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# FORMULATION AND EVALUATION OF FLOATING MATRIX PELLETS OF MONO AMMONIUM GLYCYRRHIZNATE FOR TREATMENT OF GASTRIC ULCER

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***ABSTRACT-***

*The main aim of present investigation was to formulation and optimization of sustained release matrix pellets of Mono ammonium glycyrrhizinate.*

***Results:*** *From several tests performed on the formation of pellets it was concluded that each of the factors had a significant effect on preparation of pellets by extrusionspheronization method like diluent (F 1) It was found that Lactose (250mg) shows Uniform size, Spherical shape, Good Strength from morphologystudythanpolymer (F4) It was found that Hydroxy propyl methyl cellulose K15M (100mg) shows Uniform size, Spherical shape, Good Strength.*

***Conclusion:*** *Maintain the sustained release for treatment of ulcer for prolong period of time.*

***Keywords-*** *Mono ammonium glycyrrhizinate, pellets, extrusion-spheronization.*

## I INTRODUCTION

The stomach is the most dilated part of the digestive tube, having a capacity of 1000– 1500 ml in the adult. It is situated between the end of the esophagus and the duodenum the beginning of the small intestine. It lies in the epigastria, umbilical, and left hypochondria regions of the abdomen, and occupies a recess bounded by the upper abdominal viscera, the anterior abdominal wall and the diaphragm. It has two openings and is described as having two borders, although in reality the external surface is continuous. The relationship of the stomach to the surrounding viscera is altered by the amount of the stomach contents, the stage that the digestive process has reached, the degree of development of the gastric musculature, and the condition of the adjacent intestines.

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However, borders are assigned by the attachment of the peritoneum via the greater and lesser omentum, thus dividing the stomach into an anterior and posterior surface. The principal function of the stomach is to mix the food with acid, mucus and pepsin and then release the resulting chyme, at a controlled rate into the duodenum for the process of absorption. Gastric motility is controlled by both neural and hormonal signals. Nervous control originates from the enteric nervous system as well as the parasympathetic (predominantly vagus nerve) and sympathetic systems. A number of hormones have been shown to influence gastric motility for example, both gastrin and cholecystokinin act to relax the proximal stomach and enhance contractions in the distal stomach. Other functions of the stomach include the secretion of intrinsic factor necessary for the absorption of vitamin B12.

**AIM:** The current work is developing floating matrix pellets of mono ammonium glycyrrhiznate for treatment of gastric ulcer.

**OBJECTIVE:** To prepare floating matrix pellets of mono ammonium glycyrrhiznate. To screen various factors affecting preparation. To evaluation the prepare pellets with respect to various parameter.

## II REVIEW OF LITRATURE

1-Lingam Meka: A gastro retentive floating drug delivery system with multiple-unit Minitab's based on gas formation technique was developed in order to prolong the gastric residence time

and to increase the overall bioavailability of the drug. The system consists of the drug-containing core units prepared by direct compression process, which are coated with three successive layers of an inner seal coat, effervescent layer (sodium bicarbonate) and an outer gas-entrapped polymeric membrane of an polymethacrylates (Eudragit RL30D, RS30D, and combinations of them). Only the system using Eudragit RL30D and combination of them as a gas-entrapped polymeric membrane could float. The time to float decreased as amount of the effervescent agent increased and coating level of gas entrapped polymeric membrane decreased. The optimum system floated completely within 3 min and maintained the buoyancy over a period of 12 h. The drug release was controlled and linear with the square root of time. Increasing coating level of gas-entrapped polymeric membrane decreased the drug release. Both the rapid floating and the controlled release properties were achieved in the multiple-unit floating drug delivery system developed in this present study. The analysis of the parameter dissolution data after storage at 40 °C and 75% RH for 3 months showed, no significant change indicating the two dissolution profiles were considered to be similar (f2 value is more than 50). Material:Captopril was gift sample from Nicholas Primal, India. Microcrystalline cellulose (MCC) (Avicel PH102), Hydroxyl propyl methyl cellulose (HPMC K100), Ethyl cellulose 7 cps were procured from Dr. Reddy’s Labs India. Sodium bicarbonate (Merk, India) was used as an effervescent agent with HPMC (Methocel E15LV), plasticized with polyethylene glycol 6000 (PEG 6000 Sd fines, India) as a binder. The gas

entrapped polymeric membrane used was polymethacrylates (Eudragit RL and RS, Rohm Pharma, Germany) plasticized with tritely citrate (Himedia), a water soluble plasticizer. All other reagents were of analytical grade.

2-SrisagulSungthongjeen: Anhydrous theophylline (Lianyungang Foreign Trade Corp., China) was chosen as a model drug. Microcrystalline cellulose (Avicel® PH 101, FMC, USA) was used as a pelletization aid of the core pellets. Sodium bicarbonate (NaHCO3, Carlo Erba,Italy)was used as an effervescent agent withHPMC(Methocel® E15LV, Dow Chemical, USA) plasticized with polyethylene glycol 6000 (PEG 6000, FlukaChemie, Switzerland) as a binder. The gas-entrapped polymeric membrane used was aqueous colloidal polymethacrylate dispersion (Eudragit® RL 30D, RS 30D or NE 30D, Rohm Pharma, Darmstadt, Germany) plasticized with diethyl phthalate (DEP), a water insoluble plasticizer (Eastman Kodak Co., NY, USA). All other reagents were of analytical grade.

3- J. HamdaniL: Floating pellets were prepared using the melt pelletization process in a Mi-Pro® high shear mixer (Pro-C-epT, Belgium). Formulations were based on a mixture of Compritol® and Precirol® as meltable binders and on the use of sodium bicarbonate and tartaric acid as gas generating agents. Good floating abilities were obtained by using the gas-generating agents in both the inner matrix and the outer coating layer of the pellets. In vitro evaluation of floating capability was performed both by using the resultant weight apparatus and by counting floating pellets at the surface of beakers containing 0.1N HCl solution, in vivo evaluation of floating pellets capabilities was also performed. Riboflavin-containing floating pellets (FRF) were administered orally to nine healthy volunteers versus non floating pellets (NFRF). Volunteers were divided in two groups, fasted group (n = 4) 729 kcal and fed group (n = 5) 1634 kcal as the total calorie intake on the testing day. An increase of urinary excretion of riboflavin was observed when the volunteers were dosed with the floating pellets, especially after feeding. As riboflavin has a narrow window of absorption in the upper part of small intestine, this phenomenon could be attributable to the gastric retention of floating pellets.

4-Wiesław Sawicki: The purpose of this study was to work out a method of compression of floating pellets with verapamil hydrochloride (VH) in a dose of 40 mg. It was assumed that this form should reside in the stomach floating for several hours and gradually release the drug in a controlled way. Compression of pellets into tablets, being a modern technological process, is much more perfect than enclosing them in a hard gelatin capsule. Kollicoatw SR 30 D was selected for coating. In experiments three plasticizers were examine —propylene glycol, triethyl citrate and dibuthylsebecate (all at concentration of 10%). It was found that VH release from pellets coated by the films of thesame thickness (70 mm), however, containing plasticizers is considerably different. Pellets were prepared by wet granulation of powder mixture, spheronization of the granulated mass and coating of the cores with a sustained release film. Two kinds of cellulose,microcrystalline and powdered, and sodium hydro carbonate were the main components of pellet core. Proper pellet coating film thickness, ensuring obtaining desirable VH release profile and flotation effect, was defined. X compositions of tablets with pellets were examined in order to obtain formulation, from which VH release would mostly approximate pellets before compressing. The best formulation was evaluated taking into account the effect of compression force an

tablet hardness and friability, and pellet agglomeration and flotation. Tablet cross-section photographs were taken confirming necessary coating film thickness preventing their deformation caused by compressing into tablets.

## III Materials and methods

The pellets were prepared by extrusion spheronization method. The effects of spheronization speed (RPM) and concentration of polymer and binder as important process and formulation parameters on spherical shape, uniform size and strength were investigated by preliminary studies while concentration of screening all the diluent and polymer and floating agents and binder and plasticizer and determination of timedeterminationspheronization speed (RPM). Achieve desirable drug content, in-vitro drug release at (2,4,6,8,10) hours . Characterization of prepared pellets were done with respect to dissolution rate,, drug content, morphology study and SEM, FT-IR, and DSC. FT-IR analysis was done to check the intermolecular interaction between drug and excipients.

## IV SUMMARY.

Preformulation study was carried out which include identification of drug (melting point and FTIR analysis ) , Drug - Excipient compatibility study ( FTIR was melting point and FTIR and DSC analysis ) and analytical method development.

Extrusion - spheronization method was employed for formulation of matrix pellets . Preliminary trials were carried out for screening of suitable (1) diluent (Lactose,Mccph101,Mccph102) .(2) polymer(HPMC K15M, HPMC K4M, HPMC K100M , HPC, PVPK30).(3) floatingagents (Sodium bicarbonate,Sodium carbonate,Potassium carbonate,Potassium carbonate, Calcium carbonate).(4)The binder ( starch paste).(5) The plasticizer (PEG400,PEG600).These preliminary batches are evaluated with respect to drug content, SEM ,in vitro dissolution , Floating , morphology, XRD.

## V CONCLUSION

Preformulation study prove that the drug was in the pure form and drug compatible with each other and from the preliminary study polymer Hydroxy propyl methyl cellulose K15M using for drug release and lactose was use as a diluent and sodium bicarbonate as a floating agents and starch paste as a binder and PEG400 as aplasticizer .PolymerHydroxy propyl methyl cellulose K15Mfor dissolution (drug releases : 89%)which show the control release of the drug up to 10 hours. Floating sodium bicarbonate the floating after the 10 seconds . The shape of the pellets are all shows Uniform size, Spherical shape, Good Strength .From the SEM study it was found that smooth ,spherical shape pellets with uniform size was production by extrusion spheronization .

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