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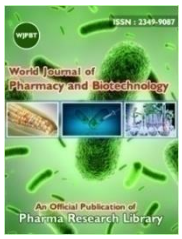

Preparation and Evaluation of Famotidine Gastroretentive Tablets by Melt Granulation Method

B. Ranganayakulu*, Avula Priyanka[1], Dr. S. Mohammed Yusuf[2]

*,[2] *Associate Professor, Srinivasa Institute of Pharmaceutical Sciences, Proddatur, A.P., India*
[1]*Srinivasa Institute of Pharmaceutical Sciences, Proddatur, A.P., India*

A B S T R A C T
The present study involves the formulation and evaluation of gastroretentive drug delivery of Famotidine tablets. This type of drug delivery helps to retain the drug in the stomach. The swelling property of the formulation helps to retain the drug in the stomach, by swelling to such an extent so that cannot pass out of the stomach. Drugs that have poor bio-availability because of their limited absorption to the upper gastrointestinal tract can be delivered efficiently into FDDS. Thereby maximizing their absorption and improving their absolute bioavailability. The floating concept can also be utilized in the development to treating various diseases.

Keywords: bioavailability, FDDS, gastroretentive drug delivery, Famotidine

AR T I C L E I N F O

Corresponding Author
B. Ranganayakulu
Associate Professor,
Srinivasa Institute of Pharmaceutical Sciences,
Proddatur, A.P. India

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1. Introduction

Dosage forms that can be retained in the stomach are called gastro retentive drug delivery system(GRDDS).GRDDS can improve the controlled delivery of drugs that have an absorption window by continuously releasing the drug for a prolonged period of time before it reaches its absorption site. Oral controlled release (CR) dosage forms (DFs) have been developed over the past three decades due to their considerable therapeutic advantages such as ease of administration, patient compliance and flexibility in formulation. However, this approach is be filled with several physiological difficulties such as inability to restrain and locate the controlled drug delivery system within the desired region of the gastrointestinal tract (GIT) due to variable gastric emptying and motility. Furthermore, the relatively brief gastric emptying time (GET) in humans which normally averages 2-3 h through the major absorption zone, i.e., stomach and upper part of the intestine can result in incomplete drug release from the drug delivery system leading to reduced efficacy of the administered dose[(1)]. Therefore, control of placement of a drug delivery system (DDS) in a specific region of the GI tract offers advantages for a variety of important drugs characterized by a narrow absorption window in the GIT or drugs with a stability problem.

2. Materials and Methods

Table 1: List of materials used

S.No.	Materials	Supplier
1.	Famotidine	Molecules India Pvt.Ltd.
2.	HPMC K4M	Sooriyan pharmaceuticals., Chennai
3.	HPMC K15M	Sooriyan pharmaceuticals., Chennai
4.	HPMC K100M	Sooriyan pharmaceuticals., Chennai
5.	Bees wax	Fine Chem, industries.
6.	Sodium bi carbonate	Fine Chem, industries.
7.	Lactose (monohydrate)	Standard chemicals
8.	Magnesium stearate	Advance labs
9.	Talc	Fine Chem, industries.

Table 2: List of instruments used

S.No.	Instruments	Manufacturer
1	Electronic balance	Shimadzu Corporation, AW220 &BX6205
2	FTIR spectrophotometer	Shimadzu Co UV-1700
3	UV/Visible spectrophotometer	Lab India UV 3000
4	Dissolution Apparatus(USP)	Electro lab Pvt. Ltd.
5	Tablet Hardness tester	Monsanto Hardness tester
6	Friability test apparatus	Roche Fribilator
7	Tap Density Apparatus	ErwekaPvt.Ltd
8	pH meter	Systonic 335
9	Tablet compression machine	Proton Multipress
10	Vernier Caplier	Digimatic

Preformulation: Preformulation studies are carried out in order to evaluate the physical and chemical properties of the drug alone and in the combined form with the excipients. These studies are important to predict the physical and chemical properties and stability of the drug and excipients.

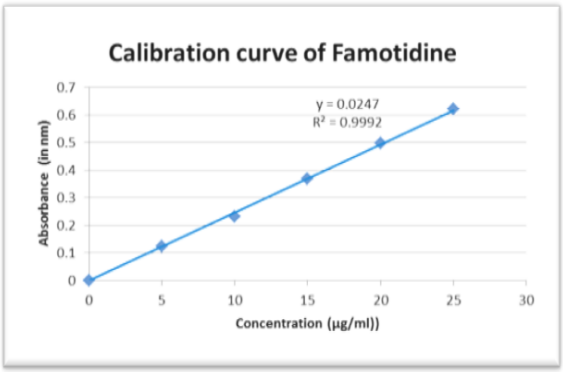

Fig 1: Calibration curve of Famotidine

3. Results and Discussion

Flow properties: The results show that the drug having poor flow.

Table 3: Flow Properties

Material	Angle of repose
Famotidine	27.14^0

Table 4: Powder Compressibility

Material	Compressibility index	Hausner's ratio
Famotidine	11.27	1.44

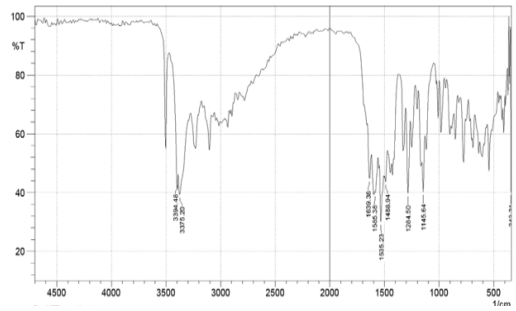

Fig 2: FT-IR of Famotidine

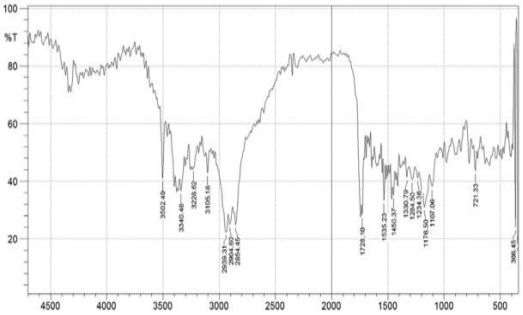

Fig 3: FTIR of Famotidine and Excipients

***In-vitro* release profile:** From the in-vitro dissolution study of all formulations, formulation F1 gave 84% release at the end of 24th hour, hence F1 have choosen as best formulation.

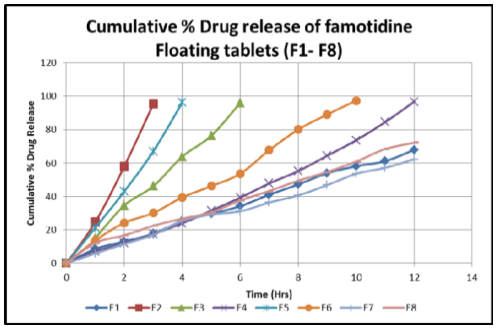

Fig 4: Showing in-vitro drug release profile for F1-F8 formulations

Drug release kinetics:

N value = 0.8274. The regression coefficient values and n values show that the drug releases follow Non - Fickian release.

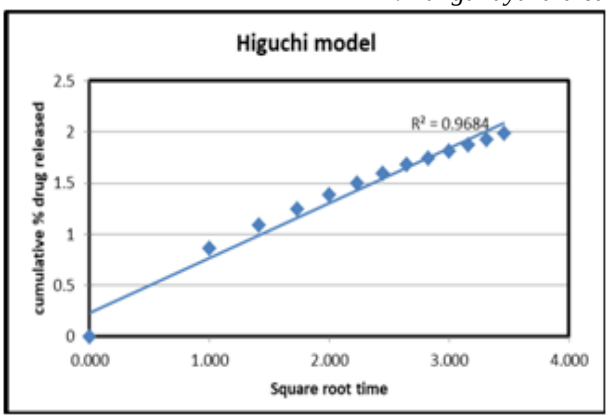

Fig 5: Higuchi Model

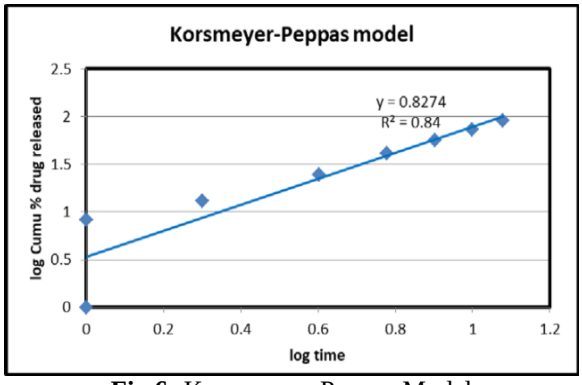

Fig 6: Korsemeyer Peppas Model

4. Conclusion

The present study involves the formulation and evaluation of gastroretentive drug delivery of Famotidine tablets. This type of drug delivery helps to retain the drug in the stomach. The swelling property of the formulation helps to retain the drug in the stomach, by swelling to such an extent so that cannot pass out of the stomach. Preformulation studies which include Organoleptic properties, Bulk and Tapped densities, Carr's index, Hausner's ratio, Melting point, pH, Solubility, were carried out are as per IP specifications. Drug-excipient compatibility studies were performed which shows that there is no interaction between drug and polymers. Evaluation studies have been performed for tablets include friability, hardness, weight variation, content uniformity, buoyancy studies are as per IP specifications. Drug release studies have been performed by using 0.1N HCl for 12 hrs. These studies have shown that the formulation F4 gave better drug release up to 12 hrs which is formulated with HPMC K100M. Drugs that have poor bio-availability because of their limited absorption to the upper gastrointestinal tract can be delivered efficiently into FDDS. Thereby maximizing their absorption and improving their absolute bioavailability. The floating concept can also be utilized in the development to treating various diseases. Buoyant delivery system considered as a beneficial strategy for the treatment of gastric and duodenal cancers.

Table 5: Formulation of Famotidine tablets

Ingredients(in mg)	Formulation batches							
	F1	F2	F3	F4	F5	F6	F7	F8
Famotidine	40	40	40	40	40	40	40	40
HPMC K4M	0	30	0	0	30	30	0	30
HPMC K15M	0	0	30	0	30	0	30	30
HPMC K100M	0	0	0	30	0	30	30	30
$NaHCO_3$	20	20	20	20	20	20	20	20
Bees wax	30	30	30	30	30	30	30	30
Lactose	98	68	68	68	38	38	38	8
Magnesium sterate	6	6	6	6	6	6	6	6
Talc	6	6	6	6	6	6	6	6
Average weight	200	200	200	200	200	200	200	200

Table 6:*In-vitro* release profile

Time(hrs)	F1	F2	F3	F4	F5	F6	F7	F8
1	8.65	24.79	15.13	7.24	21.32	13.76	5.91	12.25
2	13.12	58.12	34.67	12.09	43.13	24.27	11.64	16.79
3	17.75	95.39	46.21	17.62	67.08	30.14	17.08	22.47
4	25.34		63.90	23.98	96.34	39.51	25.42	26.75
5	29.59		76.39	31.56		46.24	29.32	30.54
6	34.23		96.14	39.34		53.69	31.13	37.67
7	41.09			47.87		67.76	36.41	43.34
8	47.23			55.23		80.09	40.69	49.50
9	53.98			64.42		89.13	46.86	54.71
10	58.14			73.7		97.43	53.63	60.92
11	61.17			84.54			57.20	68.43
12	67.91			96.78			62.32	72.19

Table 7: Drug release kinetics

Time(Hr)	cumulative % drug released	% drug remaining	Square root time	log Cumu % drug remainining	log time	log Cumu % drug released	% Drug released
0	0	100	0.000	2.000	0.000	0.000	100
1	7.24	92.76	1.000	1.967	0.000	0.860	7.24
2	12.09	87.91	1.414	1.944	0.301	1.082	4.85
3	17.62	82.38	1.732	1.916	0.477	1.246	5.53
4	23.98	76.02	2.000	1.881	0.602	1.380	6.36
5	31.56	68.44	2.236	1.835	0.699	1.499	7.58
6	39.34	60.66	2.449	1.783	0.778	1.595	7.78
7	47.87	52.13	2.646	1.717	0.845	1.680	8.53
8	55.23	44.77	2.828	1.651	0.903	1.742	7.36
9	64.42	35.58	3.000	1.551	0.954	1.809	9.19
10	73.7	26.3	3.162	1.420	1.000	1.867	9.28
11	84.54	15.46	3.317	1.189	1.041	1.927	10.84
12	96.78	3.22	3.464	0.508	1.079	1.986	12.24

Table 8: Regression coefficient of F10

Formulation	Regression coefficient (R^2) value			
	Zero-order	First order	Higuchi	Korsmeyer – Peppas (n value)
Famotidine tables	0.9955	0.7328	0.9684	0.84 (0.8274)

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