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Formulation and Evaluation of Famciclovir Floating Tablets

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ABSTRACT

Oral route of administration gets the highest priority for the delivery of drug as well as better patient compliance. Floating tablet is selected for achieving a prolonged and predictable drug delivery profile in the gastrointestinal tract to control the gastric residence time using a gastro retentive dosage form that will provide as with new and important therapeutic options. The design of oral controlled drug delivery systems is aimed primarily to achieve more predictable and increased bioavailability. However, these systems have several physiological difficulties, such as inability to restrain and localized oral control drug delivery systems within desired reasons of the gastrointestinal tract and the highly variable nature of the gastric emptying process. Gastric emptying time in humans, which is normally 2-3 hours through the main absorption area (stomach or upper part of intestine), can result in incomplete drug release from oral controlled drug delivery system leading to diminished efficacy of an administered dose. Intimate contact of oral controlled drug delivery system with the absorbing membrane has the potential to maximize drug absorption and influence the rate of drug absorption. These considerations have led to the development of oral controlled gastro retentive dosage forms possessing gastric retention capabilities. Famciclovir floating tablets are used to treat and prevent bacterial infections in the stomach and intestines.

KEY WORDS:

Bioadhesive Floating Matrix, Famciclovir, Polymers, sodium bicarbonate, and citric acid, in vitro drug release studies.

INTRODUCTION

Gastroretentive systems can increase residence time of dosage forms in the stomach thereby increase the bioavailability of drugs with narrow absorption window, drugs with less water solubility in alkaline pH of small intestine or drugs with poor stability in the intestinal or colonic environment.[1] Pharmaceutical products designed for oral delivery are mainly conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption. These immediate release dosage forms.[2,3] The design of floating drug delivery Systems (FDDS) should be primarily aimed to achieve more predictable and increased bioavailability. Now-a-days most of the pharmaceutical scientist is involved in developing the ideal FDDS.[4] Floating drug delivery system of famciclovir was developed to prolong gastric residence time, target stomach mucosa and increase drug bioavailability by using different polymers like Sodium alginate and Eudragit with different concentration.[5]

MATERIALS

Famciclovir was obtained from Hetero Labs, HYD. Sodium alginate and Eudragit were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

METHODOLOGY

Fourier transform infrared spectroscopy[6]

Fourier transform IR spectra were obtained on Bruker FT-IR spectrometer. Samples were prepared in KBr disks (2mg sample in 200mg KBr). The scanning range was 450-4000 cm^{-1} and the resolution was 4 cm^{-1}.

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Formulation development

Table 1: Composition of Famciclovir floating tablets

Ingredients	Formulations			
	F1	F2	F3	F4
Famciclovir	500	500	500	500
Sodium alginate	100	200	-	-
Eudragit	-	-	100	200
Lactose	175	75	175	75
Sodium bi carbonate (mg)	20	20	20	20
Magnesium stearate (mg)	3	3	3	3
Talc (mg)	2	2	2	2
Total Wt (mg)	300	300	300	300

Preparation of Formulation[7]

Drug and polymers pass through 40 # mesh separately and then transfer it to poly bag and mix it for 3 minutes. Add diluents and other excipients to the above mixture. Finally add the Glidant (Magnesium Stearate) and Lubricant (Talc) to the above blend mix it for 2min. Compressed the above lubricated blend by using 8 mm round punches.

Evaluation of tablets [8,9]

Physical Appearance

The general appearance of a tablet, its identity and general elegance is essential for consumer acceptance, for control of low-to-lot uniformity and tablet-to-tablet uniformity. The control of general appearance involves the measurement of size, shape, colour, presence or absence of odour, taste etc.

Size & Shape

It can be dimensionally described & controlled. The thickness of a tablet is only variables. Tablet thickness can be measured by micro-meter or by another device. Tablet thickness should be controlled within a ±5% variation of standard value.

Weight variation test

This is an in-process quality control test to ensure that the manufacturers control the variation in the weight of the compressed tablets, different pharmacopoeia specify these weight variation tests. These tests are primarily based on the comparison of the weight of the individual tablets (xi) of a sample of tablets with an upper and lower percentage limit of the observed sample average (x-mean). The USP has provided limits for the average weight of uncoated compressed tablets. These are applicable when the tablet contains 50mg or more of the drug substance or when the latter comprises 50% or more, by weight of the dosage form.

Method:

Twenty tablets were weighed individually, and the average weight was calculated. The individual tablet weights are then compared to the average weight. Not more than two tablets should differ in their average weight by more than percentages stated in USP. No tablet must differ by more than double the relevant percentage.

Content Uniformity

The content uniformity test is used to ensure that every tablet contains the amount of drug substance intended with little variation among tablets within a batch. Due to increased awareness of physiological availability, the content uniformity test has been included in the monographs of all coated and uncoated tablets and all capsules intended for oral administration where the range of size of the dosage form available include 50mg or smaller sizes.

Method:

Randomly select 30 tablets. 10 of these assayed individually. The Tablet pass the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labelled drug content and the 10th tablet may not contain

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less than 75% and more than 125% of the labeled content. If these conditions are not met, remaining 20 tablets assayed individually and none may fall outside of the 85 to 115% range.

Friability

Friction and shock are the forces that most often cause tablets to chip, cap or break. The friability test is closely related to tablet hardness and designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping. It is usually measured using the Roche friabilator.

Method:

A number of tablets are weighed and placed in the apparatus where they are exposed to rolling and repeated shocks as they fall 6 inches in each turn within the apparatus. After four minutes of this treatment or 100 revolutions, the tablets are weighed, and the weight compared with the initial weight. The loss due to abrasion is a measure of the tablet friability. The value is expressed as a percentage. A maximum weight loss of not more than 1% of the weight of the tablets being tested during the friability test is considered generally acceptable and any broken or smashed tablets are not picked.

The percentage friability was determined by the formula:

$$\% \text{ friability} = (W_1 - W_2) / W_1 \times 100$$

W_1 = Weight of tablets before test

W_2 = Weight of tablets after test

Floating lag time

The time between the introduction of the tablet into the medium and its rise to upper one thirdof the disso lution vesselis termed as floating lag time and the time for which the dosage form floats is termed as the floating or flotation time. These tests are usually performed in simulated gastric fluid or 0.1NHCl maintai ned at 37^0C, by using USP dissolution apparatus containing 900 ml of 0.1N HCl as the dissolution mediu m.

Drug release studies[11, 12]

The drug release from the Famciclovir tablets was investigated in a USP-II (paddle) apparatus, 900 ml of 0.1N HCl (50 rpm, 37°C). At predetermined time intervals, 5-ml samples were withdrawn and take 1ml sample and diluted to 10 ml and then analysed with UV spectrophotometry at λ_{max} 296 nm.

Stability studies[13, 14, 15]

The success of an effective formulation can be evaluated only through stability studies. The purpose of stability testing is to obtain a stable product which assures its safety and efficacy up to the end of shelf life at defined storage conditions and peak profile. The prepared Famciclovir floating tablets were placed on plastic tubes containing desiccant and stored at ambient conditions, such as at room temperature, 40±2°c and refrigerator 2-8°c for a period of 30 days.

RESULTS AND DISCUSSION

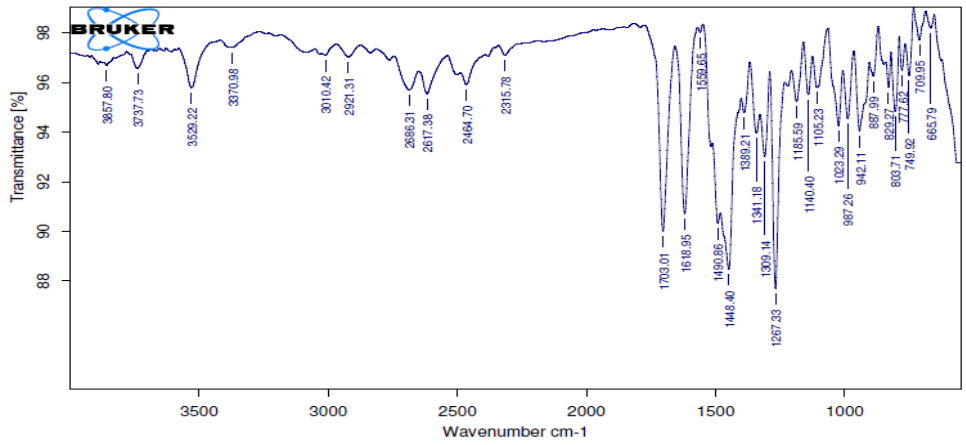

Fig-1: FT-IR Sample for Famciclovir

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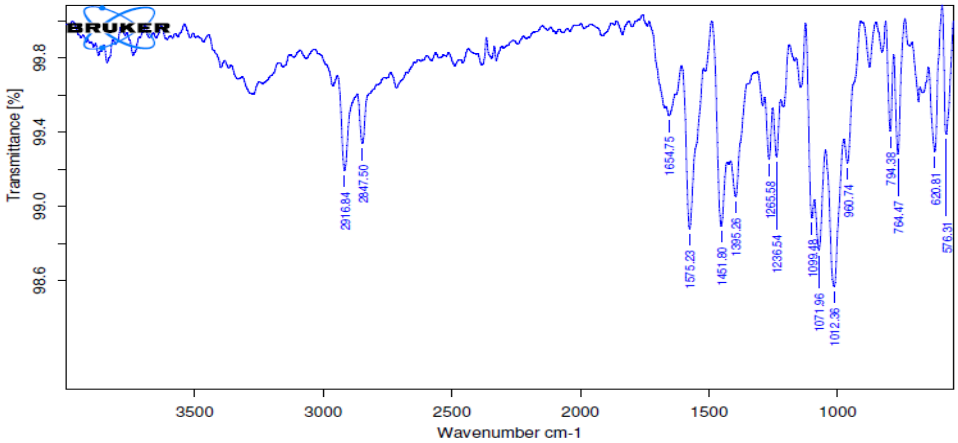


Fig-2: FT-IR Sample for Optimized Formulation

Evaluation of the Prepared Tablets for Physical Parameters

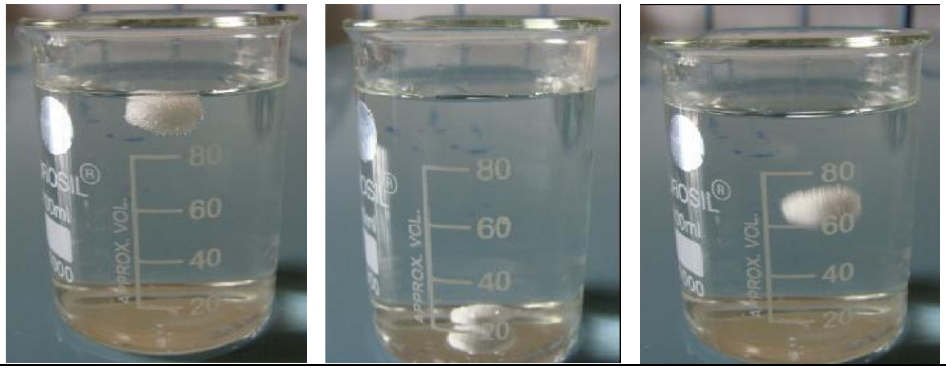
All formulations were tested for Physical parameters like Hardness, thickness, Weight Variation, Friability and found to be within the Pharmacopoeial limits. The results of the tests were tabulated. The drug content of all the formulations was determined and was found to be within the permissible limit. This study indicated that all the prepared formulations were good.

Table 2: Evaluation parameters of Famciclovir floating tablets

Parameters	F1	F2	F3	F4
Weight variation	300	299	298	300
Thickness (mm)	3.2	3.5	3.4	3.5
Hardness (kg/cm2)	4.2	4.1	3.9	4.0
Friability	0.42	0.46	0.49	0.5
Content uniformity	96.35	94.59	97.59	98.36
Floating lag time (Sec)	45	52	55	60

Floating lag time

The floating tablets of Famciclovir were prepared by using direct compression technique. Eight different formulations were prepared using different ratios of polymers. The prepared formulations were evaluated for floating lag time and buoyancy time. Sodium bicarbonate induced carbon dioxide generation in presence of dissolution medium (0.1 N HCl). It was observed that the gas generated is trapped and protected within the matrix, formed by polymers, thus density of the tablet decreased, and it becomes buoyant. The floating lag time of the optimized formulation F4 was 60 sec.



***In vitro* Dissolution studies**

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Table-3: *In vitro* drug release of Famciclovir floating tablets

% Drug Release				
Time	**F1**	**F2**	**F3**	**F4**
0	0	0	0	0
30	13.25	18.36	19.65	20.65
60	28.94	29.92	31.85	33.68
120	44.64	47.93	51.25	57.91
360	66.55	75.92	79.90	82.20

The dissolution conditions used for studying the drug release from tablet. The samples were withdrawn at predetermined time points and were analysed spectrophotometrically at 296 nm.

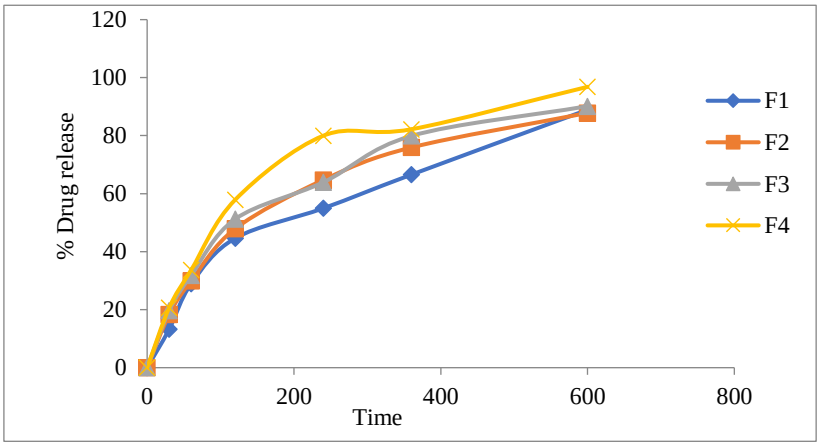

Fig 3: *In vitro* drug release for all the formulations

Stability Study:

Table-4: Stability study for optimized formulation

Formulation Code	Parameters	Initial	1st Month	Limits as per Specifications
F-4	25^0C/60%RH % Release	96.82	96.90	Not less than 85 %
F-4	30^0C/75% RH % Release	96.82	96.91	Not less than 85 %
F-4	40^0C/75% RH % Release	96.82	96.90	Not less than 85 %

There was no significant change in physical and chemical properties of the tablets of formulation F-4 after 30 days. Parameters quantified at various time intervals were shown.

CONCLUSION

The objective of the present study is to develop a Floating bio adhesive tablet of Famciclovir. In this present study an attempt was made to increase the GI residence time of Famciclovir, as the drug is having less gastric residence time, by formulating in to Floating tablets. Among all the formulations (F1-F4), it was observed that formulation-4

has shown better buoyancy and dissolution profile. So, Formulation-4 was found to be the best formulation among others.

REFERENCES

1. Fukuda M, Peppas NA, McGinity JW. Floating hot melt extruded tablets for gastro retentive controlled drug release system. *J Control Release.* 2006;115(2):121–129.
2. Robinson jr., lee vhl. Controlled drug delivery: fundamentals and applications, 2nd ed. Marcel dekker; New York: 1978. P.24-36.
3. Brahmankar dm, jaiswal sb. Biopharmaceutics and pharmacokinetics a treatise. 1st ed. Vallabh prakashan; new Delhi: 1995.p.64-70.
4. Chein yw. Novel drug delivery systems. 2nd ed.: marcel dekker new york; 1992. P.4-56
5. Gennaro ra. Remington: the science and practice of pharmacy. 20th ed. New york : Lippincott williams; 2000.p.1045.
6. Chodavarapu NP, Yendluri RB, Suryadevara H, Reddy P, Chhatoi P. Formulation and evaluation of abelmoschusesculentus mucilage-based metformin hydrochloride floating matrix tablets. Int J Pharm Tech 2011; 3:2725-45.
7. Kshirsagar RV, Jain V, Wattamwar S. Effect of different viscosity grade HPMC polymer on gastroretantive drug delivery of metformin hydrochloride. Int J Appl Pharm 2009; 1:44-50.
8. Chandiran IS, Kumar BP, Narayan V. Formulation and *in-vitro* evaluation of floating drug delivery system for salbutamol sulphate. Int J Pharm Biomed Sci 2010; 1(1):12-15.
9. Hu L, Li L, Yang X, Liu W, Yang J, Jia Y, *et al.*, Floating matrix dosage form for dextromethorphan hydrobromide based on gas forming technique. *In-vitro* and *in-vivo*evalvation healthy volunteers. Eur J Pharm Sci 2011; 42:99-105.
10. Raju BD, Sreenivas R, Varma MM. Formulation and evaluation of floating drug delivery system of metformin hydrochloride. J Chem Pharm Res 2010;2 (2):274-78.
11. Senthilkumar SK, Jaykar B, Kavimani S. Formulation and evaluation of gastro retentive floating drug delivery system of rabeprazole sodium. Int J Biopharm 2011;2(2):57-62.
12. Mohammed MS. Formulation and *in-vitro* evaluation of sustained release intragastric tablets of -Release (ER) Tablets. Pharm. Res. 10, 709-714.
13. G.Jayapal Reddy, J.Venkateshwar Rao and K.R.S. Sambasiva Rao, Enhancement of Bioavailability of Atorvastatin Calcium Through Gastric Resident Formulation Approach, Int. J. Pharm. Biol. Sci., 3 (1), 2013, 636-654.
14. Jayapal Reddy Gangadi, Venkateshwar Rao Jupally and K.R.S. Sambasiva Rao, Design and Evaluation of a Novel Floating in Situ Gel for Gastroretentive Drug Delivery of The Narrow Absorption Window Drug Atorvastatin Calcium, International Journal of Pharmaceutical Research and Biomedical Analysis, 3 (1), 2014, 14-27.
15. G. Jayapal Reddy, J. Venkateshwar Rao and K.R.S. Sambasiva Rao, Design and Evaluation of Atorvastatin Calcium Mucoadhesive Microspheres: A Novel Formulation Approach to Enhance the Oral Bioavailability, Int. J. Pharm, Biol and Chem.Sci, 2 (2), 2013, 20-31.