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Research article *Medical research*

Formulation, development and evaluation of mouth melting tablet of famotidine by using natural and synthetic superdisintegrants

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ABSTRACT

The Purpose of the present research was to prepare mouth melting tablet of Famotidine by using natural and synthetic superdisintegrants such as, ispaghula husk powder, croscarmilose, crospovidone . the objective to reduced patient compliance and the reduced onset action of due to fast pass metabolism. Tablets prepared by direct compression method. The powder mixtures prepared to both pre and post compression evaluation parameters such as micromeritics properties, tablets hardness, friability , wetting time , disintegration time and in –vitro drug release . The results of both pre and post formulations were of acceptable to good flow ability and in-vitro release determine different model viz. zero order, first order, Hixson-Crowell equation, Higuchi model & Korsmeyer-peppas model indicate that formulation F3 found to be the best fit Korsmeyer-peppas model.

Keywords : Mouth dissolving tablets , mouth melting tablets, Fast disintegrating tablets, Direct compression , Wetting time, superdisintegrants

INTRODUCTION

Mouth melting drug-delivery systems to conventional dosage forms for pediatric and geriatric patient. Traditional tablets and capsules administered with glass of water may be inconvenient or impractical for some patients who experience difficulties in swallowing traditional oral solid-dosage forms. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally less than 60 seconds. The mouth melting tablets is also known as fast melting, fast dispersing, rapid dissolve, rapid melt, and or quick disintegrating tablet. All Mouth melting tablets approved by the Food and Drug Administration (FDA) are classified as orally disintegrating tablets.

Recently, the European Pharmacopoeia adopted the term "Orodispersible Tablet" as a tablet that is to be placed in oral cavity where it disperses rapidly before swallowing.

Famotidine as a model drug was used in the formulation. Famotidine is a H_2 receptor antagonist. A thiazole ring containing H_2 blocker which binds tightly to H_2 receptors and exhibits longer duration of action despite an elimination. Famotidine after oral administration has an onset of effect within 1 hr and inhibition of gastric secretion is present for the next 10-12 hrs. Elimination is by renal and metabolic route. It is therefore important to decrease the dose of the drug for patient with kidney or renal failure. Famotidine not only decrease both basal, food-stimulated acid secretions by 90% or more but also promote healing of duodenal ulcer.

Fast disintegrating tablets of Famotidine were prepared by superdisintegrates addition method with different concentration, such as, ispaghula husk powder, croscarmilose, crospovidone, used as superdisintegrants, mannitol used as diluents.

Disintegration time is very important for FDT's, rapid disintegration assists swallowing & drug absorption in the buccal cavity, thus promoting bioavailability. Disintegration time of prepared FDT's was in the range of 42 sec to 126 sec & the order was ispaghula husk powder < croscarmilose < crospovidone. As the concentration of superdisintegrants in the formulation were increased, the disintegration time was

found to decreased, in the wetting time, crospovidone take more wetting time than comparison of ispaghula husk powder and croscarmilose.

MATERIAL

Famotidine , Ispaghula husk powder and Crospovidone were received as gift from R.K.Enterprises, Meerut , some excipients like- Croscarmilose Sodium, Mannitol, Talc, Magnesium stearate, and Microcrystalline cellulose were received as gift from CDH Laboratory, New Delhi and some excipients like- Aspartame , HCL were received as gift from Qualigens Fine Chemicals, Mumbai

Formulation of mouth melting tablets

The 9 formulation were prepared using various steps.

- All ingredients were weighed accurately.
- All ingredients were mixed together in appropriate proportions.
- Then, all mixed powder was passed through 20# mesh sieve.
- The all mixed powder was evaluated for pre compression parameters.
- The all mixed powder was compressed by tablet punching machine.
- Finally, the tablets were evaluated.

Table 1 Different Formulation of Famotidine Fast Dissolving Tablet

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Famotidine (API)	20	20	20	20	20	20	20	20	20
Ispaghula Husk	9	12	15	-	-	-	-	-	-
Croscarmilose sodium	-	-	-	9	12	15	-	-	-
Crospoidone	-	-	-	-	-	-	9	12	15
Microcrystalline cellulose	25	25	25	25	25	25	25	25	25
Microcrystalline cellulose	2	2	2	2	2	2	2	2	2
Talc	4	4	4	4	4	4	4	4	4
Magnesium stearate	2	2	2	2	2	2	2	2	2
Mannitol	148	145	142	148	145	142	148	145	142
Total	210	210	210	210	210	210	210	210	210

*** All weights are expressed in mg.**

The following parameters were mixed for the final tablets obtained

- Punch size : 12mm
- Thickness : 3±0.5mm
- Hardness : 2 ±1kg/cm^2
- Weigh variation : 1 -5%

EVALUTION PARAMETERS AND RESULT

Determination of λ_{max}

The pure drug Famotidine was scanned by uv- spectroscopy at 200-400nm to determine λ_{max}.
The peak was observed at 267nm for famotidine in 0.1N HCl .

Standard Calibration Curve

The Standard Calibration Curve of Famotidine was obtained by plotting Absorbance V/s Concentration .Table 2 shows the Absorbance values of famotidine . The standard curve is shown in Fig. no. 1 and 2

Table no. 2 The Standard Calibration result of famotidine

S.NO.	Concentration (ug/ml)	Absorbance (nm)
1	2	0.08
2	4	0.167
3	6	0.243

4	8	0.323
5	10	0.383

Equation

$y = 0.038x+.010$

$R^2 = 0.996$

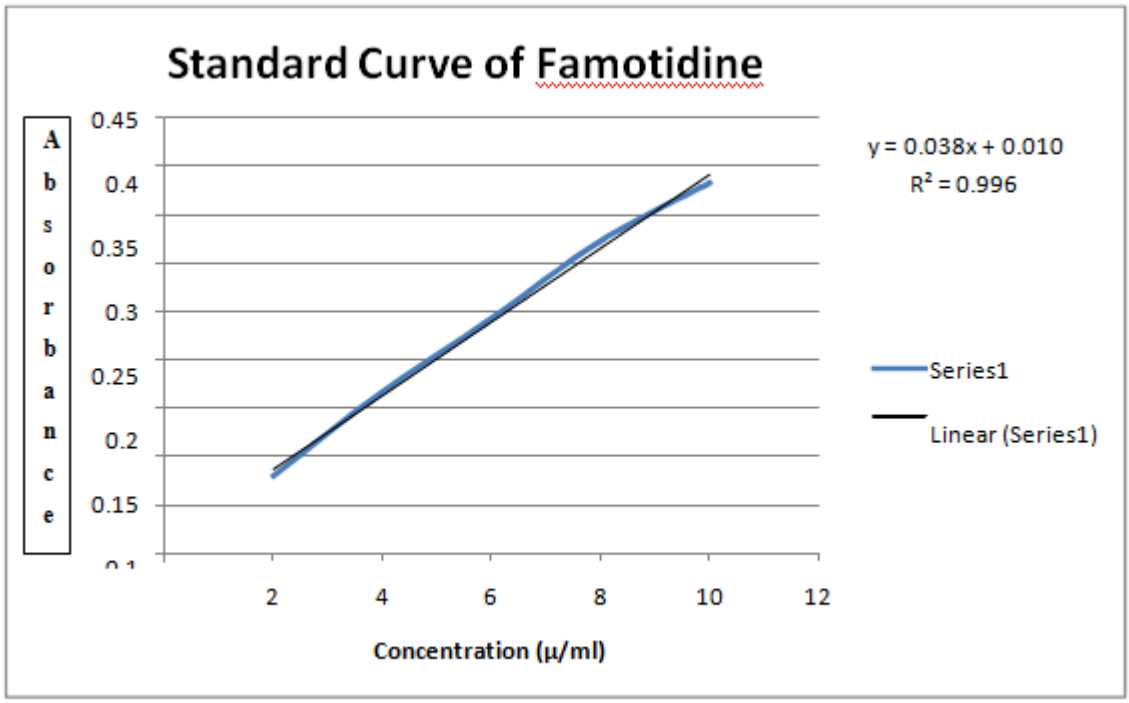


Fig .no. 1 Standard curve of famotidine in 0.1N HCL

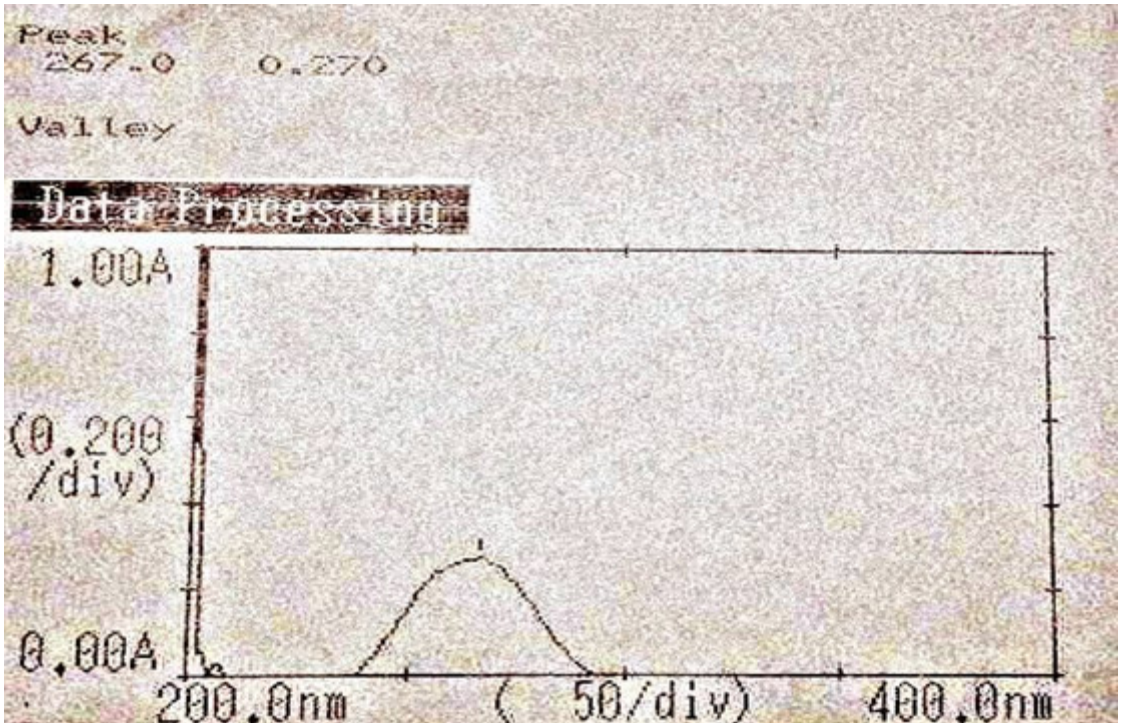


Fig. no.2 Standard curve of famotidine in 0.1N HCL by UV spectroscopy

Pre- Compression Evaluation

Bulk Density

It defined as the mass of powder divided by the bulk volume. The bulk density were found between 0.345 - 0.393 g/cc .

Tapped Density

It defined as the mass of powder divided by the tapped volume. The tapped density were found between 0.397 - 0.463 g/cc .

Compressibility Index

It is used to measure the porosity of the powder to be compressed to evaluate the inter particulate interaction . It was found between 13.67 - 17.35 . which revealed that all powders had Fair to passable flow properties .

Hausner's ratio

IT is used to know ease of flow of powder . Hausner's ratio were found between 1.13- 1.19 which revealed that all powders blend had Good flow properties .

Angle of Repose

It is defined as the maximum angle possible between the surface of pile of powder were horizontal surface. The angle of repose were found between 31.07 - 33.12 which revealed that all powder blends had good flow.

Table 3 Different Formulation of Famotidine Fast Dissolving Tablet

Formulations (code)	Bulk density (g/cc) ± S.D. n= 3	Tapped density (g/cc) ± S.D. n= 3	Carr's ratio ± S.D. n= 3	Hausner's Index % ± S.D. n= 3	Angle of repose ± S.D. n =3
F1	0.386±0.025	0.440±0.036	31.07±0. 43	14.05±3.76	1.15±0.07
F2	0.367±0.015	0.463±0.045	32.12±0.23	15.27±3.45	1.16±0.05
F3	0.393±0.027	0.448±0.052	31.87±0.32	14.44±3.33	1.14±0.07
F4	0.377±0.032	0.418±0.048	31.97±0.37	14.56±3.54	1.17±0.03
F5	0.345±0.023	0.446±0.039	31.54±0.27	15.45±4.23	1.18±0.08
F6	0.389±0.031	0.459±0.027	32.33±0.32	15.37±3.37	1.15±0.05
F7	0.376±0.028	0.445±0.033	33.12±0.21	13.67±4.47	1.19±0.02
F8	0.387±0.025	0.397±0.018	32.08±0.45	16.33±3.57	1.13±0.07
F9	0.381±0.033	0.410±0.023	31.17±0.33	17.35±2.57	1.16±0.04

*** Average of 2 readings**

Thickness

Thickness of tablets were calculated using the screw gauge. Thickness the formulation were found between 0.35±0.044 - 0.41±0.004 .

Hardness

It is the force which is required to break a tablets. Hardness for all formulations were found between 3.2±0.20 - 4.0±0.17 kg/ cm^3.

Weight Variation

The weight of the tablets was determine to ensure that a tablets contain proper amount of the drug. all formulation passed the weight variation and the percentage deviation from average weight of tablets .

Friability (%)

Friability defined as loss in weight of tablets during transportation. Friability for all formulation were found between 0.576±0.022 - 1.045±0.019.

Drug content (%)

Drug content was found between 80.30±0.18- 98.8±0.14 the for all the formulations.

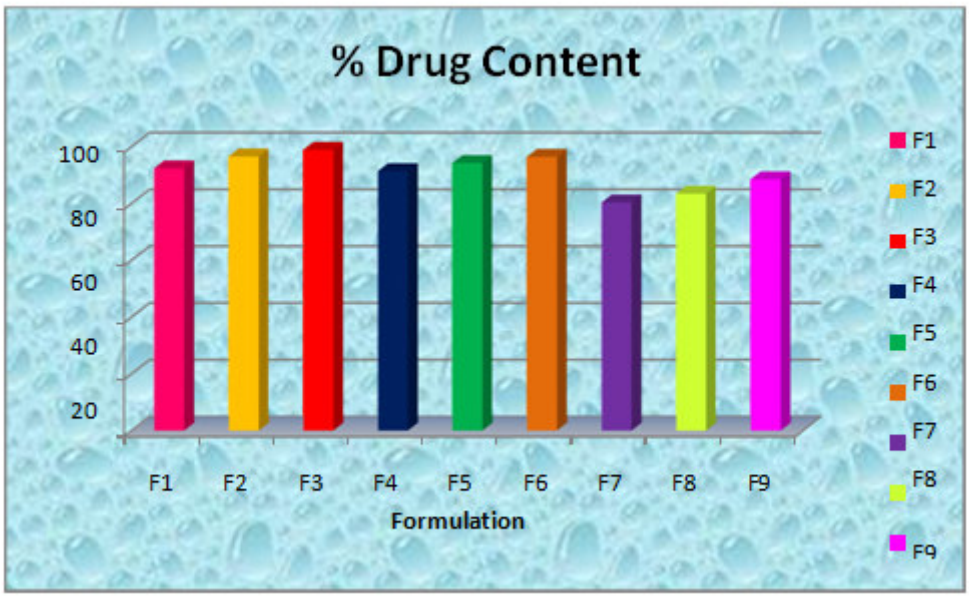


Fig.3 *In vitro* % Drug Content of various formulation of Famotidine

Table 4 Evaluation parameter of the tablet

Batch	Average weight (mg)*	Hardness (kg/cm^2)**	Friability (%)	Drug content (%)**	Thickness (mm)
F1	211.35±0.71	3.36±0.31	0.958±0.005	92.3±0.21	0.39±0.010
F2	210.3±0.21	3.43±0.23	0.856±0.010	96.5±0.14	0.38±0.004
F3	211.5±0.70	3.2±0.20	0.836±0.008	98.8±0.14	0.41±0.000
F4	210.25±0.23	3.9±0.05	1.045±0.019	91.3±0.17	0.39±0.004
F5	210.75±0.26	3.8±0.17	0.59±0.078	94.26±0.21	0.41±0.004
F6	211.2±0.41	3.5±0.07	0.74±0.122	96.36±0.17	0.35±0.044
F7	211.6±0.49	4.0±0.17	0.67±0.070	80.30±0.18	0.37±0.014
F8	211.5±0.46	4.0±0.11	0.733±0.053	83.4±0.28	0.39±0.004
F9	210.9±0.40	3.7±0.14	0.576±0.022	88.46±0.28	0.39±0.007

*** Average weight of 20 tablets was taken into consideration** Average of 3 readings**

Wetting time

Wetting time was determined because it mimics the action of saliva on tablet in oral cavity. which needs to be assessed to give an insight into capillarity and subsequently the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet. It was found between 35±1.59 - 85±1.08 seconds for all formulation.

Water absorption ratio

Water absorption ratio was found between 36.07±0.28 - 86.14±0.46 for all formulations of tablets. water absorption ratio increased which might be due to fast water uptake up to that concentration but after that water absorption ratio decreased which might be due to that gel formation occurred on initial contact of tablet with fluid and fluid could not further penetrate into the tablet.

In-Vitro disintegration time

It is the most important evaluation parameters which should be optimized in formulation of Mouth Dissolving Tablets. In-vitro disintegration time was found between 42.0±2.12 - 126±1.23 seconds for all formulations. It was observed that disintegration time was decreased on increase in concentration of natural superdisintegrants up to a certain concentration, after that concentration disintegration time increased on increase in concentration. Formulation F3 least disintegration time of 42 seconds because of higher porosity between the particles of mucilage and F7 highest disintegration time of 126 seconds because of binding effect after a certain concentration.

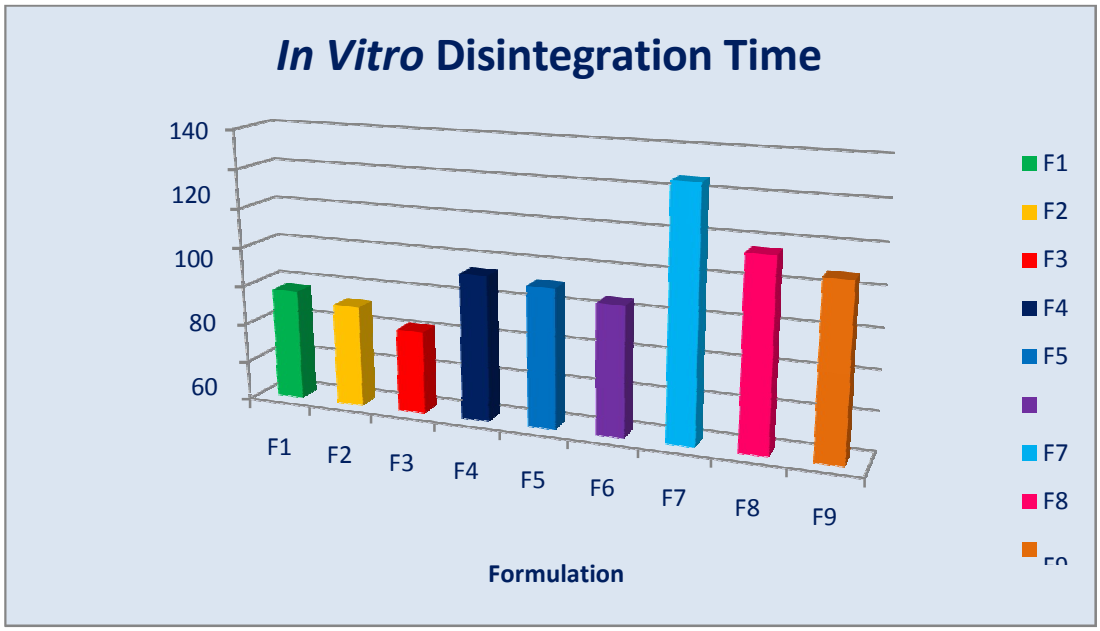


Fig.4 *In vitro* Disintegration Time of various formulation of Famotidine FDT

Table 5 Evaluation parameter of the tablet

Batch	Wetting time (sec)**	Water absorption ratio**	Disintegration time (sec)**
F1	66±2.06	72.78±0.67	56.6±1.77
F2	44±2.69	82.88±0.54	51.6±1.77
F3	35±1.59	86.14±0.46	42.0±2.12
F4	78±2.16	67.40±0.57	73.8±1.77
F5	75±1.87	73.37±0.89	70.8±2.12
F6	72±1.41	79.04±0.79	65.6±1.56
F7	85±1.08	36.07±0.28	126±1.23
F8	78±1.77	44.30±0.33	95.4±1.06
F9	74±1.23	54.13±0.65	87.0±1.45

****Average of 3 readings**

In-Vitro Drug Dissolution Studies

In-vitro dissolution study for formulated Mouth Dissolving Tablets of famotidine was carried out in 0.1 Hcl . The percentage cumulative drug release was found between 89.5±0.34-97.89±0.77% for all the formulations. Formulation F3 had highest % cumulative drug release that was 97.89±0.77% and F8 had least %cumulative drug release that was 89.5±0.34% among all formulations.

Table 6 In-vitro drug release for all formulations

Cumulative % drug release of different formulation batches*						
Formulation Code	**Time (min)**					
	5	**10**	**15**	**20**	**25**	**30**
F1	33.8±0.56	46.9±0.63	59.15±0.63	75.70±0.14	82.55±0.98	93.9±1.27
F2	35.25±0.63	44.8±0.28	57.2±0.77	76.9±0.56	85.3±0.56	95.2±0.56
F3	37.2±0.23	55.86±0.47	65.8±0.33	85.58±0.34	89.69±0.57	97.89±0.77
F4	31.72±0.67	55.53±0.39	66.87±0.74	72.67±0.67	84.19±0.23	89.5±0.34
F5	33.97±0.54	55.3±0.45	67.72±0.54	76.05±0.56	85.81±0.75	91.3±0.54
F6	34.42±0.23	55.98±0.43	68.08±0.23	73.89±0.34	83.92±0.45	92.73±0.56
F7	25.4±0.45	44.3±0.23	60.6±0.54	73.8±0.43	85.9±0.34	89.9±0.45
F8	30.19±0.19	51.48±0.34	63.31±0.23	72.94±0.75	72.94±0.75	90.58±0.18
F9	33.7±0.34	55.3±0.27	66.87±0.45	76.05±0.34	83.92±0.37	91.2±0.45

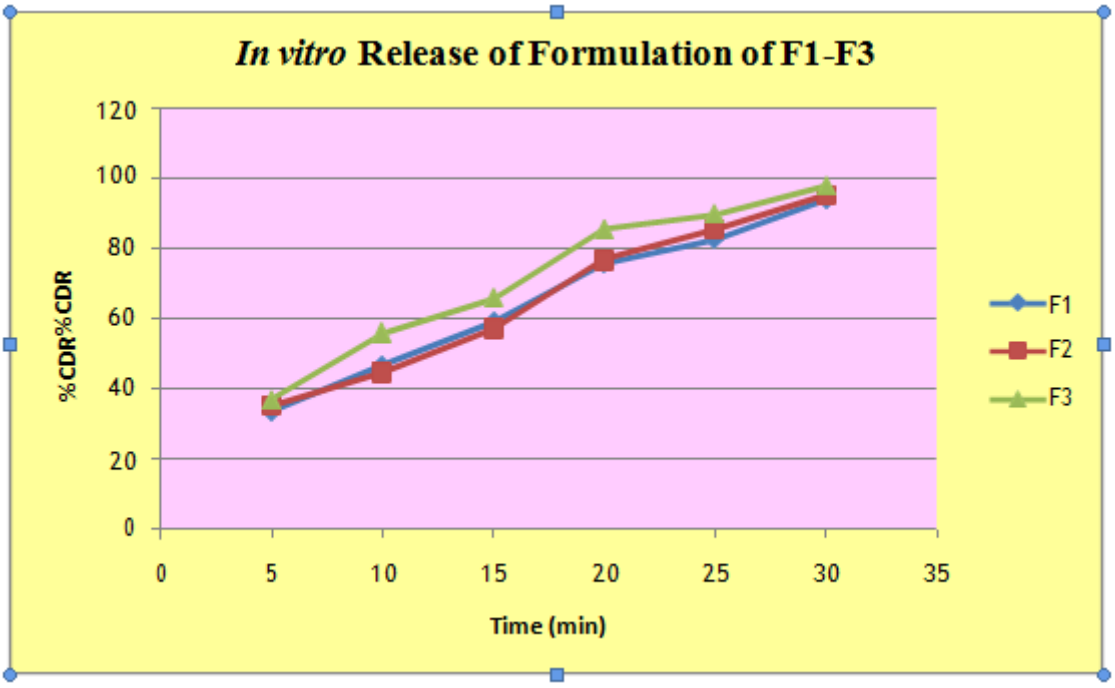


Fig. 5: In-vitro drug release of formulations F1-F3 Famotidine tablets

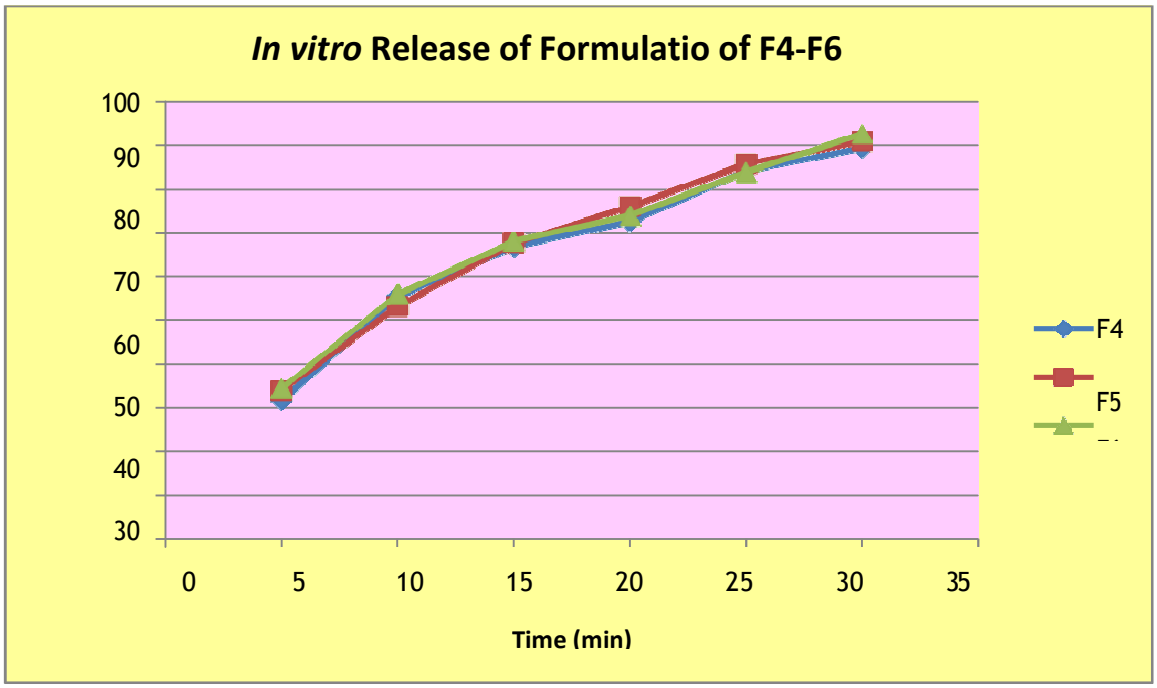


Fig. 6: In-vitro drug release of formulations F4-F6 Famotidine tablets

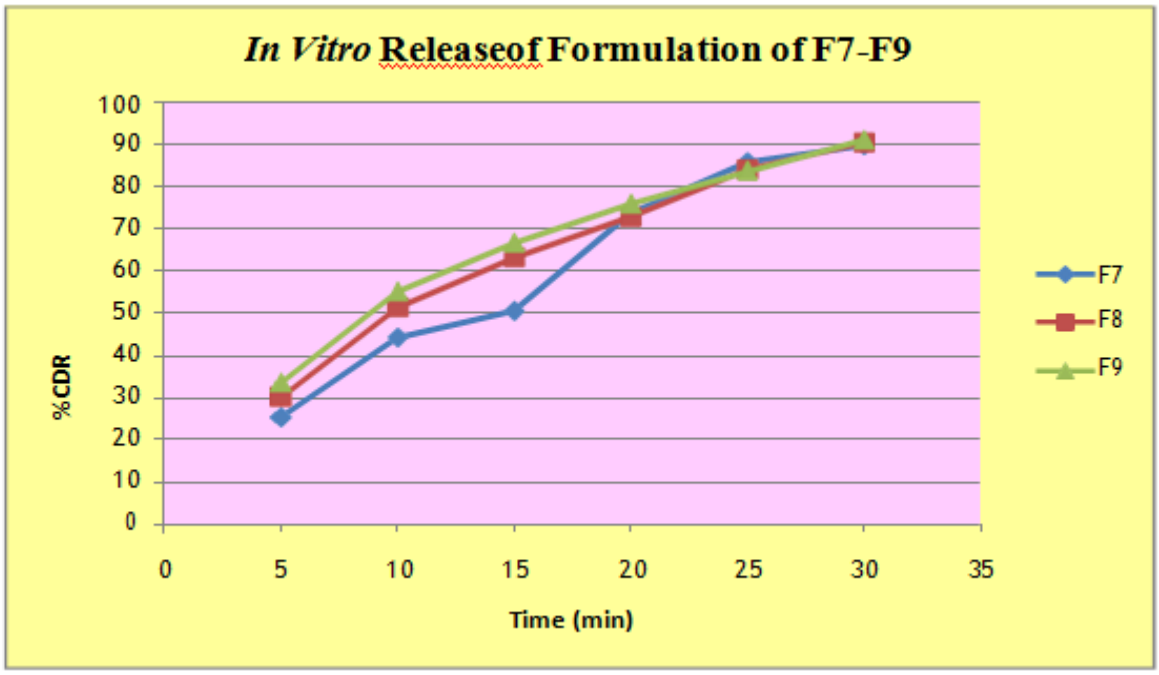


Fig. 7: In-vitro drug release of formulations F7-F9 Famotidine tablets

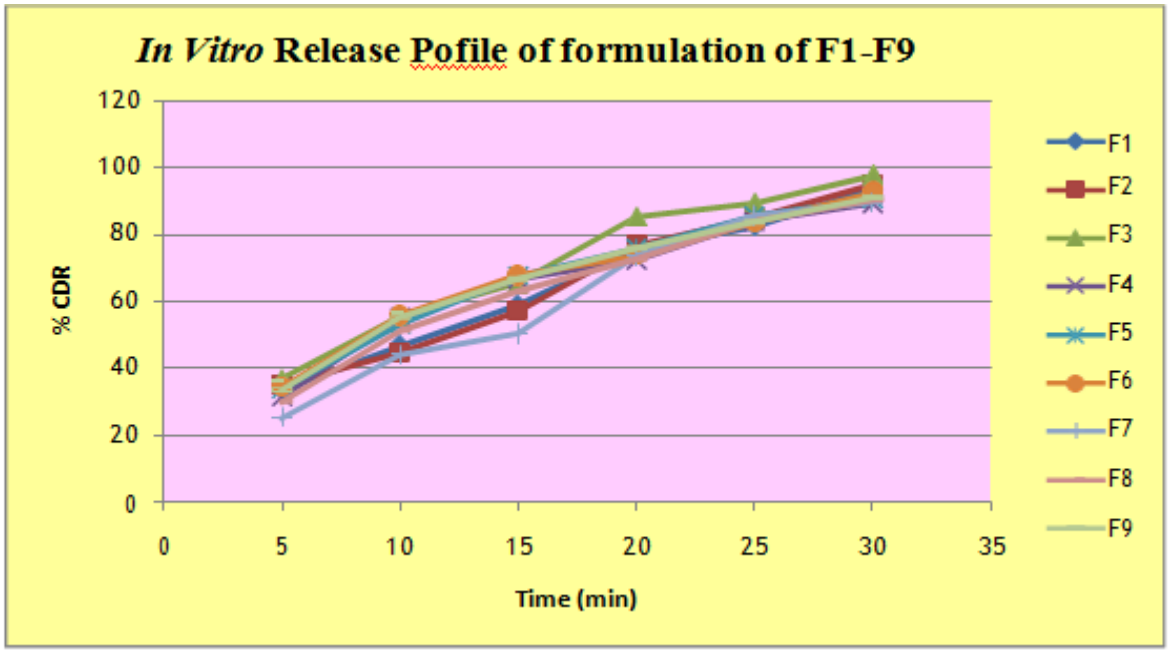


Fig. 8: In-vitro drug release of All formulation Famotidine tablets

By analysing all the above datas the formulation F3 was found to be the best formulation.

Drug Kinetics

Zero order, First order, Higuchi model, Korsmeyer-peppas model, and Hixon Crowell model were used for the evaluation of kinetic data of famotidine fast dissolving tablet. The release mechanism of famotidine fast dissolving tablet was evaluated by the n value of Korsmeyer-peppas model. The final trial was found to be F3 evaluated for kinetics parameter.

Table 7 Data for mathematical model of famotidine tablets of batch F3

Time (min)	Cumulative % drug release in %(zero order kinetics)	Log % cumulative drug remaining (first order kinetics)	Cube root drug % remaining in matrix (Hixon Crowell kinetics)
5	37.2	1.7979	3.9748
10	55.86	1.6448	3.534
15	65.8	1.534	3.2459
20	85.58	1.1589	2.434
25	89.69	1.0132	2.1764
30	97.89	0.3242	1.2826

Table 8 Data for mathematical model of famotidine tablet of batch F3

Higuchi model	Korsmeyer -peppas model		
Squar root Of time	Cumulative %drug release	Log time	Log cumulative % drug release
2.23606	37.2	0.69897	1.57054
3.162227	55.86	1	1.74710
3.87298	65.8	1.176091	1.81822
4.47213	85.58	1.301029	1.301029
5	89.69	1.39794	1.95274
5.47722	97.89	1.477121	1.99073

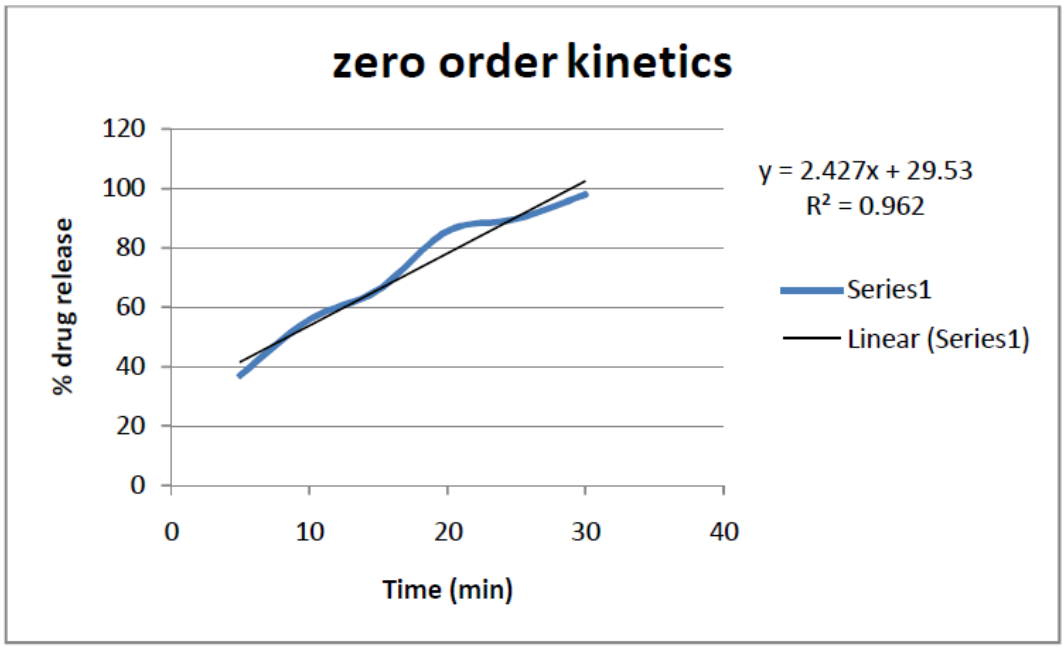


Fig 9 Zero order release model of famotidine mouth melting tablet

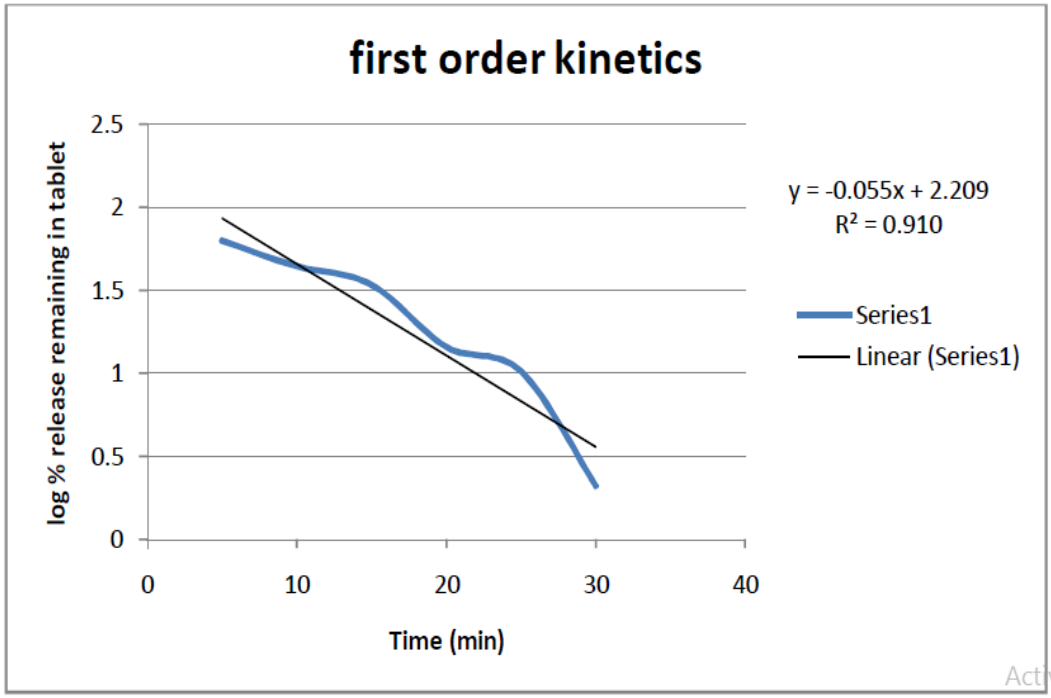


Fig. 10 First order release model of famotidine mouth melting tablet

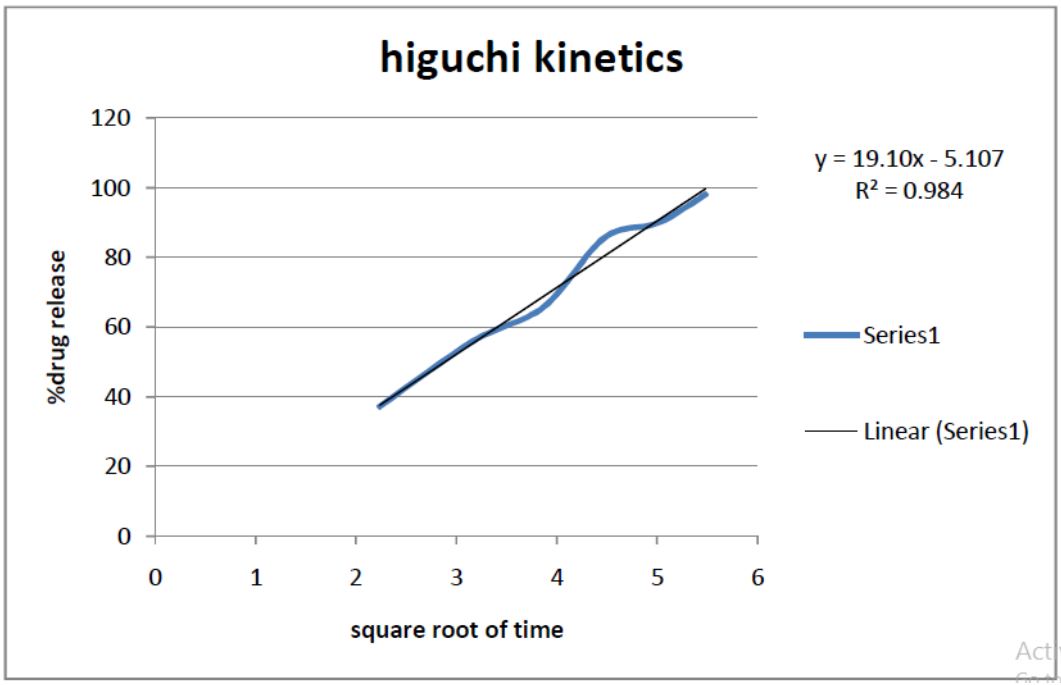


Fig. 11 Higuchi kinetics release model of famotidine MMT

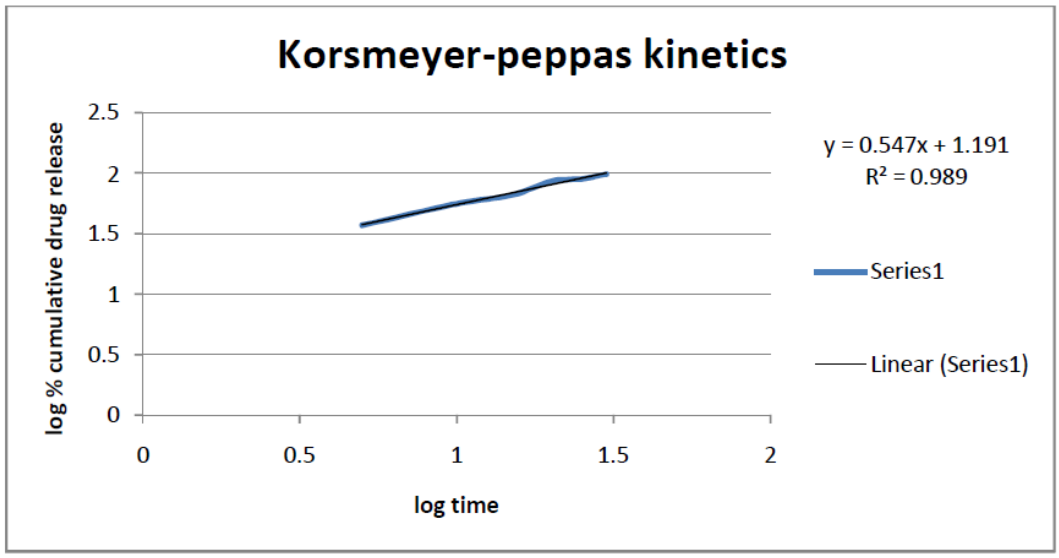


Fig. 12 Korsmeyer-peppas kinetics release model of famotidine MMT

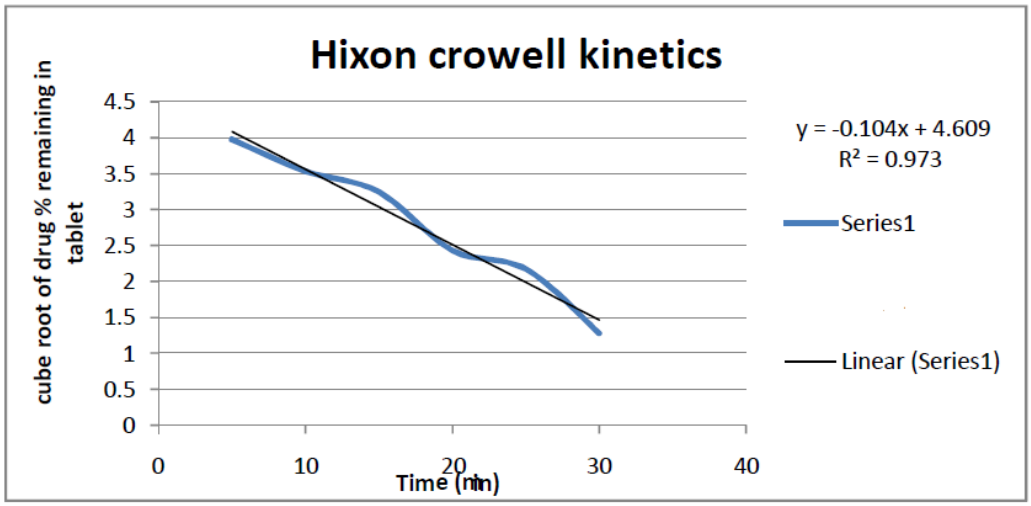


Fig. 13 Hixon Crowell kinetics release model of famotidine MMT

Table 9: Drug Kinetic model

Sr.no.	Drug kinetic model	R^2 Value
1	Zero order	0.962
2	First order	0.910
3	Korsmeyer- peppasmodel	0.989
4	Higuchi model	0.984
5	Hixson-crowell model	0.973

CONCLUSION

The conclusion drawn from the present investigation are given below:

i. Sutaible analytical method based on UV-visible spectrophotometer was developed for Famotidine. λ_{max} of 265nm is identified in 0.1NHCL.

ii. From the DSC & FT-IR spectra, the interference are verified and find that Famotidine do not interfere with excipient used.

iii. Procedure to manufacture fast dissolving tablet by dry direct compression is established.

iv. Fast dissolving tablet of Famotidine (F3) was successfully prepared using ispaghula husk powder (7.14%) by superdisintegrants addition method.

v. The tablet were prepared & based o n the result, formulation 'F3' was identified as the better formulation amongst all formulation developed for fast dissolving tablets.

vi. The manufacturing procedure was standardizes and found to were producible.

vii. *In vitro* disintegration time & wetting time show good result. Water absorption ratio indicates well absorptive in formulations.

viii. Famotidine release from fast dissolving tablet was directly proportional to the concentration of superdisitegrants used.

ix. After one month of accelerated stability developed formulation was found to be stable. By comparison of drug release before and after one-month storage (at accelerated condition) it's remain unchanged.

x. The works needs to be proved more effective by its bioavailability, pre-clinical & clinical studies.

xi. The conclusion arrived in this thesis indicated that the natural superdisintegrant, ispaghula husk powder showed better disintegrating and dissolution property than the most widely used synthetic superdisintegrants croscarmilose & crospovidone in the formulation of fast dissolving tablets.

xii. Further studied are needed to investigate these formulation for its performance *in-vivo.*

xiii. The result of the study indicates that fast dissolving tablet of Famotidine that can be successfully preparation

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