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Formulation and Evaluation of Floating Drug Delivery System for Treatment of Hyperlipidemia

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ABSTRACT

ORIGINAL RESEARCH ARTICLE

Floating drug delivery systems have gained noteworthy concentration. These systems are formulated to have a minor density than gastric fluids, allowing them to linger buoyant in the stomach for extended periods lacking affecting the gastric emptying rate. This enthusiasm ensures better localization of drug release in the stomach, resulting in improved absorption and a more effectual therapeutic effect. To achieve continued and controlled drug release, polymers play a pivotal role in modulating drug diffusion and erosion behavior.

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INTRODUCTION

Oral drug delivery is the most common and convenient route for administering therapeutic agents, primarily due to its ease of use, cost-effectiveness, patient compliance, and flexibility in dosage form design. However, one of the significant challenges in oral drug administration is the limited gastric residence time of dosage forms. Drugs that are absorbed primarily in the upper part of the gastrointestinal tract (GIT), unstable in intestinal pH, or undergo extensive hepatic metabolism tend to have reduced bioavailability and therapeutic efficacy when administered through conventional dosage forms. Recent scientific and patent literature shows increased interest in academics and industrial research groups regarding the novel dosage forms that can be retained in the stomach for a prolonged and predictable period of time. One of the most feasible approaches for achieving a prolonged and predictable drug delivery profile in the GI tract is to control the gastric residence time (GRT), using gastroretentive drug delivery system (GRDDS) that will provide us with new and important therapeutic option.Gastroretentive systems are designed to retain the dosage form in the stomach for an extended period, thereby enhancing drug absorption, improving bioavailability, and reducing the need for frequent dosing. Among various GRDDS, floating drug delivery systems (FDDS) have gained significant attention. These systems are formulated to have a lower density than gastric fluids, allowing them to remain buoyant in the stomach for extended periods without affecting the gastric emptying rate. This buoyancy ensures better localization of drug release in the stomach, resulting in improved absorption and a more effective therapeutic effect. To achieve sustained and controlled drug release, polymers play a pivotal role in modulating drug diffusion and erosion behavior.

EXPERIMENTAL WORK

Drug Identification:

Rosuvastatin was identified by the procedures described in Indian Pharmacopoeia 2009.

Physical Appearance:

The drug Rosuvastatin was supplied by Glenmark Pharmaceutical Ltd. Mumbai, as a gift sample.

Solubility Profile Studies:

Drug (10mg approx.) was added separately to a series of solvents (2 ml) in capped test tube at room temperature. These tubes were shaken mechanically for about 6 hrs using wrist action shaker and solubility was recorded.

Preparation of Standard Calibration Curve of Rosuvastatin:

Rosuvastatin (100 mg) was accurately weighed and dissolved in 100 ml 0.1N HCl to form a stock solution (1000 µg/ml). The stock solution was further diluted suitably with 0.1N HCl to get a working standard solution of concentration 100 µg/mL. Aliquots (0.2, 0.4, 0.6, 0.8, 1.0, 1.2, 1.4, 1.6, 1.8, and 2.0) mL of working standard solution corresponding to 2-20 µg were taken in a series of 10 ml volumetric flask and volume made up with 0.1N HCl. The absorbance measurements of these solutions were carried out against 0.1N HCl as blank at 244 nm.

Preparation of Floating Microspheres of Rosuvastatin

The present work was proposed to prepare and evaluate the Floating Microspheres for the site-specific delivery of an HMG CoA Reductase inhibitor drug i.e. Rosuvastatin for effective management of Hyperlipidemia. The floating microspheres were prepared by solvent evaporation technique. The polymers, ethyl cellulose (EC) and hydroxyl propyl methyl cellulose (HPMC) were dissolved in the mixture of methanol and dichloromethane in the ratio 1:1. The drug was dispersed in the solution of polymers for 10 minutes under stirring at 200 rpm. The resulting dispersion was poured slowly under stirring into distilled water (dispersion medium) containing 0.01% of Tween 80. The stirring speed was maintained at 1000 rpm and temperature was maintained at 30-40ºC. Stirring was continued for 1 hour and allow evaporation of dichloromethane and methanol completely. After evaporation of dichloromethane and methanol, the prepared microspheres were collected by filtration using filter paper, then washed 3 to 4 times with distilled water and dried at room temperature for 24 hours and stored in a desiccators.

Table 1 Formulation Plan of Floating Microspheres

Formulation Code	Dispersed Phase				Continuous Phase
	Drug (mg)	HPMC (mg)	EC (gm)	methanol: Dichloromethane (ml)	
FM1	20	500	0.50	1:1	100 ml water containing 0.01% of Tween 80
FM2	20	300	1.0	1:1	
FM3	20	400	1.5	1:1	

RESULTS AND DISCUSSION

Drug Identification

Rosuvastatin was identified by the procedures described in Indian Pharmacopoeia 2009.

Physical Appearance

The drug Rosuvastatin was supplied by Glenmark Pharmaceutical Ltd. Mumbai, as a gift sample. It was odourless, white crystalline powder.

Solubility Profile Studies

The Rosuvastatin sample was found to be freely soluble in ethanol, soluble in methanol, dichloromethane and acetone. It was also soluble in 0.1N HCl (pH 1.2) and 0.1 N NaOH. It is sparingly soluble in water and chloroform.

Table 2 Solubility Profile of Rosuvastatin

Solvent	Solubility
Distilled water	+ +
Ethanol	+ + + +

Methanol	+ + +
Dichloromethane	+ +
Acetone	+ + +
Chloroform	+ +
Toluene	-
0.1 N HCl	+ +
0.1 N NaOH	+ + +

Drug Loading and Drug Entrapment

The floating microspheres were taken for evaluation. The solution was filtered and the absorbance was measured after suitable dilution spectrophotometricaly. The amount of drug loaded and entrapped in the microspheres was calculated and recorded in table 3

Table 3 Drug Loading & Drug Entrapment

S. N.	Formulation Code	% Drug Loading	% Drug Entrapment
1.	FM1	28.26±0.20	65.72±1.50
2.	FM2	26.14±0.40	68.23±1.20
3.	FM3	32.12±0.35	78.38±1.10

In-vitro Release Study:

The drug release study was performed with selected formulation. The cumulative % drug release was calculated using standard calibration curve. The results were shown in table 4

Table 4 In vitro drug release of floating microspheres

Time (Hours)	Absorbance	% Cumulative Drug Release
1	0.000	18.10
2	0.308	28.05
3	0.435	37.10
4	0.508	41.20
5	0.668	54.20
6	0.758	62.10
7	0.825	71.25
8	0.908	77.10
9	0.985	85.10
10	1.000	89.05

CONCLUSION

Microspheres of different sizes and improved drug entrapment efficiency were obtained by varying the drug: polymer ratio. The formulations showed good flow properties, suggesting that, in future they could be easily and successfully packed and developed into a capsule dosage form.

Thus the prepared floating microspheres formulation code (FM3) may be a potential aspirant as a microparticulate controlled release drug delivery device.

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