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Review Article

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FLOATING DRUG DELIVERY SYSTEM

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Abstract

In the recent years, scientific and technological advancements have been made in the research and development of novel drug delivery systems by overcoming physiological troubles such as short gastric residence times and unpredictable gastric emptying times. FDDS is one of the techniques which shows prolong gastric retention by the principle mechanism of floatation. Several approaches are currently utilized in the prolongation of the gastric residence times, including floating drug delivery systems, swelling and expanding systems, polymeric bioadhesive systems, modified-shape systems, high-density systems and other delayed gastric emptying devices.

Keywords: Gastric retention time (GRT), Effervescent, bioadhesive, hydrodynamically.

Introduction

Gastric emptying is a complex process and makes in vivo performance of the drug delivery systems uncertain. In order to avoid this variability, efforts have been made to increase the retention time of the drug-delivery systems for more than 12 hours. The floating or hydrodynamically controlled drug delivery systems are useful in such application.

FDDS reside in the stomach for a longer period of time than conventional dosage forms. One of the several difficulties faced is the inability to confine the dosage form in the desired area of the gastrointestinal tract. The extent of gastrointestinal tract drug absorption is related to contact time with the small intestinal mucosa. Thus, small intestinal transit time is an important parameter for drugs that are incompletely absorbed. 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. The controlled GRD forms may be achieved by the mechanisms of (1) muco-adhesion, (2) flotation, (3) sedimentation, (4) expansion modified shape Systems, (5) simultaneous administration of pharmacological agent. This review focuses on the principal mechanism of floatation to achieve gastric retention.

Materials and Methods

Materials used in floating dosage form formulation:

Hydrocolloids:

Suitable hydrocolloids are synthetics, anionic or non ionic like hydrophilic gumes, modified cellulose derivatives. Eg. Accasia, pectin, agar,alginates, gelatin, casein, bentonite, veegum, MC, HPC, HEC, and Na CMC can be used.

Inert fatty materials:

Edible pharmaceutical inert fatty material, having a specific gravity less than one can be added to the formulation to increase the buoyancy. Eg.Purified grades of beeswax, fatty acids, long chain alcohols, glycerides, and mineral oils can be used.

Release rate accelerant:

The release rate of the medicament from the formulation can be modified by including excipient like lactose and/or mannitol. These may be present from about 5-60% by weight.

Release rate retardant:

Insoluble substances such as dicalcium phosphate, talc magnesium strearete decreased the solubility and hence retard the release of medicaments.

Buoyancy increasing agents:

Materials like ethyl cellulose, which has bulk density less than one, can be used for enhancing the buoyancy of the formulation. It may be adapted up to 80 % by weight.

Miscellaneous:

Pharmaceutically acceptable adjuvant like preservatives, stabilizers, and lubricants can be incorporates in the dosage forms as per the requirements. They do not adversely affect the hydrodynamic balance of the systems.

Methods of floating drug dosage form:

The formulation of FDDS is based on two of the following mechanisms-

- a) Effervescent System
- b) Non Effervescent System

Effervescent System:

Effervescent systems are matrix types which are prepared with the help of swell able polymers such as methylcellulose and chitosan and various effervescent compounds, eg, sodium bicarbonate, tartaric acid and citric acid. They are formulated in such-a-way that when in contact

with the acidic gastric contents, carbon dioxide is liberated and gets entrapped in swollen hydrocolloids, which provides buoyancy to the dosage forms.

Excipients used most commonly in these systems include HPMC, polyacrylate polymer, polyvinyl acetate, carbopole, agar, sodium alginate, calcium chloride, polyethylene oxide and polycarbonates.

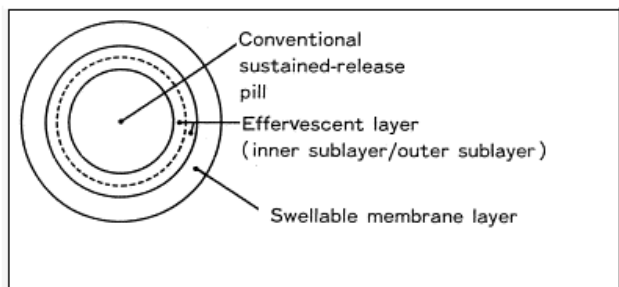


Figure 1: Single unit Effervescent FDDES

The outer layer of the effervescent FDDES is made up of swellable polymers which are permeable to the gastric fluid, which shows neutralization reaction on coming in contact with the sodium bicarbonate of effervescent layer. Further the release of carbon dioxide results in the decrease of density of the system which ensures prolonged gastric retention.

Non Effervescent System:

Non Effervescence system swells on coming in contact with gastric fluid to an extent that prevent their exit from the stomach. It acts as the 'plug-type systems' having a tendency to remain lodged near the pyloric sphincter. One of the formulation methods of such dosage forms involves the mixing of drug with a gel, which swells in contact with gastric fluid after oral administration and maintains a relative integrity of shape and a bulk density of less than one within gelatinous barrier. The air trapped by the swollen polymer confers buoyancy to these dosage forms. Examples of this type of FDDES include colloidal gel barrier, micro porous compartment system, alginate beads, and hollow microsphere.

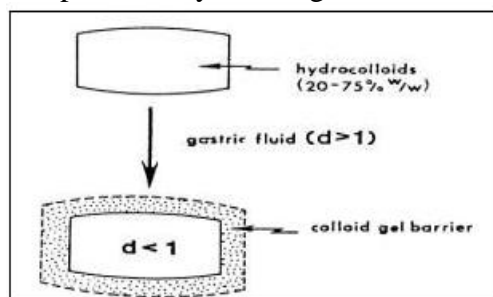


Figure 2: Non Effervescent system (Colloidal gel barrier)

Another type is a fluid-filled chamber which includes incorporation of a gas filled floatation chamber into a micro porous component that houses a drug reservoir. Aperture or openings are present along the top and bottom walls through which the gastrointestinal tract fluid enter to dissolve the drug. The other two walls in contact with the fluid are sealed so that the undissolved drug remains therein. The fluid present could be air, under partial vacuum or any other suitable gas, liquid, or solid having an appropriate specific gravity and an inert behaviour. The device is

of swallowable size, remains afloat within the stomach for prolonged time, and after the complete release the shell disintegrates, passes off to the intestine, and is eliminated.

Statistical Methods

Evaluation Parameters of FDDS:

For the evaluation of floating drug delivery system some parameters are present some of which performed in-vitro while some in vivo.

Serial No	In-vitro Method	In-vivo Method
1	Content uniformity, hardness, friability (tablets), size and shape	X-Ray method
2	Buoyancy capabilities (Resultant weight test)	Gamma-Scintigraphy
3	Floating lag time and floating time	Gastroscopy
4	Dissolution study	Ultrasonography

Table1: Various in-vitro and in-vivo evaluation parameters of floating drug delivery system.

Results

FDDS is an approach to achieve drug release for long duration. Polymers play an important role in Controlled drug delivery system. Acrylic polymers are widely used for the preparation of floating microspheres. Polymers, which can be successfully used in floating drug delivery system, are briefly discussed below:

[1] has successfully used Eudragit S100 for the preparation Jain *et. al* also reported the same findings about Eudragit. A good floating behaviour was observed, whereas dissolution rate was found to be slow, because of the low solubility of eudragit at acidic pH.

[2] also reported the same findings.

[3] prepared multiple unit floating drug delivery system based on gas formation technique. The pellets were consisting of an inner effervescent layer and an outer gas entrapping polymeric membrane of aqueous colloidal polymer dispersion of eudragit RL 30D, RS30D, and NE30D. Only the system, which uses eudragit RL30D, could float. The floating was reported for more than 24 hours.

[4] used eudragit E100 for the preparation of microspheres for fish farming. The findings were similar as reported earlier.

Discussion

Floating drug delivery offers several applications for drugs having poor bioavailability. FDDS systems have a bulk density of <1 as a result of which they can float on the gastric contents. These systems are relatively large in size and passing from the pyloric opening is prohibited. 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 Non effervescent 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. A large number of companies are focusing toward

Brand name	Drug	Dosage form	Polymers used	Manufacturers
Cifran O.D	Ciprofloxacin	Tablet	Xanthum gum and sodium alginates	Ranbaxy
Liquids Gavison	Mixtures of alginates	Liquid	Alginates	Glaxosmithkline
Madopor HBS	Levodopa and Benserazide	Capsule	HPMC	Roche
Glumetza	Metformin hydrochloride	Tablet	HPMC	Depomed

commercializing these techniques.

Table 2: Marketed Formulations of Floating Drug Delivery System

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