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DESIGN AND IN VITRO EVALUATION OF A GASTRORETENTIVE FLOATING DELIVERY SYSTEM FOR ONDANSETRON

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ABSTRACT

The present study aims to develop and evaluate a gastroretentive floating drug delivery system (GRDDS) for Ondansetron, a selective 5-HT_3 receptor antagonist widely used in the prevention of nausea and vomiting. The formulation addresses the limitations of Ondansetron's short biological half-life and moderate oral bioavailability by prolonging its gastric residence time and enabling sustained drug release. Floating tablets were prepared using a wet granulation method with sodium bicarbonate and citric acid as gas-generating agents and various polymers including HPMC K4M, Ethyl Cellulose, Eudragit RL-100, and Hydroxypropyl Cellulose (HPC). Seven formulations (F1–F7) were evaluated for pre- and post-compression parameters such as hardness, friability, swelling index, drug content, buoyancy time, and in vitro drug release profiles. Among all formulations, F7, comprising HPMC K4M and HPC, demonstrated optimal floating behavior (>12 hours), controlled drug release, and desirable physicochemical properties. The study concludes that floating drug delivery systems offer a promising approach for improving the therapeutic efficacy and patient compliance of Ondansetron.

KEYWORDS: Ondansetron, gastroretentive drug delivery system, floating drug delivery system, controlled drug release, HPMC K4M, hydroxypropyl cellulose, Eudragit RL-100, ethyl cellulose, buoyancy, swelling index, in vitro drug release, wet granulation.

INTRODUCTION

Oral drug delivery remains the most preferred route for the administration of therapeutic agents due to its convenience, ease of administration, and cost-effectiveness. However, one of the major challenges faced in this route is the limited gastric residence time of dosage forms, which can restrict the bioavailability of drugs that are primarily absorbed in the upper gastrointestinal tract (GIT). To address this, the development of Gastroretentive Drug Delivery Systems (GRDDS) has emerged as a significant advancement in pharmaceutical research. GRDDS are designed to prolong the retention of dosage forms in the stomach, thereby enhancing the absorption of drugs with narrow absorption windows, improving bioavailability, and reducing drug wastage. Among various gastroretentive approaches, Floating Drug Delivery Systems (FDDS) have shown great promise. These systems possess a lower density than gastric fluids and are capable of remaining buoyant in the stomach for extended periods, ensuring sustained drug release at the desired site of absorption. The performance of GRDDS is influenced by several physiological and formulation factors, including gastric motility, pH, dosage form size and shape, meal composition, and patient-related factors such as age, gender, and posture. FDDS are particularly beneficial for drugs that are unstable in the intestinal environment, poorly soluble at higher pH, or intended for local action in the stomach. This study focuses on the formulation and evaluation of a gastroretentive floating drug delivery system for Ondansetron, a selective 5-HT3 receptor antagonist used for the prevention of nausea and vomiting. By employing the floating mechanism, the formulation aims to optimize the drug's therapeutic efficacy by enhancing its residence time in the stomach and providing controlled release over an extended duration.

Gastroretentive drug delivery systems (GRDDS) have gained considerable attention in recent years due to their potential to improve the bioavailability of drugs with a narrow absorption window in the upper gastrointestinal

tract. These systems are particularly beneficial for drugs that are absorbed primarily in the stomach or the proximal part of the small intestine and those that are unstable in the alkaline pH of the intestine. Ondansetron, a selective 5-HT_3 receptor antagonist, is widely used in the prevention of nausea and vomiting associated with chemotherapy, radiotherapy, and postoperative procedures. Despite its efficacy, its therapeutic potential can be limited due to its relatively short biological half-life (3–4 hours) and moderate oral bioavailability (approximately 60%). To address these limitations, the development of a gastroretentive floating drug delivery system (FDDS) for ondansetron presents an effective strategy to enhance its gastric residence time and ensure a more consistent release and absorption profile. This study focuses on the formulation and evaluation of a floating drug delivery system for ondansetron, aiming to optimize its pharmacokinetic properties, prolong gastric retention, and ultimately improve patient compliance and therapeutic efficacy.

MATERIALS AND METHOD

Ondansetron from Zeel Pharma, Mumbai, India, HydroxyPropyl Methyl Cellulose-K4M, Eudragit RL-100, Hydroxy Propyl Cellulose from Colorcon Pvt.Ltd, Goa, Ethyl cellulose, Micro Crystalline Cellulose, Polyvinyl pylorridone, Sodium Bicarbonate, Citric Acid, Iso Propyl Alcohol, Magnesium Stearate, Lactose from SD Fines, Mumbai, India.

2 Preparation of floating tablets of Ondansetron

Each floating tablets containing 250mg Ondansetronwere prepared by a conventional wet granulation method, employing sodium bicarbonate, citric acid as gas generating agent and different polymers in each formulation. (Table 6.3))

3 Preparation of granules

- (Ondansetron, and hydrophilic polymers were passed from sieve of # 40 and mixed for 10 min.
- Gas generating agent was then passed through sieve of# 60 added to the above mixture.
- Prepare binding solution of polyvinyl pyloridone in Isopropyl alcohol.
- Bind above mixture with the help of binding solution.
- Dry at room temperature and pass from sieve of# 40
- Magnesium stearate was passed through sieve of # 60 and added to the above mixture.
- The whole bulk of granules were then mixed thoroughly for 15 min.
- The granules were then compressed to form a tablet.

Table 1.1: Table showing the formulation codes and polymer content.

Formulation Code	F1	F2	F3	F4	F5	F6	F7
DRUG	16	16	16	16	16	16	16
HPMC K4M	3	--	--	--	2	2	2
ETHYL CELLULOSE	--	3	--	--	3	--	--
EUDRAGIT-RL-100	--	--	6	--	--	3	--
HPC	--	--	--	6	--	--	3
$NaHCO_3$	1	1	1	1	1	1	1
CITRIC ACID	3	3	3	3	3	3	3
Mg. STEARATE	1	1	1	1	1	1	1
LACTOSE	1	1	1	1	1	1	1
Total (mg) 25	25	25	25	25	25	25	25

RESULT

Preformulation Studies

Characterization of ondansetron

A. Organoleptic properties

Ondanstron was discovered to be a crystalline powder that ranged in colour from yellow white to light white. It has a distinctive smell and a bitter taste.

B. Meltingpoint

Ondansetron's melting point was discovered to be between 218 and 225°C.

C. FTIRspectroscopy

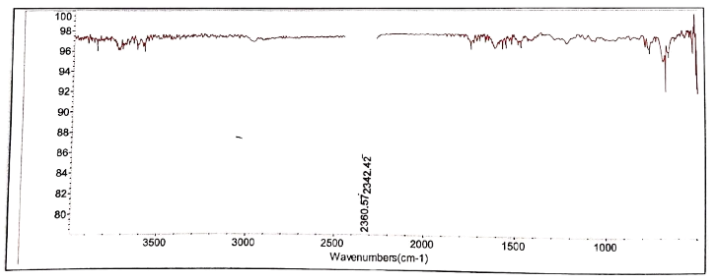

Figure 1.2: FTIR Spectrum Of Ondansetron.

D. UVspectroscopy(Determinationofamax)

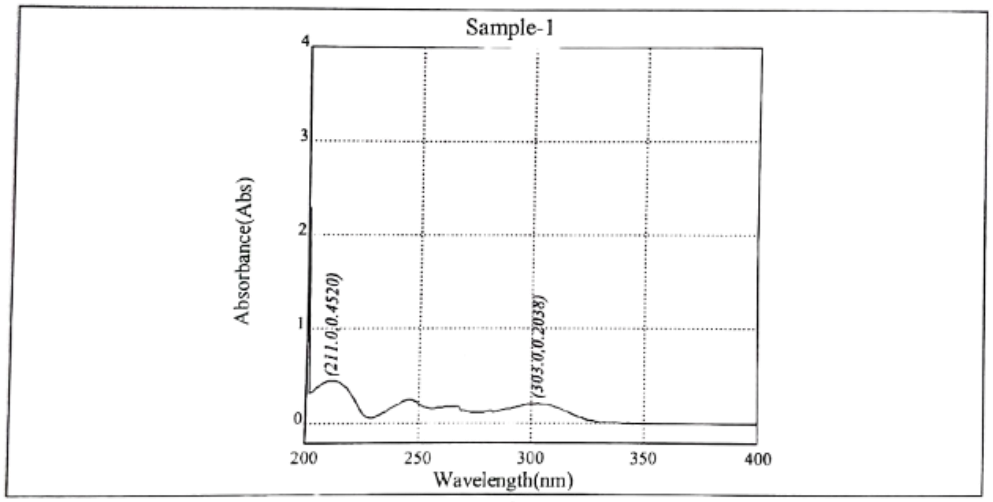

Figure 1.3: UV spectrum of Ondansetron.

E. Calibration curve for ondansetron

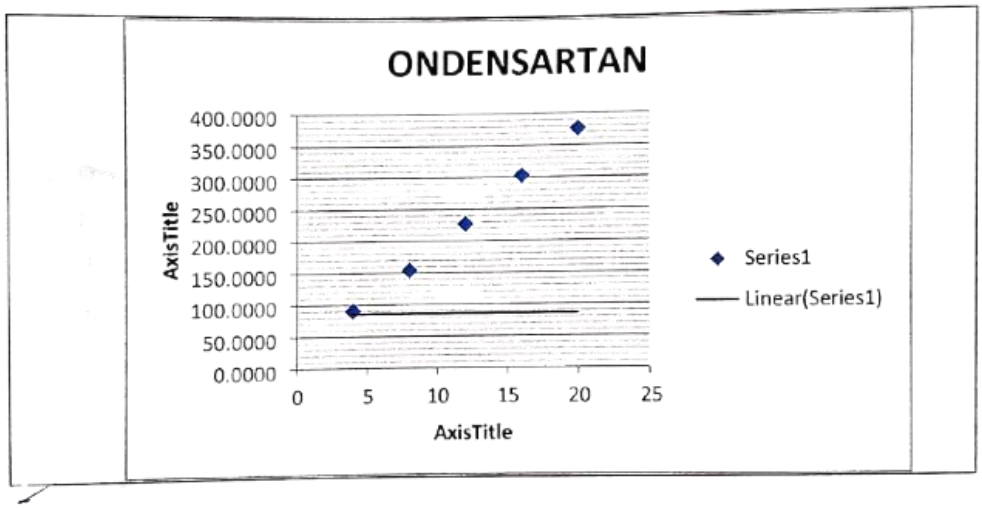

Figure 1.4: Calibration Curve For Ondansetron.

F. Differential Scanning Calorimetry study

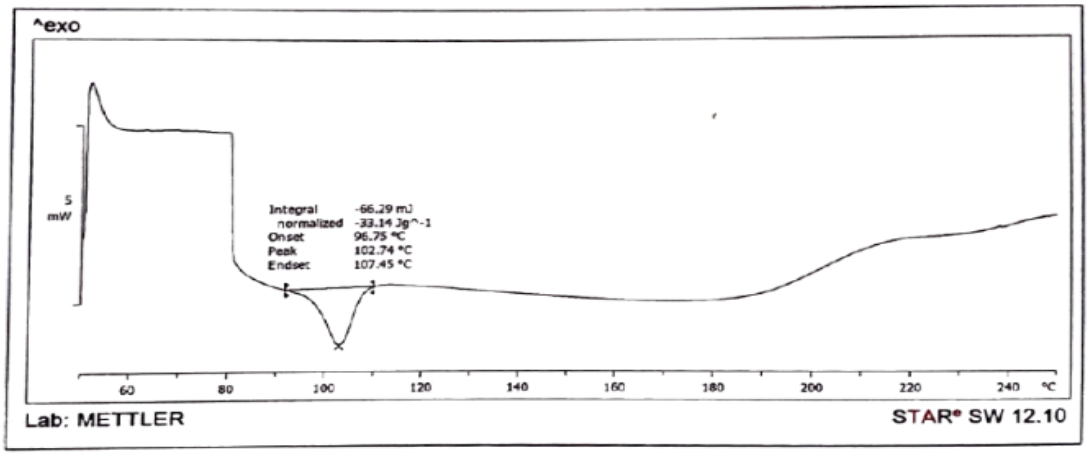

Figure 1.5: DSC Graph Of Ondansetron.

G. Drugexcipients interaction

It was carried out by using FTIR and Differential Scanning Calorimetry (DSC). Thesetechniques have been used to study the physical and chemical interaction betweendrugand excipients used.

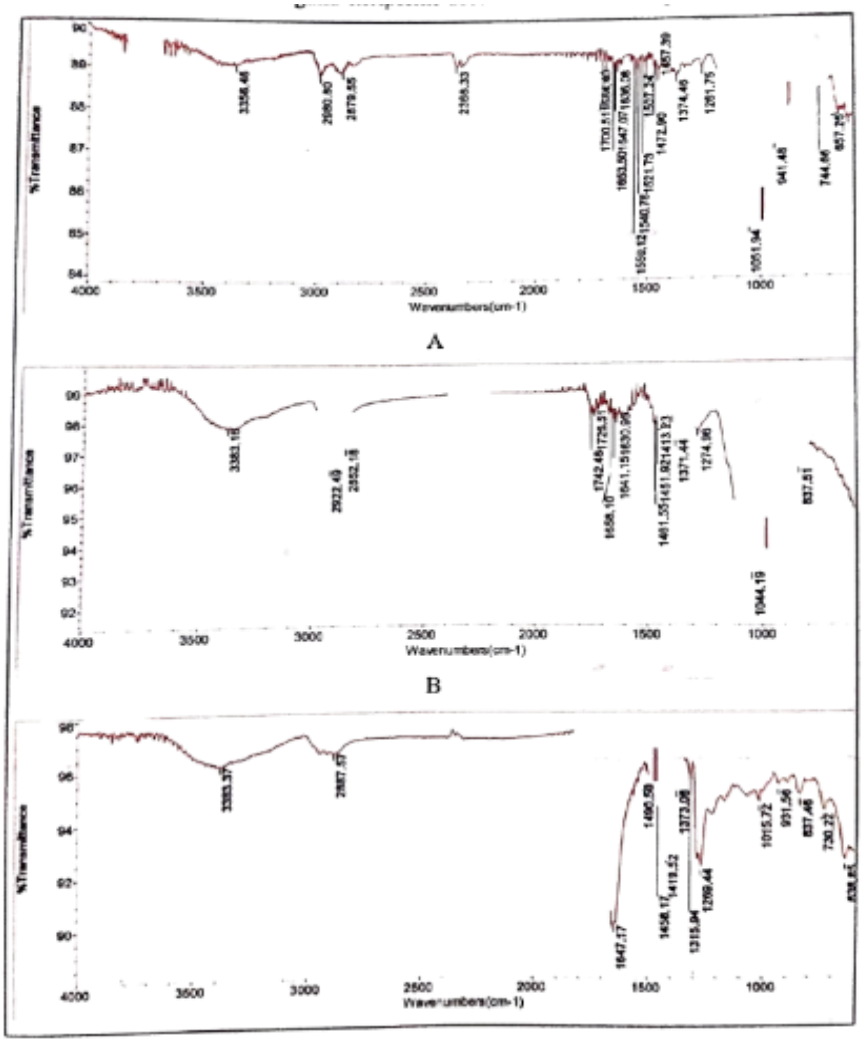

Figure 1.6: Comparative study of drug and excipients by FTIR spectrum (A)Drug+HPMC K4M (B) Drug+ethyl cellulose(C) Drug+Eudragit RL-100(D)Drug+HPC.

Evaluation of granules

Table 1.2: Evaluation parameters ofgranules.

Formulations	Bulk Density (g/cc)	apped Density (g/cc)	Carr'scompressibility index	Hausner's ratio	Angle of repose (degree)
F1	0.211	0.380	0.444	1.800	35.68
F2	0.221	0.387	0.428	1.751	42.30
F3	0.214	0.378	0.433	1.766	35.68
F4	0.229	0.370	0.381	1.615	35.68
F5	0.22	0.367	0.400	1.668	41.34
F6	0.218	0.390	0.441	1.788	35.68
F7	0.221	0.385	0.462	1.859	40.69

Evaluation Of Tablets

A. Tablet thickness and size

Table 1.3: Size and thickness of tablets.

Formulations	Thickness(mm)	Diameter(mm)
F1	5.0	10.5
F2	5.2	11.2
F3	5.2	9.5
F4	5.3	11.5
F5	5.4	10.9
F6	5.4	11.2
F7	5.3	11.5

Table 1.4: Table thardness, friability and average weight.

Formulations	Hardness (kg/cm^2)	Friability (%)	Average weight(m g)
F1	3.8	0.21	482
F2	4.2	0.43	497
F3	3..6	0.28	500
F4	4.3	0.30	489
F5	3.8	0.47	493
F6	4.6	0.49	490
F7	4.3	0.51	487

B. Drugcontent

Table 1.5: Drug Content.

Formulation	Assay
F1	94.16%
F2	99.23%
F3	100.86%
F4	98.27%
F5	96.80%
F6	95.26%
F7	99.86%

C. Buoyancy time

Table 1.6: Total Floating Time.

Formulation	TFT(hrs)
F1	>12
F2	10.5
F3	9.5
F4	11.5
F5	12
F6	12
F7	>12
F8	>12

D. Swelling Index of Tablet

Table 1.7: Swelling index of formulations.

Formulation	TIME(HRS)						
	0	**1**	**2**	**3**	**4**	**5**	**6**
F1	0	41.25	54.48	65.32	70.02	88.12	101.43
F2	0	35.21	48.92	55.76	69.52	78.2	89.44
F3	0	28.45	42.78	53.81	67.72	75.02	84.88
F4	0	45.73	59.76	67.72	78.85	89.45	101.24
F5	0	36.76	48.98	59.54	67.06	81.78	93.46
F6	0	32.55	43.35	57.32	62.45	74.09	87.98
F7	0	49.25	61.54	72.9	82.37	92.54	125.67

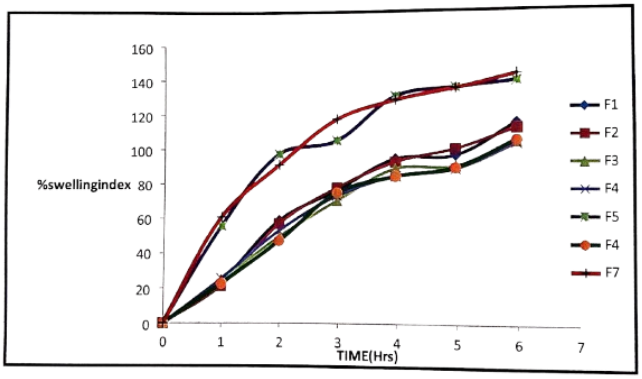

Figure 1.8: Swelling behaviour of formulations F1 to F7.

E. Release Profile Comparison

Table 1.8: The values of Similarity Factor (f2) and Difference factor (fl) ofrelease files of cefuroxime axetil floating tablets.

Formulation	Similarity Factor (f2)	Difference factor (fl)
(F1) F5	39	29
(F1) F6	50	16
(F1) F7	36	30
(F2) F5	29	55
(F3) F6	38	29
(F4) F7	40	21

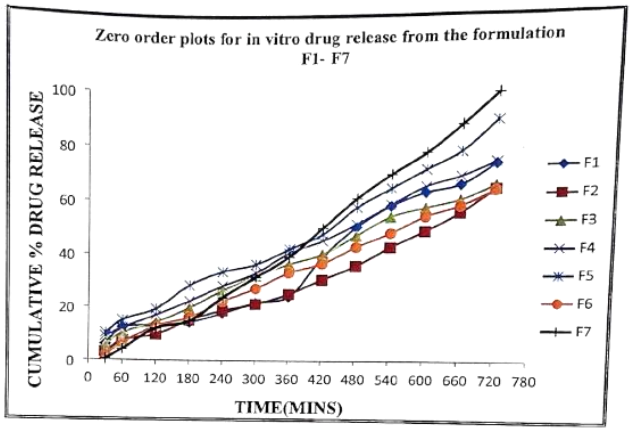

Figure 1.9: Zero order plots of the in vitro drug release from the formulations F1-F7.

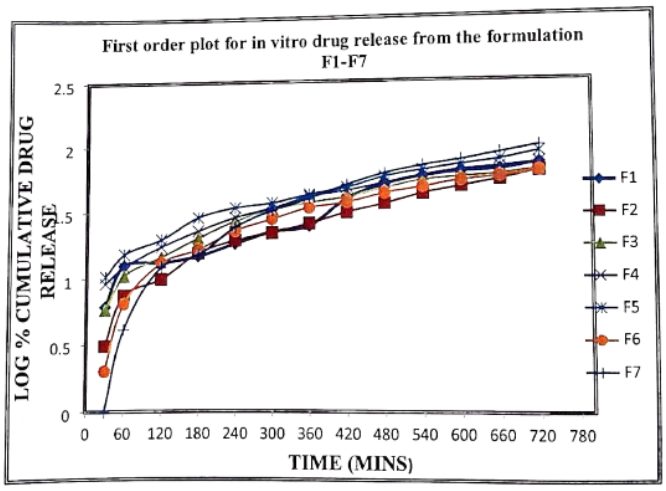

Figure 1.10: First order plots of the in vitro drug release from the formulations F1-F7.

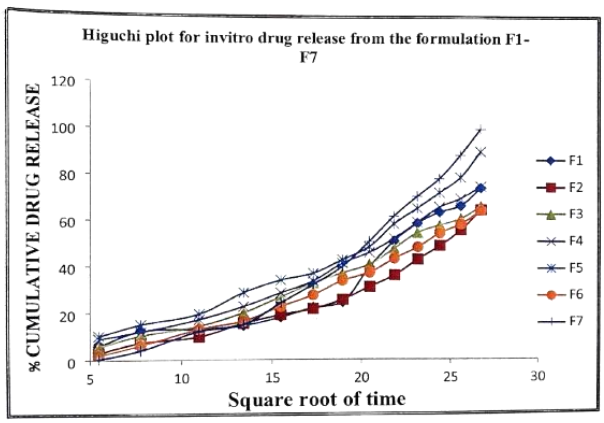

Figure 1.11: Higuchi plots of the in vitro drug release from the formulations F1- F7.

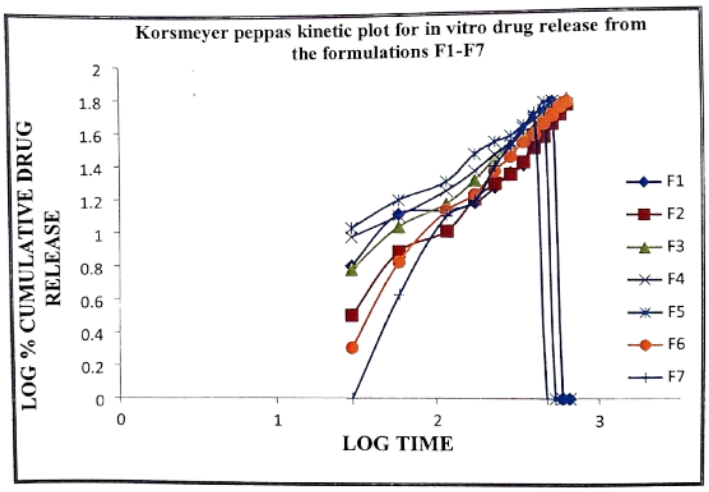

Figure 1.12: Korsmeyers peppas plots of the in vitro drug release from the formulation F1-F7.

CONCLUSION

The present investigation deals with the formulation and evaluation of effervescent based floating tablet of Ondansetron using four different polymers such as HPMC K4M, Ethyl cellulose, Eudragit-RL 100, HPC. For the present study an attempt was madeto prepare the GRDDS of Ondansetron with four different polymers such as HPMC K4M, Ethyl cellulose, Eudragit-RL 100, HPC and their combinations. The study reveals that the drug release from formulations is depend upon the swelling. molecular weight and diffusion ability of polymers. From the observation it is concluded that formulation containing HPMC K4M and HPC i.e F1 & F4 shows the better release rate as it is used alone and having good swelling properties. The drug release from F6 (HPMC K4M: Eudragit RL 100) shows that, as HPMC K4M used in combination with eudragit RL 100, the drug release of formulation is decreases as compare to F1 (HPMC K4M). This is because of the swelling properties of polymers. Developed floating tablets possessed the required physico-chemical parameter such as like hardness, friability, weight variation, drug content, swelling index and floating properties. All the developed floating tablets floated up to 12 h. From the above observation it is concluded that formulation F7 (HPMC-K: HPC) is the best formulation among all other 6 formulations because it is showing very controlled release of drug from Tablet formulations. Thus, the objective of the present work of formulating a floating dosage form for Ondansetron by using different proportions and combinations of release rate controlling and gel forming polymers has been achieved with success.

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Conflict Of Interest

The authors declare that there is no conflict of interest regarding the publication of this research work.

REFERENCE

1. Chawla, G., Gupta, P., Bansal, A.K., Gastroretentive drug delivery systems. In: Jain N.K., editor. Progress in controlled and novel drug delivery system. 1" ed. New Delhi (India): CBS Publishers and Distributors, 2004; 76-97.
2. Kawashima, Y., Takeuch, H., Yamamoto, H., Gastrointestinal retentive microparticulate system to improve oral drug delivery. In: Wise DL, editor. Handbook of pharmaceutical controlled release technology. New York: Marcell Dekker Inc, 2000; 505-25.
3. Arora, S., Ali, J., Ahuja, A., Khar, R.K., Baboota, S., Floating drug delivery systems: A Review. AAPS PharmSciTech., 2005; 6: Article 47.
4. Chatterjee, C., Human physiology. 11th ed. Place: Medical allied Agency, 2001; 1: 435-36.
5. Deshpande, A.A., Shah, N.H., Rhodes, C.T., Malick, W., Development of a novel controlled-release system for gastric retention. Pharm Res., 1997; 14: 815-819.
6. Vyas, S.P., and Khar, R.K., Controlled Drug Delivery Concept And Advances. New Delhi: Vallabh Prakashan. 1 "edition, 2000; 1: 54,155,196.
7. Arora, S., Javed, A., Ahuja, A., Khar, R.K., Baboota, S., Floating drug delivery system: A review. AAPS PharmSciTech., 2005; 6: Article 47.
8. Tortora, G.J., Grabowski, S.R., eds. Principles of Anatomy and Physiology. John wiley & sons. Inc. 10 hedition., 2003; 1861.
9. Garg, S., Sharma, S., Gastroretentive drug delivery systems. Business Briefing: Pharmatech, 2005; 67: 265-272.

10. Yeole, P.G., Khan, S., and Patel, V.F., "Floating drug delivery system: Need and development", Indian J. Pharm. Sci, 2005; 67: 265-272.
11. Aurora, J., and Sant, V. A., gastric retention drug delivery system. WO 048223, 2007.
12. Jain N.K., In Controlled and Novel Drug Delivery, 1st Edn, CBS Publishers & Distributors, 1998, 1-3Singh, B.N., Kim, K.H., Drug Delivery: Oral Route. In: Swarbrick J, Boylan JC, editors. Encyclopedia of pharmaceutical technology. 3rd ed. New York (USA): Informa Healthcare Inc, 2007; 1: 1242-1265.
13. Nayak, A., Maji, R., and Das, B., "Gastroretentive drug delivery systems: A review", Asian Journal of Pharmaceutical and Clinical Research, 2010; 3: 2-10.
14. Singh, S., Joshi, V., and Barpete, P., "Gastroretentive drug delivery system: Current approaches", Journal of Pharmacy Research, 2009; 2: 881-886.
15. Garg, R., Gupta, G., Progress in controlled gastroretentive delivery systems, Tropical Journal of Pharmaceutical Research, 2008; 3: 1055-1066.
16. Garg, S., and Sharma, S., "Gastroretentive drug delivery systems", Business Briefing: Pharnatech, 2003; 160-166.
17. Mazer, N., Abisch, E., Gfeller, J.C., Laplanche, R., Bauerfeind. P., Cucala, M., Intragastic behavior and absorption kinetics of a normal and "floating" modified-release capsule of isradipine under fasted and fed conditions. J Pharm Sci., 1988; 77(8): 647-57.
18. Jain, N.K., editor. Progress in controlled and novel drug delivery system. ed. New Delhi (India): Singh, B, Ahuja N. Response surface optimization of drug delivery system. In: Jain CBS Publishers and Distributors, 2004; 76-97.
19. Bardonnet, P.L., Faivre, V., Pugh, W.J., Piffaretti, J.C., Falson, F., Gastroretentive dosage forms: overview and Special case of Helicobacter pylori. J Control Rel., 2006; 111: 1-18.
20. Liu, S., Wang, N., Liu, R., Oral modified release drug delivery for water insoluble drugs. In: Liu R, editor. Water insoluble drug formulation, 2nd ed. Boka Raton (FL): CRC press, 2008; 609-32.
21. Loganathan, V., Saravanakumar, T., Bhojwani, A., Mullaichavam, A., Nandgude, T. Formulation, development and evaluation of Ofloxacin containing floating drug delivery system. Asian J Pharm., 2006; 1: 22-24.
22. Klausner, E.A., Lavy, E., Friedman, M., Hoffman, A., Expandable gastroretentive dosage forms. J Control Rel., 2003; 90(2): 143-162.
23. Gupta, P., Vermani, K., Garg, S., Hydrogels. Drug Discov Today, 2002; 7: 569-579.