeutics agent for their systemic effect. The high level of patient compliance in taking oral dosage forms is due to the ease of administration, patient compliance, flexibility in formulation and handling of these forms. This system has been of limited success. Oral dosage forms have proved to be successful in achieving a plethora of controlled release objectives ranging from immediate release to site specific delivery (Garg et al., 2003; Patel et al.,2006, Ahmed et al., 2002). An although tremendous advances have been seen in oral controlled drug delivery system during last two decades [1]. Oral formulations are being developed into different types, such as controlled release, delayed release, fast dissolving and taste masking formulations (Appaji, 2001) and other delivery technologies are being tried to deliver already existing and new drug molecules, oral formulations still control more than 60% of the market inability to restrain and localize the DDS within the desired regions of the GIT (Rouge et al., 1996; Hajeri and Amiji, 2002).This approach has several physiological difficulties such as inability to restrain and locate the controlled drug delivery system within the desired region of the gastrointestinal tract (GIT) due to variable gastric emptying and motility[2]. Gastro-Retentive Drug Delivery Systems Gastroretentive systems can remain in the gastric region for several hours and hence significantly prolong the gastric residence time of drugs. Prolonged gastric retention improves bioavailability, reduces drug waste, and improves solubility for drugs that are less soluble in a high pH environment. It has applications also for local drug delivery to the stomach and proximal small intestines. Slowed motility of the gastrointestinal tract by concomitant administration of drugs or pharmaceutical excipients also increase gastric retention of drug [3].

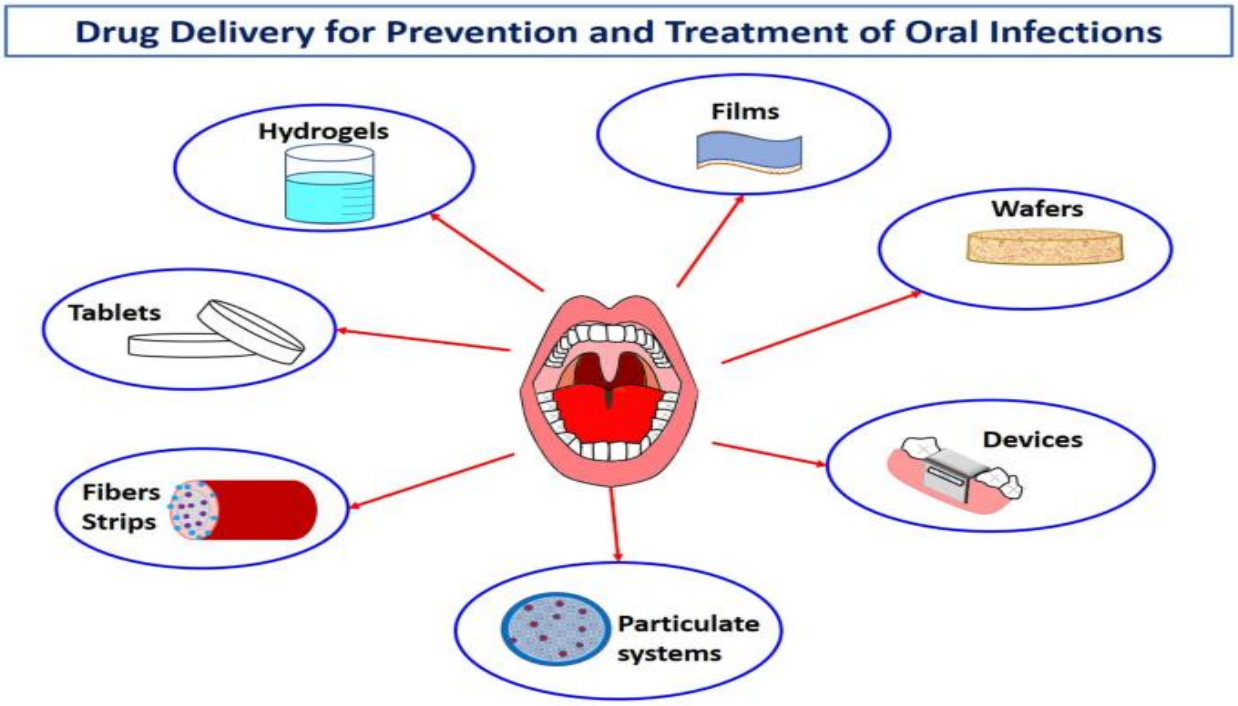

Fig.1 Different Forms of Drug delivery through mouth.

Approaches to Gastro-Retentive Drug Delivery Systems

The controlled gastric retention of solid dosage forms may be achieved by the mechanism of mucoadhesion, floatation, sedimentation, expansion, modified shape systems or by the administration of pharmacological agents, that delaying gastric emptying [4, 5].

Based on these approaches, floating drug delivery systems seems to be the promising delivery systems for control release of drugs (Vedha hari b.n.et al, 2010, Drs Jose Gutierrz Rocca et al, 2003). These efforts resulted in GRDFs that were designed, in large part, based on the following approaches [6-10]. (Figure 2)

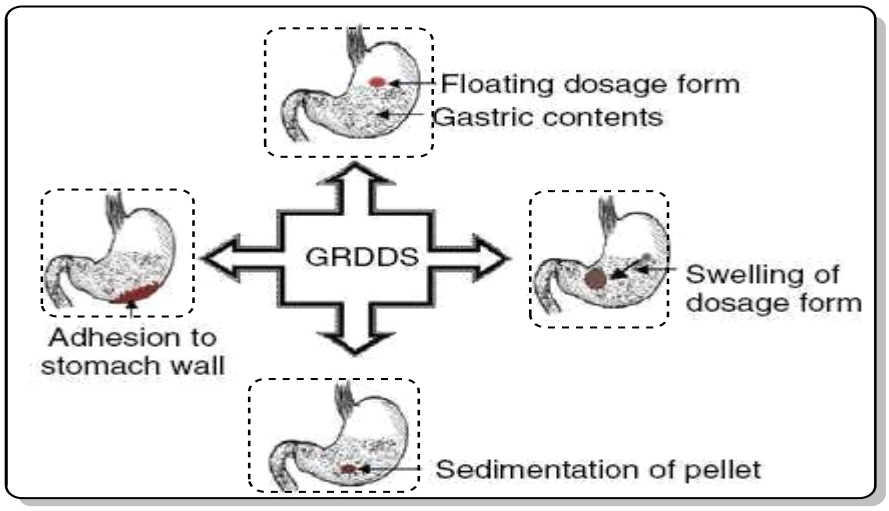

Fig.2 Retention approaches in floating process [11].

Factors Affecting Gastric Retention

Gastric residence time of an oral dosage form is affected by several factors. To pass through the pyloric valve into the small intestine the particle size should be in the range of 1 to 2 mm.15 The pH of the stomach in fasting state is ~1.5 to 2.0 and in fed state is 2.0 to 6.0. A large volume of water administered with an oral dosage form raises the pH of stomach contents to 6.0 to 9.0. Stomach doesn't get time to produce sufficient acid when the liquid empties

the stomach, hence generally basic drugs have a better chance of dissolving in fed state than in a fasting state. The rate of gastric emptying depends mainly on viscosity, volume, and caloric content of meals. Nutritive density of meals helps determine gastric emptying time.

It does not make any difference whether the meal has high protein, fat, or carbohydrate content as long as the caloric content is the same. However, increase in acidity and caloric value slows down gastric emptying time. Biological factors such as age, body mass index (BMI), gender, posture, and diseased states (diabetes, Chron's disease) influence gastric emptying. In the case of elderly persons, gastric emptying is slowed down. Generally females have slower gastric emptying rates than males[12]. Stress increases gastric emptying rates while depression slows it down. Several formulation parameters can affect the gastric residence time. More reliable gastric emptying patterns are observed for multiparticulate formulations as compared with single unit formulations, which suffer from "all or none concept." As the units of multiparticulate systems are distributed freely throughout the gastrointestinal tract, their transport is affected to a lesser extent by the transit time of food compared with single unit formulation[14]. Size and shape of dosage unit also affect the gastric emptying. Garg and Sharma reported that tetrahedron- and ring-shaped devices have a better gastric residence time as compared with other shapes. The diameter of the dosage unit is also equally important as a formulation parameter. Dosage forms having a diameter of more than 7.5 mm show a better gastric residence time compared with one having 9.9 mm. The density of a dosage form also affects the gastric emptying rate. A buoyant dosage form having a density of less than that of the gastric fluids floats.

Since it is away from the pyloric sphincter, the dosage unit is retained in the stomach for a prolonged period. Timmermans et al studied the effect of buoyancy, posture, and nature of meals on the gastric emptying process in vivo using gamma scintigraphy[13]. To perform these studies, floating and nonfloating capsules of 3 different sizes having a diameter of 4.8 mm (small units), 7.5 mm (medium units), and 9.9 mm (large units), were formulated. On comparison of floating and non-floating dosage units, it was concluded that regardless of their sizes the floating dosage units remained buoyant on the gastric contents throughout their residence in the gastrointestinal tract, while the non-floating dosage units sank and remained in the lower part of the stomach.

Floating units away from the gastroduodenal junction were protected from the peristaltic waves during digestive phase while the non-floating forms stayed close to the pylorus and were subjected to propelling and retropelling waves of the digestive phase (Figure 2). It was also observed that of the floating and non-floating units, the floating units were had a longer gastric residence time for small and medium units while no significant difference was seen between the 2 types of large unit dosage forms.

Applications of Floating Drug Delivery Systems

Floating drug delivery offers several applications for drugs having poor bioavailability because of the narrow absorption window in the upper part of the gastrointestinal tract. It retains the dosage form at the site of absorption and thus enhances the bioavailability.

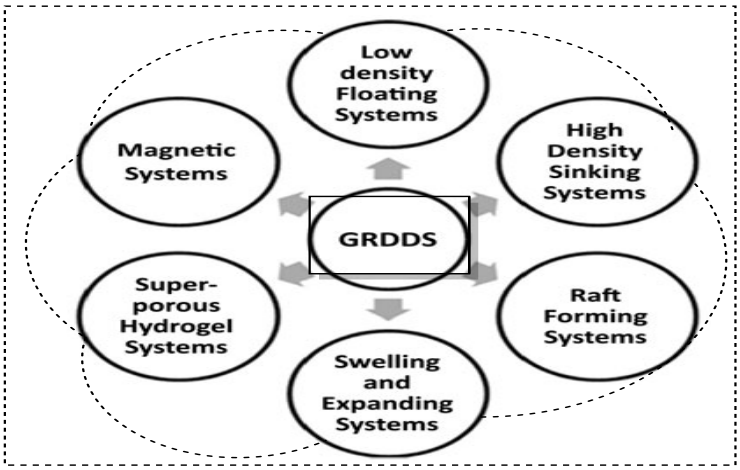

Fig.3 Several importance of Floating approaches of delivery system.

Conclusion

Drug absorption in the gastrointestinal tract is a highly variable procedure and prolonging gastric retention of the dosage form extends the time for drug absorption. FDDS promises to be a potential approach for gastric retention. Dosage forms with a prolonged GRT will bring about new and important therapeutic options. The currently available polymer-mediated Noneffervescent and effervescent FDDS, designed on the basis of delayed gastric emptying and buoyancy principles, appear to be a very much effective approach to the modulation of controlled oral drug delivery. Number of commercial products and patents issued in this field are the evidence of it. The FDDS become an additional advantage for drugs that are absorbed primarily in the upper part of GI tract, i.e., the stomach, duodenum, and jejunum. Some of the unresolved, critical issues like the quantitative efficiency of floating delivery systems in the fasted and fed states, role of buoyancy in enhancing GRT of FDDS and more than that formulation of an ideal dosage form to be given locally to eradicate H.Pylori, responsible for gastric ulcers worldwide. Due to the complexity of pharmacokinetic and pharmacodynamic parameters, in vivo studies are required to establish the optimal dosage form for a specific drug.

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