Gastroretentive Floating Film Drug Delivery System

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ABSTRACT:

Drug delivery research has yielded many scientific and technological advances. Floating film drug delivery systems, an advanced substitute for traditional dosage forms such as tablets, capsules, and liquids, are made of drug-loaded polymeric film, which is primarily composed of active pharmaceutical ingredients, polymers, film forming agent, and plasticizer with the appropriate solvent. Gastroretentive floating films are primarily made using solvent evaporation and solvent casting methods. This article focuses on the general consideration of gastroretentive floating films drug delivery systems, including their benefits and drawbacks as well as preparation methods and evaluation parameters such as percent moisture absorption, folding endurance, tensile strength, drug content, and dissolution. The layer-by-layer film technology, which uses various polymers to provide regulated or sustained drug administration, will emerge as a viable alternative for multidrug therapy. In related disorders like diabetes and hypertension, among others, a multilayer strategy will become increasingly important.

Introduction:

Formulation of novel drug delivery system:–

A novel drug delivery system (NDDS) is a fresh strategy for delivering pharmaceutical chemicals in the body where they are needed to safely produce the intended pharmacological effects. It involves creative creation, formulations, new technology, and novel approaches. For instance.

E.g. Controlled method of administering medication
Nano-transporters
System of vesicular drug delivery
Nasal brain pharmacokinetic system

Drug delivery system in gastro-retentive:

Drug delivery systems in the gastro-retentive are made to be kept in the stomach for an extended period of time, release their active ingredients, and allow the drug to be continuously and continuously ingested into the upper gastrointestinal (GI) tract. Gastro-retentive medication delivery systems benefits-

1. Compared to the administration of non-gastroretentive drug delivery, the bioavailability of therapeutic agents can be markedly increased by this gastroretentive drug delivery strategy, particularly for those that are processed in the upper GIT. The amount of drug absorption is influenced by a number of interrelated elements that are connected to drug absorption and transit in the gastrointestinal tract (GIT) and work simultaneously.
2. Sustained release may cause a flip-flop in the pharmacokinetics of medications with comparatively short half life. It can also allow for lower dosage frequency and better patient compliance.
3. They also have an edge over their traditional approach since they can use it to get around the problems caused by the gastric emptying time (GET) and the gastric retention time (GRT). Because their bulk density is lower than that of the stomach fluids, these devices are projected to stay buoyant on the gastrointestinal fluid without influencing the intrinsic rate of employing.
4. Drugs from dosage forms that provide local therapy in the stomach and small intestine can be released from capsules more slowly and continuously through the use of gastroretentive drug delivery. As such, they are helpful in the management of conditions pertaining to the stomach and small intestine.
5. The gradual, regulated administration of medication A gastroretentive dose form minimizes or eliminates symptoms by providing adequate local action at the sick location.
6. The variation in medication concentrations and effects is reduced by the use of gastroretentive dose forms. As a result, negative impacts linked to peak concentrations that are concentration dependent might be displayed. This characteristic is especially crucial for medications with limited therapeutic indexes.
7. Drug efficiency can be increased by using gastroretentive drug delivery, which can reduce the body's counteractivity.
8. Better selective receptor activation is made possible by a decrease in drug concentration fluctuations.
9. The extended period of time over a critical concentration made possible by the prolonged mode of drug release from gastroretentive dosage forms improves the chemical results and the pharmacological effect.

**Disadvantages of gastro-retentive drug delivery systems**

1. Unsuitable for drugs with limited acid solubility. E.g. Phenytoin.
2. Unsuitable for drugs those are unstable in acidic environment. E.g. Erythromycin.
3. Drugs that irritates or causes gastric lesions on slow release. E.g. Aspirin & NSAID’s.
4. Drugs that absorb selectively in colon E.g. Corticosteroid.
5. Drugs that absorb equally well through GIT. E.g. Isosorbide, dinitrate, Nifidipine.
6. Floating drug delivery systems require high fluid level in stomach to float and work effectively.

**Types of GRDDS**

1. Expandable System
2. Mucoadhesive System
3. High Density System
4. Floating drug delivery system
5. Low Density System

**Floating drug delivery system**

Floating drug delivery system (FDDS) are also known as Floating Film Drug Delivery Systems. These systems have bulk density lower than gastric fluids and thus remains suspended in the stomach without affecting the rate of gastric emptying for a long time the system of residues of the drug is emptied from the stomach.

**Floating Films**

**The advantages of film drug delivery**

1. include a significant increase in the bioavailability of drugs, particularly those metabolized in the upper gastrointestinal tract.
2. Sustained release of drugs with a relatively short half-life can result in flip-flop pharmacokinetics and reduce dosing frequency, leading to improved patient compliance.
3. The film is designed to remain buoyant on gastric fluid without impacting the rate of gastric emptying due to its low density.
4. Gastro-retentive floating drug delivery systems offer prolonged and sustained drug release in the stomach and small intestine, making them useful in treating disorders related to these organs.
5. By providing site-specific drug release and minimizing fluctuations in drug concentration, this approach reduces undesirable side effects.

Disadvantages:
1. It requires a lot of fluid in the stomach to allow the membrane to float around the stomach.
2. GRFFDDS is not suitable for drugs that cause abdominal pain.
3. Bioadhesion in acidic environments and high mucotolerance may raise the question of the effectiveness of this technique.

MANUFACTURING METHOD:

1. Solvent casting method:
2. Semi-solid casting:
3. Solid dispersion extrusion
4. Layer by layer method
5. Hot melt extrusion
6. Rolling method
7. Mercury substrate method

1. Solvent casting method:

The film was made by solvent casting method with different polymers. The amount of drug in the film was less than 50 mg in a film of 4x2 cm. An appropriate amount of API and floating agent was dissolved in an appropriate amount of solvent, such as methanol, and slowly added to the polymer solution with continuous stirring by magnetic stirring when the drug-polymer mixture was homogeneously mixed, followed by an appropriate amount of plasticizer. was added with constant stirring and the resulting solution was poured into a Petri dish. Then dry the membrane and remove the membrane from the Petri dish and evaluate it.

![Figure: Solvent casting method](image)

Advantages:
Better clarity than extrusion and better thickness uniformity.
The film has a good gloss and no defects such as cast line.
The membrane has better physical properties and greater flexibility.

2. Semi-solid casting method:

The semi-solid casting method is mostly useful when the film component contains an acid-insoluble polymer. Here, initially water-soluble polymers dissolve in water. The resulting solution is added to the acid-insoluble polymer solution, which is formed separately. Both solutions are well mixed. After mixing the two solutions, an appropriate amount of plasticizer is added to the final solution to obtain a gelled mass. Finally, the gel mass is poured onto tapes or films using thermally controlled drums. Maximum film thickness should be between 0.015” and 0.05”. The ratio of acid-insoluble polymer to film-forming polymer should be 1:4. Examples of acid-insoluble polymers are cellulose acetate butyrate and cellulose acetate phthalate, of.

3. Solid dispersion extrusion:

The solid dispersion extrusion method involves a solid dispersion of the drug induced into a molten polymer solution for the drug to be loaded. The drug is dissolved in a suitable liquid solvent and the resulting solution is added to a suitable polymer obtained at a temperature below 70 °C without removing the liquid solvent to form a solid dispersion. Finally, the resulting solid dispersions are formed into a film using dyes.
4. Layer-by-layer method :-

Layer by Layer technology where one layer is a controlled release polymer and the other layer is a slow release polymer. So, in this way, one can move to a multi-layered approach, so that this drug delivery plays an important role in related diseases such as diabetes, hypertension, etc. For this type of disease, a multilayer membrane with a different drug release profile through the different layers can be used. Prepared from a film made of different polymers. The solvent plays an important role in the preparation of gastroretentive membranes. Water can be used as a solvent for drugs that are insoluble or poorly soluble in water, so that the film dries in a short time after its preparation.

5. Hot melt extrusion :-

In this method, the mass is first prepared under temperature and speed control. The film is then covered and dried in a drying tunnel, where temperature, air circulation and line speed are again regulated. Then there is cutting, and in the last step the membranes are pierced, bagged and sealed.

Advantages:
1) Without using water or solvent.
2) A better alternative to a poorly soluble drug.
3) API compressibility is not necessarily important.
4) Fewer processing steps.
5) Less energy compared to high shear methods.

Disadvantages:
1) Limited number of polymers available.
2) Temperature drop due to high temperature use.
3) All excipients must not contain water or other volatile solvents.
4) The flow properties of the polymer are important in processing

6. Rolling method :-

In this system, a solution or suspension containing the drug is rolled onto the substrate. The solvent is basically water and a mixture of water and alcohol. The film is dried with rollers and given the desired shape and size.

7. Mercury substrate method :-

The film is made by the method of mercury substrate, in this method the medicinal substance is dissolved in a polymer solution together with other additives in the composition, such as plasticizers, gas-generating substances. The solution should be on the surface of a sheet of mercury covered with an inverted funnel to prevent evaporation of the solvent.

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