

FORMULATION AND EVALUATION OF FENOVERINE FLOATING TABLETS

RASHMITHA V, MADHUSUDAN RAO Y, PAVANI S*

Department of Pharmaceutics, Vaagdevi College of Pharmacy, Kakatiya University, Hanamkonda, Telangana, India.

Email: pavanisrm@gmail.com

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ABSTRACT

Objective: The purpose of this research was to develop a fenoverine gastroretentive drug delivery system which, following oral administration should have the ability to enhance and prolong the period of gastric residence time (GRD) with the desired *in vitro* release profile.

Methods: In the present study, fenoverine floating tablets were prepared using an effervescent method using sodium bicarbonate and citric acid as a gas-generating agent. The tablets were formulated using direct compression technology using xanthan gum and sodium alginate as polymers. Pre-compression powders were evaluated for angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, and the prepared tablets were evaluated for weight variation, thickness, diameter, hardness, friability, drug content, floating lag time, total floating time, and *in vitro* dissolution studies. The formulations were optimized for the different concentrations of xanthan gum, sodium alginate, and their combinations.

Results: All the prepared formulations showed well *in vitro* buoyancy. The tablets remained buoyant for 6–12 h. The *in vitro* drug-release pattern of fenoverine floating tablets was adapted to different kinetic models with the highest regression to zero-order and Korsmeyer-Peppas, and the mechanism was found to be a Fickian mechanism.

Conclusion: Out of all the formulations prepared, *in vitro* dissolution studies of the F4 formulation were found to be maximum than other batches, which exhibited desired sustained release time followed by acceptable floating properties.

Keywords: Fenoverine, Gastric residence time, Effervescent method, Buoyancy, Floating properties.

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INTRODUCTION

The oral route is the most appropriate and widely used route for the delivery of drugs to the systemic circulation. This route has high acceptability for patients, particularly due to ease of administration. Over the years, oral dosage forms have become increasingly world-wide in the pharmaceutical field, with controlled release drug delivery (CRDDS) systems that release the drug at a predetermined, predictable, and controlled rate playing a major role [1]. The main imperative for the successful action of oral controlled drug delivery systems was to have good drug absorption throughout the gastrointestinal tract (GIT). The most preferable approach of oral controlled drug delivery is gastroretentive drug delivery system, where the dosage form can remain in the stomach for a prolonged period, thereby increasing the gastric residence time (GRT) and targeting site-specific drug release in the upper GIT for producing local or systemic effects. It is obtained by retaining the dosage form in the stomach and by releasing it in a controlled manner [2]. The following two parameters are optimized to develop sustainable orally controlled releasing drug delivery systems that deliver a drug for the required duration for optimal treatment at a therapeutically efficient range to a desirable place [3]. (a) Gastrointestinal transit modulation time: To modulate the transit time for GIT so that dosage form can be taken to or around the target absorption site and thus extend the time limit for maximizing the delivery of drugs. (b) Minimizing the elimination of the first hepatic pass: If the drug to be given undergoes extensive first-pass hepatic removal, preventive measures should be developed to either bypass or minimize the extent of hepatic metabolism. The purpose of the work is to develop drug delivery systems of fenoverine in which after oral administration should have the ability to prolong the gastric residence time with the desired *in vitro* release profile. Fenoverine is an antispasmodic drug used to relieve muscle spasm, cramps associated with the stomach, and abdominal pain associated with irritable bowel syndrome [4,5].

Due to the shorter half-life of Fenoverine (5-7 h) it requires frequent daily dosing and its therapeutic use in chronic conditions necessarily involves its formulation into a sustained release dosage form [6]. It is the most suitable drug to be formulated as a floating drug delivery system as it helps in increasing the gastric residence time and helps to have good control over the fluctuations in plasma drug concentration.

MATERIALS AND METHODS**Materials**

Fenoverine was obtained as a gift sample from Euro drugs, sodium bicarbonate, xanthan gum, and sodium alginate obtained from Research-lab fine chem. Industries, citric acid from HiMedia laboratory, Talc from Sd fine-Chem Ltd, magnesium stearate from Qualikems Fine Chemicals Pvt. Ltd, and Lactose from Yarrow Chem products, all the ingredients, and reagents used were of analytical grade.

Methods*Pre-formulation studies*

Pre-formulation studies are carried out to know and understand the physical and chemical behavior of a drug and also to know the drug-excipient compatibility using FTIR.

Solubility studies

Solubility was determined by weighing accurately 1 g of the drug and transferring it into 5 different 10 ml volumetric flasks containing different solvents (water, ethanol, methanol, DCM, and 0.1N HCl), respectively [6].

FTIR studies

It is often used to identify organic, inorganic, and polymeric materials present in the dosage form, analyse pure drug formulations, polymer, and drug-loaded polymer formulations, as well as functional group

determination. The spectra were scanned at ambient temperature over the wave-number range of 3600–400 cm² [7,8].

Micromeritic properties of powder blend [9-11]

Angle of repose

It is a maximum angle between the surface of a pile of powder and its horizontal plane. It is determined by pouring the powder to flow through a funnel and fall freely onto the surface. Then, the height and diameter of the resulting cone are measured using the following equation. $\tan \theta = h/r$; where, θ is the angle of repose, h = height of the pile, and r = radius of the pile.

Bulk density and tapped density

A known amount of powder blend was taken from each formula and introduced into a 10 ml measuring cylinder and shaken lightly to break up the agglomerates. After measuring, the initial volume of the powder bulk density was calculated using the following formula.

Bulk density = (weight of the powder) / (bulk volume of the powder)

The cylinder containing the sample was tapped using a mechanical tapped density tester (Electrolab) that provides a fixed drop of 14±2 mm at a nominal rate. The cylinder tapping was continued until no further change in the volume was noted. The tapped density was calculated using the following formula.

Tapped density = (weight of the powder) / (tapped volume)

Compressibility index and Hausner's ratio

They were measured using the following formula.

$$\text{Carr's index} = \frac{\text{Tapped density} - \text{Bulk density} \times 100}{\text{Tapped density}}$$

Hausner's ratio = Tapped density / Bulk density

Analytical method for calibration curve of fenoverine

The maximum wavelength of fenoverine was measured using UV-visible spectroscopy which was found to be 261 nm. The secondary stock solution (100 µg/ml) was prepared from the primary stock solution (1 mg/ml) with 0.1 N HCl as a buffer. Further dilutions were made from the secondary stock solution to obtain 2–10 µg/ml. The absorbance of each aliquot was measured at 261 nm against 0.1N HCl as blank. Then, a graph of concentration of drug versus absorbance was plotted by applying linear regression analysis [8]. The standard regression equation obtained for fenoverine was $y=0.054x+0.013$ with a coefficient of regression (R^2) of 0.997.

Formulation of floating tablets

The required amount of the ingredients was weighed as per the composition mentioned in Tables 1 and 2, followed by sieving and blending. All the pre-compression parameters were studied and finally compressed into tablets by direct compression method using a rotary tablet machine at specific pressure using 8 mm round punches, and the weight of the tablet was compressed to 200 mg.

Post-compression characterization

Weight variation

It is determined by taking 20 tablets randomly from each formulation and weighing them individually using an electronic balance, and the average weight was calculated which was compared with an individual weight of the tablet. The deviation for any two tablets should not exceed more than the average weight [12-14].

Hardness and thickness

Hardness is the ability of the tablet to withstand mechanical shocks during handling. It is determined by the Monsanto hardness tester

by randomly selecting three tablets from each formulation, which is measured in terms of kg/cm² [13]. The thickness of the tablet was determined randomly by selecting three tablets from each formulation using vernier calipers which were expressed in mm. The extent of deviation in the tablet formulation should not exceed the limit of ± 5% of their determined values.

Friability

It is used to determine the physical strength of uncoated tablets upon exposure to mechanical shock and attrition with the help of Roche friabilator, which is expressed in terms of percentage. In this, ten tablets were weighed and placed in the friabilator and operated at 25 rpm for about 4 min (100 revolutions) [15]. Then, the tablets were dedusted and reweighed. The friability was calculated using the following equation.

$$\text{Friability} = \frac{\text{Initial weight} - \text{Final weight} \times 100}{\text{Initial weight}}$$

Drug content

Ten tablets were taken and placed in a mortar and crushed into a fine powder. An accurately weighed powder equivalent to 100 mg of fenoverine was transferred into a 100 ml volumetric flask containing 100 ml of 0.1N HCl, and the absorbance was measured against blank at 261 nm.

In vitro buoyancy studies

The *in vitro* buoyancy was determined by finding the floating lag time (FLT) and total floating time (TFT). This is carried out by placing the tablet in a 100 ml beaker containing 0.1N HCl [16]. The time required for the tablet to rise from the bottom of the beaker to the surface and float was measured as FLT and the duration of the tablet that constantly floats on the dissolution medium was noted as TFT.

In vitro dissolution studies

It was performed using USP Type I (basket) dissolution apparatus at a rotational speed of 50 rpm. The dissolution medium consists of 900 ml of 0.1 N HCl, maintained at a temperature of 37±0.5°C [16]. At predetermined time intervals, a 5 ml sample was withdrawn from the dissolution apparatus and replaced with a fresh dissolution medium. The collected samples were filtered through a 0.45 µm membrane filter and diluted if necessary with 0.1 N HCl. The absorbance of these

Table 1: Composition of fenoverine floating tablets containing xanthan gum or sodium alginate

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8
Fenoverine	100	100	100	100	100	100	100	100
Xanthan Gum	30	35	40	45	-	-	-	-
Sodium alginate	-	-	-	-	30	35	40	45
Sodium bicarbonate	30	30	30	30	30	30	30	30
Citric acid	15	15	15	15	15	15	15	15
Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Lactose	22	17	12	7	22	17	12	7

Table 2: Composition of fenoverine floating tablets containing a combination of polymers (xanthan gum and sodium alginate)

Ingredients (mg)	F9	F10	F11	F12	F13	F14	F15
Fenoverine	100	100	100	100	100	100	100
Xanthan Gum	15	20	15	30	15	30	10
Sodium alginate	15	15	20	15	30	10	30
Sodium bicarbonate	30	30	30	30	30	30	30
Citric acid	15	15	15	15	15	15	15
Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Lactose	22	17	17	7	7	12	12

solutions was measured at 261 nm. The cumulative percentage of drug release was calculated using the equation obtained from a calibration curve.

Kinetic analysis of drug release data

Several different kinetic models will describe the total release of drugs from dosage forms [17]. As qualitative and quantitative changes in the formulation may alter the release of drugs and the performance of *in vivo*, it is always desirable to develop tools that facilitate the development of the product by reducing the need for biostudies. In this regard, the use of data on *in vitro* drug dissolution to predict *in vivo* bioperformance can be considered as a rational development of controlled release formulations. The method of approaches used to examine the kinetics of drug release from controlled release formulation is model dependent methods (zero order, first order, Higuchi, Korsmeyer-Peppas, etc.) [18].

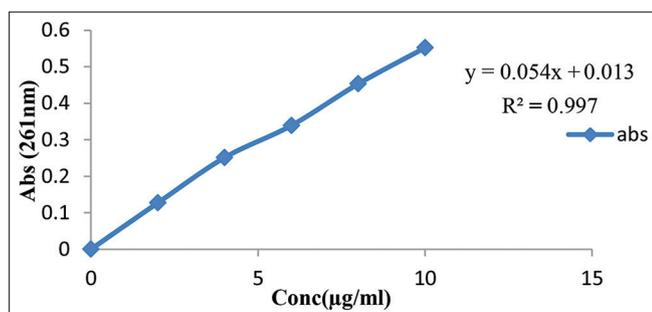


Fig. 1: Standard curve of fenoverine at λ max 261 nm

RESULTS AND DISCUSSION

Fenoverine floating tablets were prepared by direct compression method. Various evaluation parameters were measured. From the solubility studies, it was found that fenoverine was practically insoluble in water and DCM, slightly soluble in ethanol, methanol, and freely soluble in 0.1N HCl. A standard calibration curve for fenoverine was acquired by measuring the absorbance at 261 nm in 0.1N HCl and by plotting the graph of absorbance against concentration. The standard plot of fenoverine was shown in Fig. 1.

Pre-formulation parameters

From the FTIR studies, it was observed that all the major peaks of fenoverine remained the same and compatible with excipients used in the study. Parameters such as the angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio were evaluated to determine the flow properties of the prepared powder mixture [19-21]. The results of the pre-compression parameters are shown in Table 3. The angle of repose and compressibility index for all the formulations were found to be in the range that indicated good flow properties and hence were suitable for compression into floating tablets.

The quantitative evaluation and assessment of a tablet's chemical, physical, and bioavailability properties are important in the design of a tablet and to monitor product quality. These properties are important since chemical breakdown or interactions between tablet components may alter the physical tablet properties and greatly affect the bioavailability of the tablet system. There are various standards that have been set in the various pharmacopeia. These include the diameter, size, shape, thickness, weight, hardness, disintegration, and dissolution

Table 3: Pre-compression characterization of the powder blend

Formulation	Carr's index (%)	Bulk density (g/cc)	Tapped density (g/cc)	Angle of repose (θ)	Hausner's ratio
F1	21.7±0.65	0.47±0.06	0.62±0.09	28.9±0.52	1.06±0.05
F2	22.7±0.55	0.48±0.09	0.64±0.04	27.7±0.36	1.16±0.26
F3	23.4 ± 0.62	0.49 ± 0.05	0.61±0.06	28.9±0.52	1.18±0.03
F4	24.6±1.21	0.50±0.07	0.65±0.04	29.9±0.51	1.17±0.06
F5	21.2±0.02	0.48±0.13	0.59±0.05	27.6±0.42	1.14±0.03
F6	21.6±0.37	0.50±0.02	0.60±0.02	28.2±0.23	1.14±0.16
F7	22.5±0.46	0.49±0.06	0.61±0.06	28.6±0.50	1.15±0.05
F8	23.9±1.02	0.50±0.14	0.64±0.08	29.2±0.50	1.17±0.06
F9	23.7±0.59	0.51±0.02	0.58±0.02	26.5±0.38	1.13±0.27
F10	24.2±0.09	0.49±0.12	0.62±0.05	28.6±0.54	1.16±0.02
F11	23.5±0.04	0.48±0.06	0.61±0.08	29.1±0.42	1.14±0.22
F12	23.9±0.58	0.48±0.19	0.59±0.06	28.4±0.50	1.07±0.03
F13	22.3±0.72	0.50±0.03	0.62±0.03	27.6±0.49	1.14±0.25
F14	23.6±0.22	0.47±0.07	0.64±0.03	28.4±0.52	1.17±0.02
F15	24.2±0.52	0.48±0.09	0.62±0.06	28.9±0.47	1.16±0.06

Table 4: Physicochemical evaluation parameters of fenoverine tablets

Formulation	Weight variation (mg)	Hardness (kg/cm ²)	Thickness (mm)	Friability (%)	Drug content (%)
F1	195.4±0.40	4.2±0.32	3.2±0.16	0.27±0.06	96.32±1.2
F2	196.2±0.68	4.3±0.73	3.1±0.22	0.25±0.01	97.36±1.4
F3	198.6±1.40	4.4±0.34	3.1±0.38	0.23±0.04	96.69±1.2
F4	199.6±0.38	4.5±0.84	3.4±0.16	0.21±0.02	99.89±1.6
F5	194.6±0.38	4.3±0.62	3.3±0.14	0.20±0.04	95.33±1.4
F6	196.7±1.21	4.3±0.64	3.1±0.15	0.27±0.02	96.69±1.3
F7	196.6±0.92	4.3±0.32	3.2±0.12	0.22±0.06	96.97±1.3
F8	197.6±0.65	4.4±0.39	3.3±0.15	0.29±0.05	97.66±1.6
F9	195.6±0.90	4.0±0.40	3±0.18	0.26±0.04	92.21±1.1
F10	197.1±1.40	4.4±0.52	3.1±0.16	0.24±0.02	94.32±1.3
F11	197.2±0.48	4.6±0.64	3.1±0.14	0.24±0.06	95.12±1.4
F12	198.5±0.55	4.5±0.32	3.2±0.12	0.25±0.05	97.18±1.6
F13	198.4±0.91	4.3±0.34	3.4±0.02	0.23±0.04	93.55±1.2
F14	196.4±0.64	4.2±0.24	3.3±0.12	0.27±0.04	94.33±1.3
F15	199.2±0.90	4.5±0.21	3.3±0.18	0.19±0.06	98.18±1.4

character [22-24]. The diameter and shape depend upon the die and punches selected for the compression of tablets. The results of the physicochemical properties of tablets prepared are shown in Table 4. The results showed uniformity in weight and thickness of the tablets. The results also revealed that the tablets would not break during handling and transportation and maintain integrity throughout the storage.

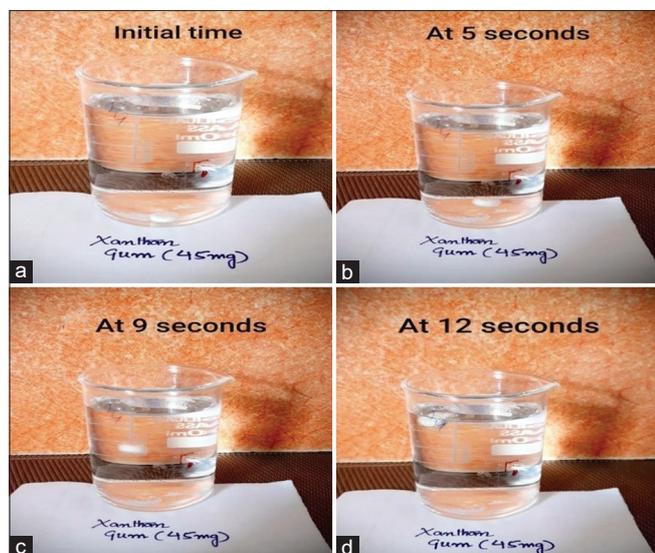


Fig. 2: Pictorial representation of buoyancy of floating tablet (F4)

In vitro buoyancy studies

The *in vitro* buoyancy studies in 0.1N HCl revealed good buoyancy for all the formulations, where the buoyancy lag time was found to be <20 s (Table 5). Sodium bicarbonate and citric acid were used as effervescent agents. Upon contact with an acidic medium, the fluid permeates into the tablet, which generates CO₂. The gas generated is trapped and protected within the gel, formed by the hydration of polymer; thereby lowering the density of the tablet below 1 g/cm³, where the tablet becomes buoyant to float.

In the present study, fenoverine was formulated into a controlled release floating tablet. The preliminary studies indicate that the tablet containing fenoverine alone could not maintain the integrity of the tablet up to 12 h where it disintegrated completely after 6 h, and rapid erosion was observed when placed in the dissolution medium because of its low viscosity. Hence, this can be overcome by combining the fenoverine with xanthan gum and sodium alginate as polymers which controlled the release of drugs and help in maintaining the tablet integrity [25-28]. From the present study, it was observed that the formulations containing xanthan gum as polymer have increased the viscosity of tablets in the dissolution medium and shown prolonged drug release for about 12 h (Fig. 2).

In vitro drug release studies

Drug release from fenoverine floating tablets was studied for about 12 h in 0.1N HCl as shown in Figs. 3-5. Total 15 formulations were prepared, where the first four F1-F4 formulations contain xanthan gum as polymer, F5-F8 contain sodium alginate as polymer, and F9-F15 contains a combination of xanthan gum and sodium alginate. Polymers were used in concentrations of 30%, 35%, 40%, and 45%. The release of fenoverine from the tablets is dependent on the percentage of release retardant contained within the tablet.

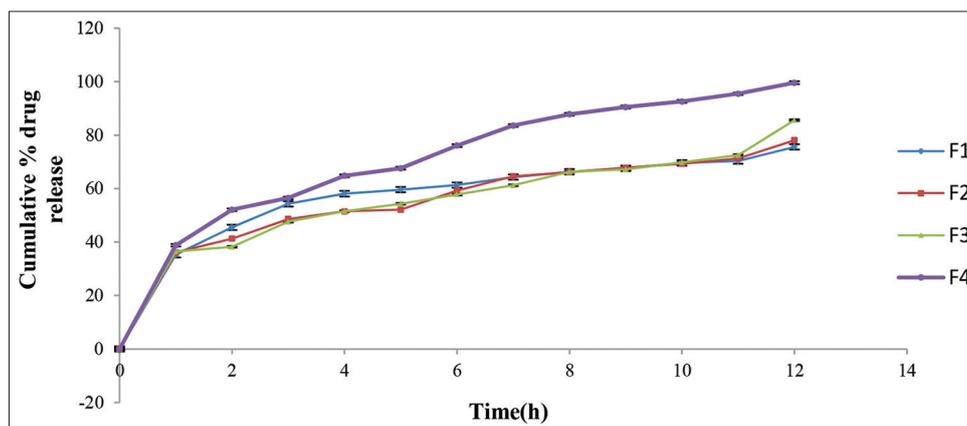


Fig. 3: Graphical representation of drug release of F1-F4 containing xanthan gum

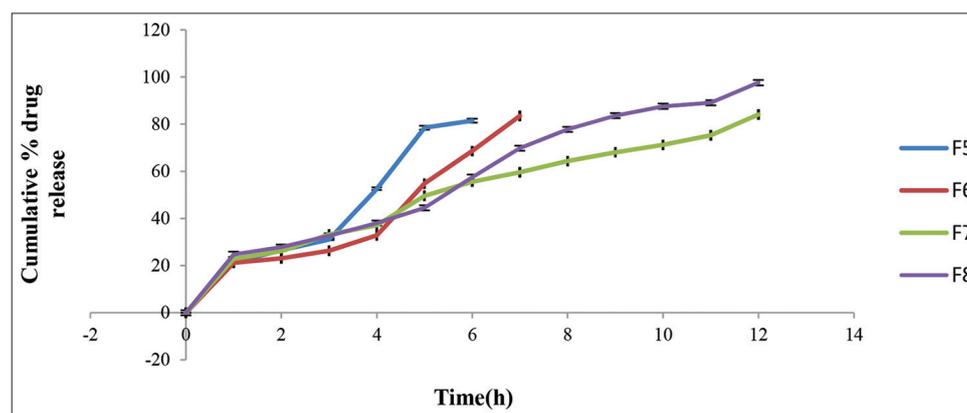


Fig. 4: Graphical representation of % drug release of F5-F8 containing sodium alginate

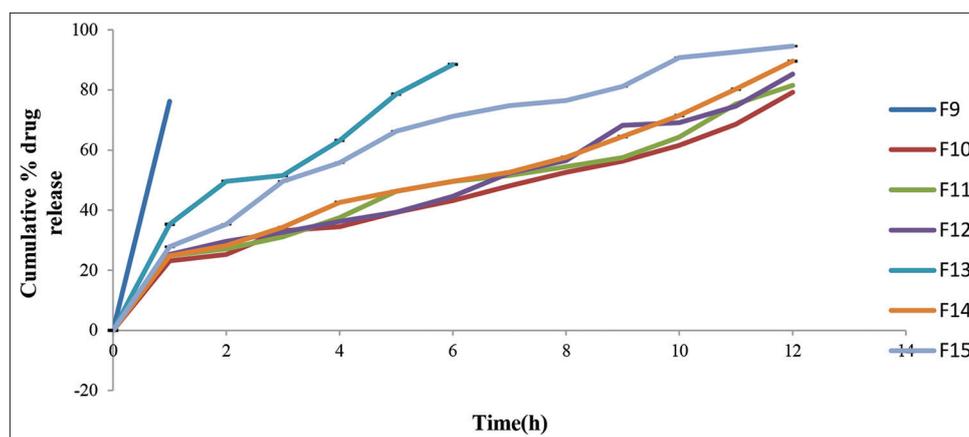


Fig. 5: Graphical representation of % drug release of F9-F15

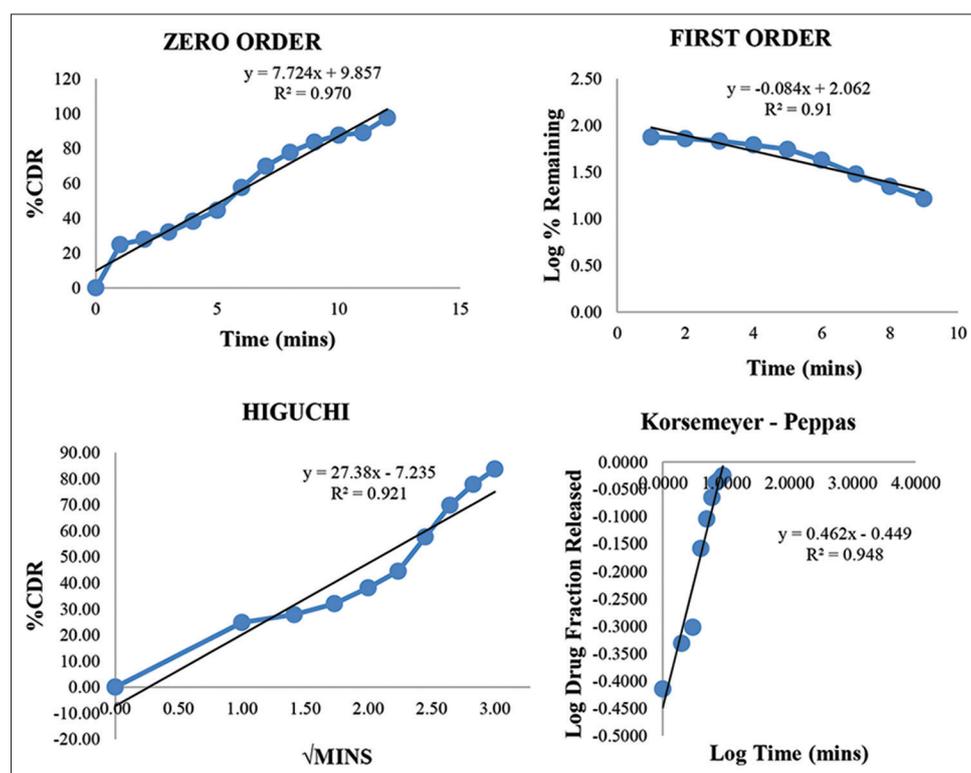


Fig. 6: Release kinetic models of optimized formulation (F4)

Table 5: Floating properties of prepared tablets

Formulation code	Floating lag time (s)	Total floating time (h)
F1	14	≥12
F2	14	≥12
F3	13	≥12
F4	12	≥12
F5	14	5
F6	16	6
F7	16	12
F8	15	≥12
F9	-	Dispersed
F10	14	≥12
F11	15	≥12
F12	13	≥12
F13	13	6
F14	19	≥12
F15	17	≥12

It was observed that as the percentage of the polymer was increased, the drug release from the tablet decreased. Upon comparison of both

the polymers, xanthan gum has shown better control of drug release from the tablet up to 12 h because of its higher molecular weight, high swelling rate, gel consistency, and sustained release behavior. The results have shown that xanthan gum has a greater drug retarding ability. Among the formulations containing xanthan gum (F1-F4), F4 has shown greater drug release for a relatively prolonged period.

The drug release data of fenoverine floating tablets were fitted into various mathematical models (zero order, first order, Higuchi, Korsmeyer-Peppas) [29,30] given Fig. 6 to evaluate the kinetics and mechanism of drug release. The model that gives a high R^2 value is considered the best fit for the release data.

CONCLUSION

Fenoverine floating tablets were prepared using xanthan gum and sodium alginate as polymers in optimized concentrations by the direct compression method. The results of the present study indicate that the tablets containing fenoverine alone cannot control its release effectively for 12 h, where this problem is overcome by combining the drug with

polymers such as xanthan gum and sodium alginate, which helped in increasing the viscosity of the formulation in the dissolution medium and thereby prolonging the drug release effectively for 12 h. Among various formulations, the F4 formulation containing 45% of xanthan gum was considered as the best formulation based on the drug release pattern, where it has shown 99.6% of drug release at the end of 12 h. From the present study, it was concluded that the formulation F4 has shown better swelling properties with desired drug release kinetics, which especially follows zero-order release and floating behavior.

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AUTHORS CONTRIBUTIONS

All the authors contributed to the preparation of the final manuscript.

CONFLICTS OF INTEREST

There are no conflicts of interest regarding the publication of this article to disclose.

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