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An Improved Method for Gastro- Retentive Drug Delivery Using Micro balloons

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ABSTRACT: Theadministrationofdrugs inthe formofmicroballoons orallyis the most commonandpreferred method. Gastric retention by use of microballoons is proposed as a viable option. Non-effervescent systems comprising empty spherical particles without a center, ideally measuring fewer than 200 micrometers indiameter, are the basis for the microballoon drug delivery method. Floating medicine delivery using microballoons has recently emerged as a promising new topic in the pharmaceutical industry. Microballoons, or hollow microspheres, have a number ofother names. Microballoons are a smooth, breathable materialthat floats well in stomach juice. The medicine is retained in the stomachthanks to the microballoons. It's able to discharge its contents slowlyand steadily. Microballoons are unfilled spherical vehicles. That can maintain its buoyancy in the stomach for an extended amount of time without irritating the intestines. GRDDS, benefits, drawbacks, methods of production of microballoons, applications, and assessment procedures are all discussed in depth as they relate to the physical characteristics of microballoons.

KEY WORDS: Gastro-retention drug delivery devices such as microballoons, gastric retention microspheres, and hollow microspheres

I. INTRODUCTION

Drugs may be delivered to the stomach with the help of microballoons, which do not need an effervescent mechanism. Microballoons, also known as hollow microspheres, are tiny, hollow sphere-shaped particles. Some of the features of these microballoons include the presence of proteins or synthetic polymers in freely flowing powder form and a size of fewer than 200 micrometers.1

Due to its hollow construction and inherent buoyancy,microballoonsareconsideredtobeone of the most promising buoyant systems of the future.

Within the microsphere, space plays a key role. Methods such as simple solvent evaporation, emulsion solvent diffusion, solvent diffusion evaporation, spray drying, single emulsion,double emulsion, co- acervationphase separation, etc.2 are all used in their production.

Gastro Retentive Drug Delivery System (GRDDS)

Gastro retentive drug delivery is an approach to prolong gastric residence time, thereby targeting site-specific drug release in the upper Gastro Intestinal Tract (GIT) for local or systemic effect. It is obtained by retaining dosage form into stomach and by releasing in the controlled manner.

To overcome physiological adversities suchas short Gastric Residence Times (GRT) and unpredictable Gastric Emptying Times (GET). Thisdosage forms will be very much useful to deliver narrow absorption window drugs.

Oral route is most acceptable route for drug administration. Apart from conventional dosage forms severalotherformsweredeveloped in order to enhance the drug delivery forprolonged timeperiodand fordeliveringdrugto a particular target site.

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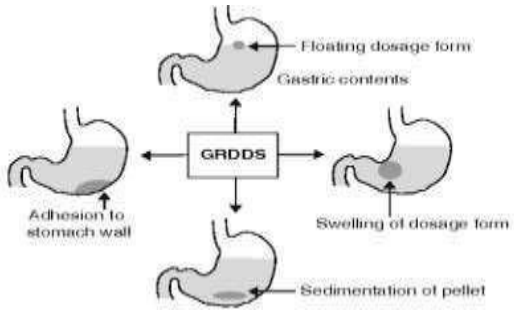

Figure1: Gastroretentivedrugdeliverysystem

Factorsaffectingphysicochemical properties of microballoons

- Stirringrate
- Temperatureofpreparation
- Plasticizer
- Volumeofaqueousphase
- Effectofsolvent
- Amount ofpolymerand viscosity
- Solventratio
- Emulsifierconcentration

Application

- For reduction of adverse effect of gastric irritation, gastro retentive floating microspheres are very effective.
- This system is stable in stomach forlong period of time.
- Microballoons are effective method in deliveryof drug with poor bioavailability.
- Dye to increase in gastric retention time the higher dose ofdrug is reduced because of low dose frequency.

Advantages

- Dosingfrequencyisdecreasesbecauseof improvement in patient compliance.
- Maintainconcentrationofplasmadrug.
- Increasesgastricretentiontime.
- Controlledmannerofprolongedperiodis release the drug.
- Dosedumpinghavingnorisk.
- For decreasing of material densitymicroballoonsaremostlyused.
- Gastricretentiontime is increased cause of buoyancy by microballoons.

Disadvantages

- This kind of dosage forms should not be chewed or crushed.
- The release rate of controlled release dosage formmaydiffer fromthe rateoftransit though gut.
- Theformulationsarerelease modified.
- Higher drug load include in the controlled- release release formulations.
- In from one dose to another dose the release rate is different.

II. METHODSOFPREPARATION

Solventevaporationmethod

Systems like Eudragit, HPMC KM4, ethyl cellulose, etc., are used to enhance polymers likethese.Themedicationiscombinedwiththe polymers,andthenthewholething isdissolved in an acetone and ethanol solution. After the solution has been mixed, 100 ml of liquid paraffin isaddedandrotated at

1500rpm.Aftertheemulsionhasbeenmade, it is heated for three hours at 35 degrees Celsius. The acetone is then evaporated until only the microspheres remain, and the whattman filter paperisusedtoseparatethem.Thefloatingand prolonged release qualities are bestowed onto these microballoons.3

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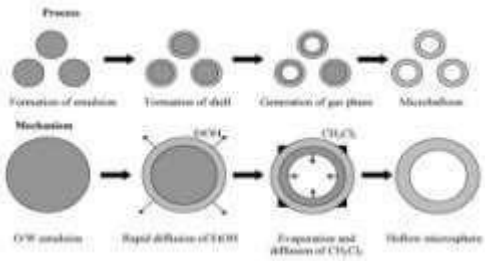
Figure2:solventevaporationmethod



Emulsionsolventdiffusionmethod

The drug polymer combination was dissolved in an ethanol:dichloromethane solution. Polyvinylalcohol solution is being rotated at 1500 rpm for 1 hour while this combination is being added drop by drop.4

In this technique, the organic solvent has a higher affinity for the drug than the aqueous solvent does. Organic solvent isused to dissolve this medication. The organic solvent is used to disperse the solution throughout the aqueous phase, where the emulsion droplets are formed. Emulsion droplets in the aqueous phase disseminate this organic solvent. Diffusion of the drug's aqueous phase into droplets is performed by the crystallizer.3,5

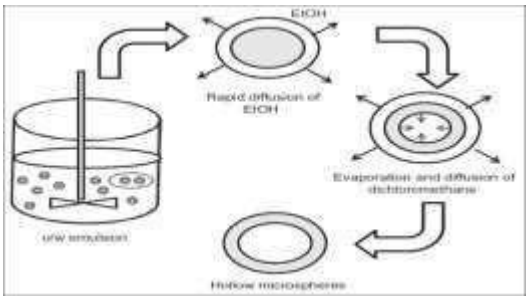


Figure3:emulsionsolventdiffusion method

Solventdiffusionevaporationtechnique

This approach combines elements of both the evaporationanddiffusionoftheemulsionsolvent. At room temperature, a mixture of ethanol and dichloromethane (1:1) containing these two drug

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polymers plus 0.1% of a surfactant such PEG is prepared.The80mlofproducedsolutionisdiluted gradually with the 0.46% w/w polyvinyl alcohol used as an emulsifier. a propeller

Organic solvent is being evaporated using an agitatorstirrerfor1hour.Thesolutionisthen filtered.6

The selected optimal formulation is based on a number of processes, including polymer ratio, stirringspeed,emulsifierconcentration,anddrug: polymer ratio.6

Spraydrying

This method is most active industrial process for drying and formation ofparticle. It is a best process where the required bulk density, particle size distribution and particle shape can be obtain.[7]

Doubleemulsiontechniques

The polymer is dissolved in organic solvent like dichloromethane and acetone etc. to production of slurry. Then the slurry is sprayed intothe drying chamber and concentration gradient of solvent form. This process is used because the time of the solute diffusion is longer than the solvent during the drying process in the droplet evaporation.[8]

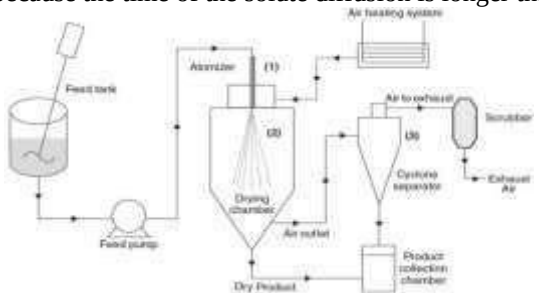

Figure4:spraydrying

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1. **Bulkdensity**

Bulk density is calculated by following equation:- Bulkdensity=massofmicrospheres/bulkvolume

2. **Tappeddensity**

Itiscalculatedbyfollowingequation:-
Tappeddensity=massofmicrospheres/tapped volume

3. **Hausner'sratio**

Hausner's ratio is calculated by followingequation:-

Hausner'sratio =tapped density/bulk density

4. **Carr'sindex**

Itiscalculatedbyfollowingequation:-
Carr's index= (bulkdensity– tappeddensity/ tapped density) x 100

5. **Angleofrepose**

The powder mass is allow to flow throughthe funnel orifice kept to a plane paper kept onthehorizontalsurface, giving a heap angle of paper The angle of repose is calculated by followingequation:-
tanϴ=h/r

Invitrobuoyancy

Suitable quantity of microballoons is placed in 900 ml of 0.1N HCl. This mixture is rotating at 100 rpm for 8-10 hrs. in dissolution apparatus. After this rotation the layer of buoyant microballoons are separated by filtration. Particles which is including in the layer of sinking particulate are separated.

Particles of both types (buoyant microspheres and settled microspheres) are dried until constant weight is reached. The fractions of microballoons are weighed.[13]

Buoyancyiscalculatedbyfollowing

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equation:-Buoyancy(%)=[Wf/(Wf+ Ws)]x 100 Where, Wf = weight of floating microsphere
Ws=weightofsettledmicrosphere

Scanningelectronmicroscopy

Dry microballoons are placed on electron microscope brass stub a coated. The spectro- random canning of the stub is taking pictures of microballoons. The microballoons are viewed at a voltage of 20KV of microscope.[14]

Invitrodrug releasestudies

The release rate is determined by microballoons in United States Pharmacopoeia XXIII basket type dissolution apparatus.

Weighed microballoons are equivalent to dose of drug and place in the basket of apparatus. Themaintainedtemperatureandrotationspeed by dissolution fluid. Addition of 5 ml ofdissolution fluid maintained initial volume of the dissolution fluid.[15]

Dataanalysisofreleasestudies

This type of study include five kinetic models like Zero order, First order, Higuchi matrix, Peppas-Korsmeyer and Hixon-Crowell release
equations are used to process the in vitro release data.[16,17]

Swellingstudies

These types of studies are used for calculation of molecular parameters of polymers. Determination of swelling studies takes place using optical microscopy, dissolution apparatus and other techniques. These techniques are includingCLSM, Cryo-SEM,andLSIetc.Forthe swelling studies, dissolutionapparatus isusedand it is calculated as following equation:[18]
Swellingratio=weightofwetformulation/weight

Invivostudies

To performedthe in vivo studies, usethe suitable animal models examples like ratand beagle dogs etc. the radio graphical studies investigate the floating behavior using sulphate microballoons.[19,20]

III. CONCLUSION

Microballoons are a kind of gastro retentive medicationdeliverydevicethatmayfloatabove gastric contents and remain in the stomach for an extended length of time due to their low density and high buoyancy. Based on this analysis, we demonstrated that our medication delivery technology is superior to the statusquo. In the fields of sick cell sorting,diagnostics, innovative medication administration, and efficient in vivodistribution, microballoons play a pivotal role. Preparation techniques for microballoons are limited to those that include emulsification.

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