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Brief Report

FLOATING DRUG DELIVERY SYSTEMS

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BRIEF REPORT

Floating drug delivery systems (FDDS) were developed to keep medications in the stomach, and are particularly useful for pharmaceuticals with low solubility and stability in intestinal fluids. The idea behind FDDS is to make the dose form less thick than the gastric juices in order for it to float on top of them. FDDS are low-density hydrodynamically controlled systems with enough buoyancy to float above gastric contents and remain buoyant in the stomach for an extended period of time without altering the gastric emptying rate. With the release of the medication, the stomach's residual system is emptied. As a result, the stomach residence period is increased, and the fluctuations in plasma drug concentrations are better controlled.

The notion of buoyant preparation is a simple and practical method for increasing stomach capacity. In some cases, extending the stomach retention of a delivery method is desirable for achieving increased therapeutic efficacy of the medicinal ingredient. Medications with improved absorption at the proximal part of the gastrointestinal system and drugs with limited solubility that breakdown in alkaline pH, for example, have been proven to be effective in extending gastric retention. Furthermore, prolong gastric retention of the therapeutic moiety for sustained drug delivery to the stomach and proximal small intestine in treating certain ulcerative conditions, and thus offer numerous advantages including improved bioavailability and therapeutic efficacy with reduced dosing frequency.

Despite significant advances in drug delivery, the oral route of administration has garnered more attention and success than other routes because gastrointestinal physiology allows for more

Flexibility in dosage form formulation than other routes. As a result, researchers are constantly looking for new strategies to administer medications over a long period of time with a well-controlled release profile. The capacity to delay and control the emptying period of a dose form in the stomach is exceedingly varied. Gastric transit time is a useful advantage for dose forms that spend more time in the stomach than traditional dosage forms. Oral dose forms such as tablets and capsules provide a specific medication concentration in the systemic circulation while providing little control over drug administration and causing significant variability in plasma drug levels.

Many attempts have been made to develop sustained release preparations with extended clinical effects and reduced dosing frequency. A problem frequently encountered with conventional sustained release dosage forms is the inability to increase their residence time in stomach and no control over drug delivery, leading to fluctuations in plasma drug level.[1] Gastric emptying occurs during fasting as well as fed states. The pattern of motility is however distinct in the 2 states. During fasting state inter digestive series of electrical events take place which cycle both through stomach and intestine every 2 to 3 hours.

Types of Floating Drug Delivery Systems (FDDS) Based on the mechanism of buoyancy, two distinctly different technologies have been utilized in development of FDDS which are:
Effervescent System and
Non-Effervescent System

Effervescent system

Effervescent systems include use of gas generating agents, carbonates (example. sodiumbicarbonate) and other organic acids (e.g. citric acid and tartaric acid) present in the formulation to produce carbon dioxide (CO_2) gas, thus reducing the density of system and making it float on the gastric fluid. An alternative is the incorporation of matrix containing portion of liquid, which produce gas that evaporates at body temperature. These effervescent systems are further classified into two types:

1. Gas generating systems
2. Volatile liquid/vacuum systems

Gas-generating systems intra gastric single layer floating tablets or Hydrodynamically Balanced System (HBS)

These are formulated by intimately mixing the CO_2 generating agents and the drug within the matrix tablet. These have a bulk density lower than gastric fluids and therefore remain floating in the stomach unflattering the gastric emptying rate for a prolonged period. The drug is slowly released at a desired rate from the floating system and after the complete release the residual system is expelled from the stomach. This leads to an increase in the gut and a better control over fluctuation in plasma drug concentration

Sustained release layer multiple unit type floating pills

Floating drug delivery is of particular interest for drugs that act locally in the stomach are primarily absorbed in the stomach are poorly soluble at an alkaline pH have a narrow window of absorption and are unstable in the intestinal or colonic environment. Types of Floating Drug Delivery Systems (FDDS) Based on the mechanism of buoyancy, two distinctly different technologies have been utilized in development of FDDS.

Non Effervescent Systems

The non-effervescent FDDS is based on the mechanism of swelling of polymer or bioadhesion to mucosal layer in GI tract. The most commonly used excipients in non-effervescent FDDS are gel forming or highly swellable cellulose type hydrocolloids, polysaccharides and matrix forming material such as polycarbonate, polyacrylate, polymethacrylate, polystyrene as well as bioadhesive polymer such as chitosan and carbopol. The various types of this system are as follows:

Single layer floating tablets

They are formulated by intimate mixing of drug with gel-forming hydrocolloid, which swells in contact with gastric fluid and maintains bulk density of less than unity. The air trapped by the swollen polymer confers buoyancy to these dosage forms.

Bilayer floating tablets

A bilayer tablet contains two layers, immediate release layer which releases initial dose from system while the another sustained release conventional tablets. Eg: A bilayer floating capsule of misoprostol, which is a synthetic analog of prostaglandin E1, which is used as a protectant of gastric ulcers caused by administration of NSAIDs. Various approaches for preparation of gastroretentive drug delivery system include floating systems, swellable and expandable systems, high density systems, bioadhesive systems, altered shape systems, gel forming solution or suspension system and sachet systems. Among these, the floating dosage form has been used most commonly. The floating systems include gas-generating systems, non-effervescent systems and raft forming systems. The floating oral delivery system is expected to remain buoyant in a lasting way upon the gastric contents and enhance bioavailability of all drugs which are well absorbed from the GI tract.

Alginate beads multi-unit

Floating dosage forms are developed from freeze dried calcium alginate. Spherical beads of approximately 2.5 mm diameter can be prepared by dropping a sodium alginate solution into aqueous solution of calcium chloride, causing precipitation of calcium alginate leading to formation of porous system, which can maintain a floating force for over 12 h. When compared with solid beads, which gave a short residence time of 1 h, these floating beads gave a prolonged residence time of more than 5.5 h.

Hollow microspheres

Hollow microspheres (microballoons), loaded with drug in their outer polymer shells were prepared by a novel emulsion solvent diffusion method. The ethanol:dichloromethane solution of drug and enteric acrylic polymer was poured into an agitated aqueous solution of PVA that was thermally controlled at 4000 . The gas phase generated in dispersed polymer droplet by evaporation of dichloromethane formed an internal cavity in microsphere of polymer with drug. The microballoons floated continuously over the surface of acidic dissolution media containing surfactant for more than 12 h in vitro.

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