



FORMULATION AND EVALUATION OF GASTRO RETENTIVE FLOATING TABLETS OF NIZATIDINE

¹Yasmina Khatun, ¹A. V. Jithan

¹Omega College of Pharmacy, Ghatkesar, RR District, jaukunuru@gmail.com.

Received: 26-11-2025 / Revised Accepted: 28-11-2025 / Published: 30-11-2025

ABSTRACT

Objectives: The purpose of present investigation was to develop and evaluate floating drug delivery system of an Anti-Hyperlipidemic Agent.

Methods: The floating tablets of Nizatidine were prepared by using PEO (Polyethylene oxide), Guar Gum, Xanthan gum, Sodium alginate polymers. The pre-compression and post-compression evaluation were performed as per pharmacopoeial standards. The tablets were prepared by direct compression method. Dissolution measurements were carried out in a (USP) dissolution testing apparatus II.

Results: Compatibility study was performed by FTIR. The compatibility study of the prepared Nizatidine floating tablets confirms that there is no interaction between the drug and polymers used. The release data were subjected to different models in order to evaluate their release kinetics and mechanisms. The drug release kinetics was observed by super case II transport mechanism. The floating lag time were found to be significantly increased with the increasing concentration of the polymers.

Interpretation & Conclusion: After the dissolution study of prepared Nizatidine floating tablet it was concluded that the formulation F12 with Sodium alginate 100mg shows better sustained release effect i.e the drug release was 99.24±1.45% at the end of 12th hour. The release kinetic data implies that the release mechanism of all the formulations was super case II transport mechanism. The developed floating tablets of Nizatidine may be used to prolong drug release for at least 12h, thereby improving the bioavailability and patient compliance.

Keywords: Nizatidine gastro retentive floating drug delivery, Sodium alginate, FTIR.

INTRODUCTION

Because of its cost-effectiveness, patient compliance, convenience of administration, and versatility in dosage form design, oral medication delivery is the most popular and practical method of delivering therapeutic agents. However, the short stomach residence duration of dose forms is one of the major obstacles to oral medication delivery. When given in traditional dosage forms, drugs that undergo considerable hepatic metabolism, are unstable in intestinal pH, or are absorbed largely in the upper section of the gastrointestinal tract (GIT) typically have lower bioavailability and therapeutic effectiveness.¹

Gastroretentive drug delivery systems, which are designed to remain in the stomach for a long period and release their active ingredients, allow drugs to be continually and continuously injected into the upper part of the gastrointestinal tract². A modified release drug delivery system with a longer residence time in the stomach is particularly desirable for drugs that act locally in the stomach, have an absorption window in the stomach or upper part of the small intestine, are unstable in the intestinal or colonic environments, or have low solubility at high pH values.³

Floating drug delivery systems, low density systems, raft systems with alginate gel, bioadhesive or mucoadhesive systems, high density systems, superporous hydrogel, and magnetic systems are some of the methods currently employed to create an effective gastroretentive drug delivery system. The floating dosage forms have been utilized the most out of all of these.⁴

Address for Correspondence: Yasmina Khatun, Omega College of Pharmacy, Ghatkesar, RR District, Email: jaukunuru@gmail.com.

How to Cite this Article: Yasmina Khatun, FORMULATION AND EVALUATION OF GASTRO RETENTIVE FLOATING TABLETS OF NIZATIDINE, World J Pharm Sci 2025; 13(04): 89-99; <https://doi.org/10.54037/WJPS.2022.100905>

Copyright: 2022@ The Author(s). This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License (CC BY-NC-SA), which allows re-users to distribute, remix, adapt, and build upon the material in any medium or format for noncommercial purposes only, and only so long as attribution is given to the creator. If you remix, adapt, or build upon the material, you must license the modified material under identical terms.

Because floating medication delivery systems have a lower bulk density than gastric fluids, they stay afloat in the stomach for an extended amount of time without influencing the pace at which the stomach empties. The medication is gradually removed from the system at the appropriate pace while it is floating on the contents of the stomach. The residual system is drained from the stomach following medication release. Increased stomach retention duration and regulation of the variation in plasma drug concentration are the outcomes of this.⁵

In order to treat stomach ulcers and gastroesophageal reflux disease, nizatidine, a selective histamine type-2 receptor antagonist (H₂ blocker), suppresses the release of gastric acid. Nitidine has a half-life of one to two hours.⁶

MATERIALS

Nizatidine was procured from Manus Akteva Biopharma LLP, Xanthan gum HPMC K 4M, Magnesium Stearate, Talc were procured from Shreeji chemicals, Mumbai, Sodium bicarbonate, Lactose were procured from S.D fine chemicals, Mumbai, Sodium alginate and Carbopol 934P were procured from Choice Organ chem LLP and Neutron Drugs & Pharmaceuticals Pvt Ltd and Hydrochloric acid from Center drug house (p) Ltd, Mumbai.

METHODOLOGY

Pre formulation studies⁷⁻¹¹

It is one of the important prerequisites in development of any drug delivery system. Preformulation studies of the drug were performed, which included melting point determination, solubility and compatibility studies.

Solubility studies:

Solubility of Nizatidine was carried out in different solvents like- distilled water, 0.1 N HCL 7.4 pH & 6.8 pH buffers and organic solvents like Ethanol & Methanol. Solubility studies were performed by taking excess amount of drug in different beakers containing the solvents. The mixtures were shaken for 24 hrs at regular intervals. The solutions were filtered by using whattmann's filter paper grade no. 41. The filtered solutions were analyzed spectrophotometrically.

Determination of melting point

Melting point of Nizatidine was determined by capillary method. Fine powder of Nizatidine was filled in glass capillary tube (previously sealed on one end). The capillary tube is tied to thermometer and placed in oil bath (light paraffin oil bath), The temperature at which it starts to melt was noted.

Determination of absorption maximum (λ_{max}):

The wavelength at which maximum absorption of radiation takes place is called as λ_{max} . This λ_{max} is characteristic or unique for every substance and useful in identifying the substance. For accurate analytical work, it is important to determine the absorption maxima of the substance under study. Most drugs absorb radiation in ultraviolet region (190-390nm), as they are aromatic or contain double bonds. Accurately weighed 10mg Nizatidine separately was dissolved in 2-3 ml of methanol in a clean 10ml volumetric flask. The volume was made up to 10ml with 0.1N HCL buffer which will give stock solution-I with concentration 1000 μ g/ml. From the stock solution-I, 1ml was pipette out in 10ml volumetric flask. The volume was made up to 10ml using 0.1N HCL buffer to obtain stock solution-II with a concentration 100 μ g/ml. From stock solution-II, 1ml was pipette out in 10ml volumetric flask. The volume was made up to 10ml using 0.1N HCL buffer to get a concentration of 10 μ g/ml. This solution was then scanned at 200-400nm in UV-Visible double beam spectrophotometer to attain the absorption maximum (λ_{max}).

Construction of calibration curve:

Accurately weighed 10mg Nizatidine was dissolved in methanol taken in a clean 10ml volumetric flask. The volume was made up to 10ml with 0.1N HCL buffer which gives a concentration of 1000 μ g/ml. From this standard solution, 1ml was pipette out in 10ml volumetric flask and volume was made up to 10ml using 0.1N HCL buffer to obtain a concentration of 100 μ g/ml. From the above stock solution, aliquots of 0.2, 0.4, 0.6, 0.8, 1.0 and 1.2 ml each was transferred to a separate 10ml volumetric flask and solution was made up to 10ml using 0.1N HCL buffer to obtain a concentration of 2, 4, 6, 8, 10 and 12 μ g/ml respectively. The absorbance of each solution was measured at 325 nm.

Compatibility

FTIR

Compatibility studies were performed through FTIR spectroscopy. The IR spectrum of pure drug and physical mixture of drug and polymer was studied. The characteristic absorption peaks of Nizatidine obtained were obtained at 4000-500cm⁻¹. It has been observed that there is no chemical interaction between Nizatidine and polymer's used. From the fig no 5.3, 5.4, 5.5, 5.6, & 5.7 it was observed that peak obtained in spectra drug and polymers. which show there were no interaction between drug and polymers.

Pre-compression evaluation

Angle of Repose

Angle of repose was determined by using funnel method. The blend was poured through funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose was calculated using the formula.

$$\phi = \tan^{-1} \frac{h}{r}$$

Bulk Density

Apparent bulk density (ρ_b) was determined by pouring the blend into a graduated cylinder. The bulk volume (V_b) and weight of powder (M) was determined. The bulk density was calculated using the formula.

$$\rho_b = \frac{m}{V_d}$$

Tapped Density

The measuring cylinder containing known mass of blend was tapped for a fixed time. The minimum volume (V_t) occupied in the cylinder and weight (M) of the blend was measured. The tapped density (ρ_t) was calculated using the following formula.

$$\rho_t = \frac{m}{V_t}$$

Carr's compressibility index

The simplest way of measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility. The compressibility index of the granules was determined by Carr's compressibility index, which is calculated by using the following formula

$$I = \frac{V_o - V_t}{V_o} \times 100$$

Hausner ratio

Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula

$$\text{Hausner ratio} = \frac{\rho_t}{\rho_d}$$

Preparation of Nizatidine floating tablets

By direct compression method

Nizatidine floating was prepared by direct compression technique using drug and variable concentration of polymers (Carbopol 934P, Sodium alginate, Xanthan gum, HPMC K4M, Sodium Bicarbonate, Lactose, Mg-stearate, and Talc). The respective powders & optional additives (composition listed in table-5.3) were blended thoroughly with a mortar and pestle. The powder blended was then lubricated with Mg-stearate and purified talc and then compressed on a tablet punching machine.

Composition of Nizatidine Floating Tablets

Table.1 Composition of Nizatidine floating tablet with FLT and TFT

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Nizatidine	150	150	150	150	150	150	150	150	150	150	150	150
PEO (Polyethylene oxide)	150	125	100	-	-	-	-	-	-	-	-	-
Guar Gum	-	-	-	150	125	100	-	-	-	-	-	-
Xanthan	-	-	-	-	-	-	150	125	100	-	-	-
Sodium	-	-	-	-	-	-	-	-	-	150	125	100
NAHCO ₃	20	20	20	20	20	20	20	20	20	20	20	20
Citric acid	10	10	10	10	10	10	10	10	10	10	10	10
Mg stearate	2	2	2	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2	2	2	2
Lactose	66	91	116	66	91	116	66	91	116	66	91	116
Total	400	400	400	400	400	400	400	400	400	400	400	400
FLT (Seconds)	124	112	103	112	99	80	100	92	76	89	67	46
TFT (hrs)	>12	>12	12	>12	>12	>12	>12	>12	12	>12	>12	>12

Preparation of Nizatidine floating tablets**By direct compression method**

Nizatidine floating was prepared by direct compression technique using drug and variable concentration of polymers (Carbopol 934P, Sodium alginate, Xanthan gum, HPMC K4M, Sodium Bicarbonate, Lactose, Mg-stearate, and Talc). The respective powders & optional additives (composition listed in table-5.3) were blended thoroughly with a mortar and pestle. The powder blended was then lubricated with Mg-stearate and purified talc and then compressed on a tablet punching machine.

Post-compression evaluation parameters for formulated tablets⁶¹⁻⁶⁴**a. Weight variation**

Twenty tablets from each formulation were selected at random and average weight was determined. Then the individual tablets were weighed and were compared with average weight.

b. Hardness

The hardness of the tablet from each formulation was determined using Pfizer hardness tester.

c. Friability

Friability of the tablets was determined using Roche Friabilator. This device subjects the tablets to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Pre weighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed. The friability (f) is given by the formula.

$$\text{Friability (f)} = \left(1 - \frac{W_0}{W}\right) \times 100$$

Where, W_0 is weight of the tablets before the test and W is the weight of the tablet after the test.

d. Thickness and diameter

The thickness and diameter of tablet was carried out using Digital caliper. Five tablets were used for the above test from each batch and results were expressed in millimeter.

e. Drug content

Powder one tablets extraction was carried out using 0.1 N HCL. The concentration was determined spectrophotometrically against appropriate blank. Calculate the content of Nizatidine specific absorbance at 325 nm. As given in IP.

f. In-vitro buoyancy studies

The in vitro floating behavior of the tablets was studied by placing them in 100 ml beaker 100 ml of 0.1 N HCL (pH 1.2, 37 °C). The time, tablet required for the emerge on the surface is floating lag time (FLT) or buoyancy lag time (BLT) and the time tablet constantly float on the surface of the medium is called total floating time (TFT).

g. In-vitro dissolution studies

The release rate of Nizatidine from floating tablet was determined using the United States Pharmacopoeia (USP) dissolution testing apparatus II. The dissolution test was performed using 900ml of 0.1 N HCL, at $37 \pm 0.50^\circ\text{C}$ and 50 rpm. The samples were taken at pre-selected time intervals with replacement of equal volume of dissolution medium.

Kinetic Analysis of In-Vitro Release Rates of Gastro Retentive Tablets

The results of in vitro release profile obtained for all the formulations were plotted in modes of data treatment as follows:-

Zero Order Kinetic

It describes the system in which the drug release rate is independent of its concentration.

$$Q_t = Q_0 + K_0 t$$

If the zero order drug release kinetic is obeyed, then a plot of Q_t versus t will give a straight line with a slope of K_0 and an intercept at zero.

First Order Kinetic

It describes the drug release from the systems in which the release rate is concentration dependent.

$$\log Q_t = \log Q_0 + kt/2.303$$

Higuchi Model

It describes the fraction of drug release from a matrix is proportional to square root of time.

$$M_t / M_\infty = kHt^{1/2}$$

Korsmeyer-Peppas model (Power Law)

The power law describes the drug release from the polymeric system in which release deviates from Fickian diffusion, as expressed in following equation.

$$M_t / M_\infty = ktn$$

$$\log [M_t / M_\infty] = \log k + n \log t$$

RESULTS AND DISCUSSION

PREFORMULATION STUDIES

Determination of melting point

The melting point of Nizatidine was found to be in range of 131°C.

Determination of Solubility

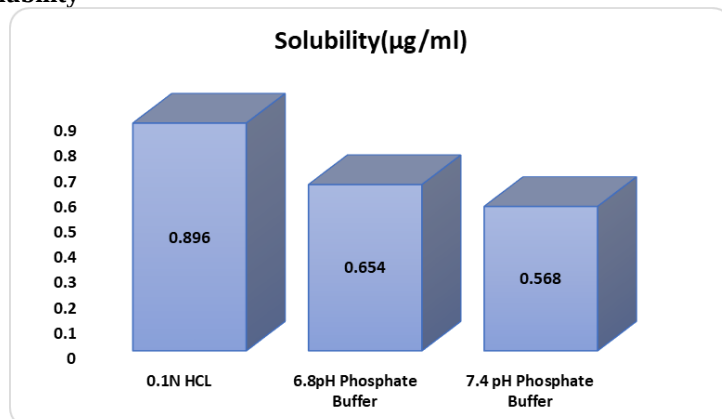


Figure.1 Solubility studies of pure drug

Discussion:

From the above obtained solubility studies we can say solubility of the drug is more in 0.1N HCl than the other buffers.

ESTIMATION OF NIZATIDINE BY UV SPECTROSCOPY

Determination of lambda max

UV Spectra of Nizatidine at 4 µg/ml concentration the Wavelength of maximum absorption in 0.1N HCl solution was found to be 278.0 nm.

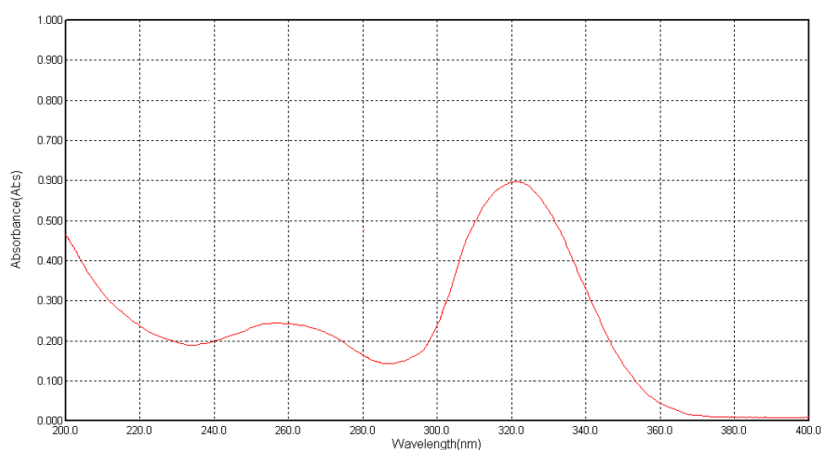


Figure.2 UV Spectrum Of Nizatidine

Discussion: The maximum absorbance of the Nizatidine in 0.1N HCl was found to be 325 nm for 50% concentration solution as shown in Fig. Hence, the wavelength of 325 nm was selected for analysis of drug in dissolution media.

Calibration curve

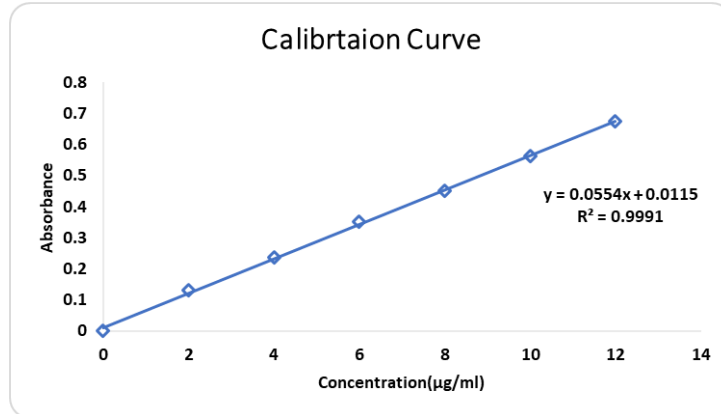


Figure.3 Standard calibration curve of Nizatidine in 0.1N HCl

Discussion:

The linearity was found to be in the range of 2-12µg/ml in 0.1 N HCl. The regression value was closer to 1 indicating the method obeyed Beer-lambert's law.

COMPATABILITY STUDIES

FTIR Spectroscopy

Identification of Nizatidine

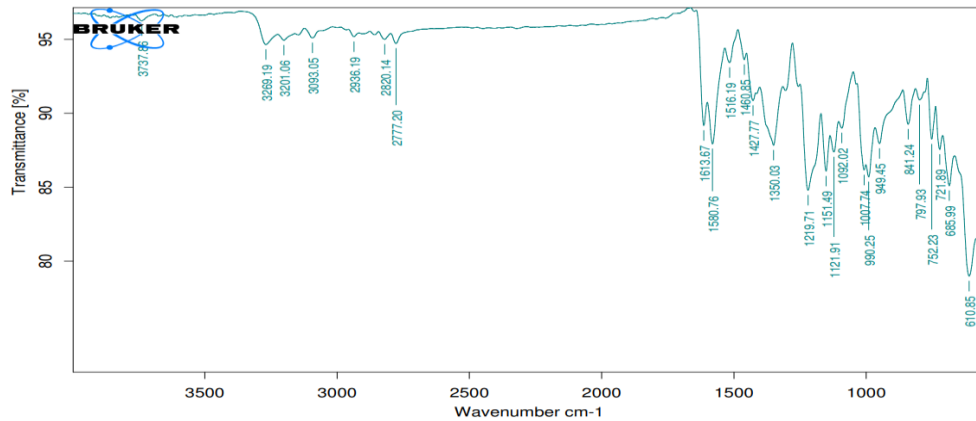


Figure.4 IR spectra of Nizatidine.

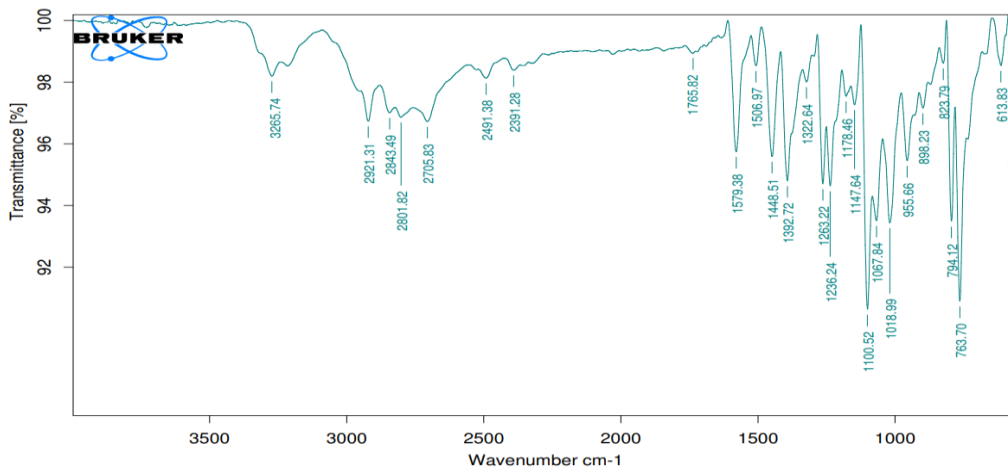


Figure.5 FT-IR Spectra of Nizatidine best formulation.

Discussion: From the compatibility studies it was concluded that the functional groups that were present in the pure drug were also found in the optimized formulation with very minute changes, from this we can conclude that the drug and excipients have no interactions.

PRE-COMPRESSION EVALUATION OF NIZATIDINE FLOATING TABLETS

Table.2 pre-compression parameters of Nizatidine floating tablets

Formulation code	Angle of repose (°) ±SD	Bulk density (gm/cm³)±SD	Tapped density (gm/cm³)±SD	Hausner ratio (HR)±SD	Carr index (CI) ±SD
F1	24.43±0.18	0.378±0.015	0.447±0.018	1.24±0.018	17.48±0.58
F2	26.14±0.75	0.385±0.042	0.464±0.025	1.19±0.024	15.72±0.94
F3	27.12±0.19	0.398±0.026	0.485±0.046	1.16±0.015	14.17±0.25
F4	28.75±0.38	0.415±0.031	0.497±0.028	1.14±0.019	13.24±0.47
F5	25.36±0.45	0.368±0.015	0.456±0.042	1.22±0.024	18.48±0.46
F6	26.86±0.37	0.397±0.019	0.468±0.019	1.18±0.012	17.21±0.14
F7	27.18±0.49	0.405±0.010	0.485±0.045	1.16±0.015	15.36±0.47
F8	28.57±0.85	0.418±0.011	0.499±0.018	1.13±0.019	14.08±0.28
F9	26.25±0.68	0.384±0.005	0.468±0.013	1.17±0.014	16.24±0.48
F10	27.64±0.84	0.395±0.010	0.475±0.009	1.15±0.023	14.04±0.29
F11	28.48±0.45	0.418±0.010	0.496±0.022	1.13±0.015	13.28±0.46
F12	29.85±0.28	0.426±0.011	0.514±0.027	1.10±0.034	11.12±0.18

All the values are expressed as mean ± SD. (n=1)

Discussion: The angle of repose of different formulations was $\leq 29.85 \pm 0.28^\circ$ which indicates that material had good flow property. So, it was confirmed that the flow property of blends was free flowing. The bulk density of blend was found between $0.378 \pm 0.015 \text{ g/cm}^3$ to $0.426 \pm 0.011 \text{ g/cm}^3$. Tapped density was found between $0.447 \pm 0.018 \text{ g/cm}^3$ to $0.514 \pm 0.027 \text{ g/cm}^3$. These values indicate that the blends had good flow property. Carr's index for all the formulations was found to be between 11.12 ± 0.18 - 18.48 ± 0.46 . and Hausner's ratio from 1.10 ± 0 .

POST COMPRESSION EVALUATION OF NIZATIDINE FLOATING TABLETS

Table.3 Post-compression evaluation of Nizatidine floating tablets

Formulation code	Weight variation Average wt in (mg)±SD	Hardness (Kg/cm²) ±SD	Diameter in (mm) ±SD	Thickness in (mm) ±SD	Friability (%) ±SD	Drug content uniformity (%) ±SD
F1	400.15± 1.02	7.37± 1.41	6.14± 1.14	3.24± 1.08	0.79± 0.02	93.49±0.48
F2	399.78± 1.16	7.25± 1.28	6.34± 1.07	3.37± 1.07	0.74± 0.01	94.52±0.28
F3	398.69± 1.10	7.14± 1.41	6.29± 1.20	3.45± 1.09	0.67± 0.03	96.14±0.46
F4	399.87± 1.75	7.14± 1.62	6.15± 1.16	3.16± 1.06	0.94± 0.02	93.27±0.47
F5	401.45±1.20	7.36± 1.84	6.24± 1.05	3.26± 1.04	0.89± 0.01	95.43±0.65
F6	402.28± 1.15	7.78± 1.45	6.58± 1.14	3.47± 1.06	0.85± 0.02	97.24±0.45
F7	399.45± 1.30	7.28± 1.25	6.21± 1.02	3.16± 1.07	0.85± 0.03	98.85±0.28
F8	401.48± 1.45	7.24± 1.68	6.39± 1.12	3.28± 1.08	0.79± 0.02	96.45±0.18
F9	399.85± 1.20	7.58± 1.97	6.46± 1.04	3.36± 1.08	0.65± 0.01	97.15±0.36
F10	401.47± 1.18	7.35± 1.41	6.37± 1.12	3.35± 1.05	0.76± 0.02	97.24±0.21
F11	398.19± 1.06	7.56± 1.28	6.49± 1.04	3.51± 1.06	0.67± 0.03	98.67±0.25
F12	400.04± 1.42	7.78± 1.20	6.74± 1.10	3.69± 1.07	0.45± 0.01	99.45±0.41

All the values are expressed as mean ± SD. (n=3)

Discussions:

Weight Variation Test: The percentage weight variations for all formulations were given. All the formulated (F1 to F12) tablets passed weight variation test as the % weight variation was within the pharmacopoeial limits. The weights of all the tablets were found to be uniform with low standard deviation values.

Hardness test: The measured hardness of tablets of all the formulations ranged between 7.14 ± 1.41 - $7.78 \pm 1.20 \text{ kg/cm}^2$. This ensures good handling characteristics of all batches.

Thickness and Diameter: The measured Thickness and Diameter of tablets of all the formulations ranged between 3.16 ± 1.06 - $3.69 \pm 1.07 \text{ mm}$ and 6.14 ± 1.14 - $6.74 \pm 1.10 \text{ mm}$.

Friability Test: The % friability was less than 1 % in all the formulations ensuring that the tablets were mechanically stable.

The Drug Content: The Content of drug content for F1 to F12 was found to be between $93.27 \pm 0.47\%$ - $99.45 \pm 0.41\%$. It complies with official specifications.

IN-VITRO DRUG RELEASE STUDIES**Table.4 In-vitro drug release data of Nizatidine floating tablets of Batch F1 to F6**

% Cumulative release						
Time (Hrs)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
1	21.56±1.74%	15.23±1.06%	19.45±1.54%	23.44±1.34%	15.58±1.45%	17.32±1.45%
2	29.64±1.69%	27.48±1.47%	25.84±1.20%	29.75±1.05%	18.26±1.21%	23.33±1.48%
3	36.45±1.34%	32.85±1.69%	34.18±1.62%	33.94±1.24%	24.18±1.48%	28.77±1.27%
4	42.21±1.25%	40.18±1.45%	45.62±1.45%	38.74±1.37%	37.48±1.26%	38.45±1.46%
5	49.62±1.46%	49.65±1.20%	51.21±1.34%	46.83±1.20%	43.63±1.74%	49.71±1.58%
6	57.26±1.42%	57.32±1.37%	59.57±1.47%	55.86±1.45%	57.21±1.45%	58.58±1.78%
7	63.84±1.36%	62.85±1.06%	65.48±1.20%	67.48±1.26%	64.28±1.20%	69.47±1.26%
8	79.25±1.45%	69.45±1.02%	71.28±1.34%	72.38±1.45%	75.48±1.46%	72.42±1.48%
9	85.68±1.20%	76.12±1.26%	79.64±1.28%	79.48±1.25%	81.24±1.44%	78.56±1.84%
10	93.45±1.34%	83.24±1.36%	85.26±1.64%	85.39±1.48%	89.48±1.09%	83.38±1.46%
11	99.15±1.45%	89.64±1.45%	90.24±1.24%	98.73±1.20%	93.48±1.06%	87.48±1.57%
12		98.24±1.20%	98.65±1.47%		98.24±1.27%	98.57±1.74%

#All the values are expressed as mean ± SD.(n=1)

Table.5 In-vitro drug release data of Nizatidine floating tablets of Batch F7 to F12

% Cumulative release						
Time(Hrs)	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0
1	10.27±1.48%	14.24±1.45%	18.89±1.37%	15.04±1.45%	18.05±1.26%	24.98±1.06%
2	16.47±1.67%	19.66±1.34%	24.32±1.42%	18.91±1.07%	24.95±1.45%	32.95±1.24%
3	21.48±1.54%	24.21±1.69%	29.62±1.26%	27.64±1.24%	28.27±1.74%	39.83±1.69%
4	28.75±1.34%	29.35±1.45%	32.41±1.42%	34.47±1.67%	36.11±1.45%	43.82±1.24%
5	35.83±1.02%	35.39±1.65%	37.37±1.95%	38.55±1.00%	48.03±1.02%	55.77±1.42%
6	39.96±1.89%	42.85±1.24%	42.65±1.45%	50.08±1.26%	52.94±1.20%	62.48±1.06%
7	49.11±1.64%	49.70±1.36%	49.87±1.20%	57.03±1.21%	56.63±1.24%	69.42±1.48%
8	53.98±1.29%	52.92±1.42%	56.51±1.37%	66.11±1.34%	68.26±1.62%	75.42±1.59%
9	59.64±1.24%	58.63±1.26%	67.51±1.45%	69.34±1.29%	74.87±1.20%	79.99±1.43%
10	71.46±1.64%	66.23±1.74%	74.09±1.06%	75.40±1.27%	85.94±1.09%	88.37±1.06%
11	79.26±1.48%	83.73±1.02%	82.86±1.16%	84.95±1.45%	88.73±1.45%	95.33±1.02%
12	98.36±1.37%	98.41±1.34%	98.89±1.25%	98.21±1.27%	99.64±1.05%	99.24±1.45%

All the values are expressed as mean ± SD. (n=3)

Discussion:

From the in vitro drug release in studies, it was observed that the formulations containing Sodium alginate as a polymer in different concentrations like 150mg, 125mg and 100mg, reveals that the decreased in the polymer concentration increases the drug release time and the F12 formulation containing Sodium alginate 100 mg concentration shows maximum amount of drug release (99.24±1.45%) at the end of 30mins.

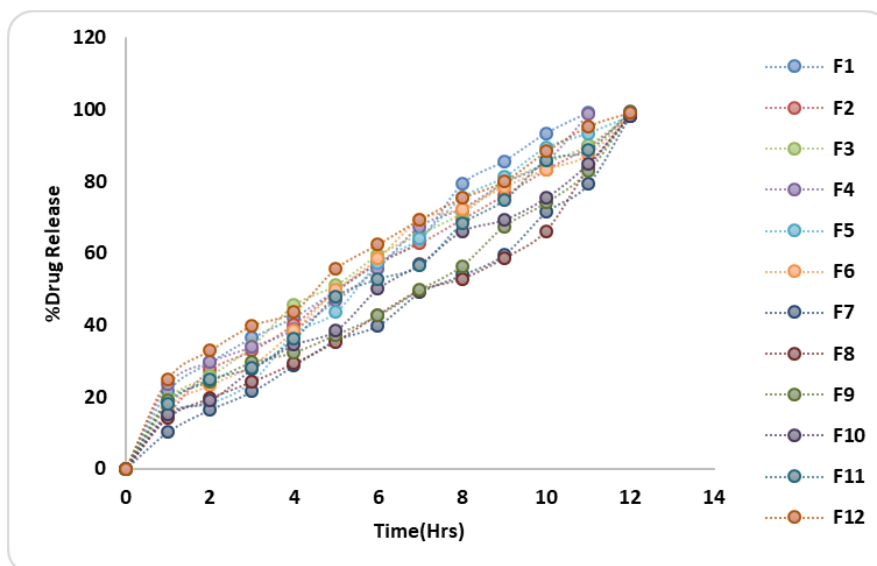


Figure.5 *In-vitro* drug release profile of Nizatidine floating tablets of batches F1 to F12

Drug release kinetics:

Zero Order Release Studies for Optimized Formulation:

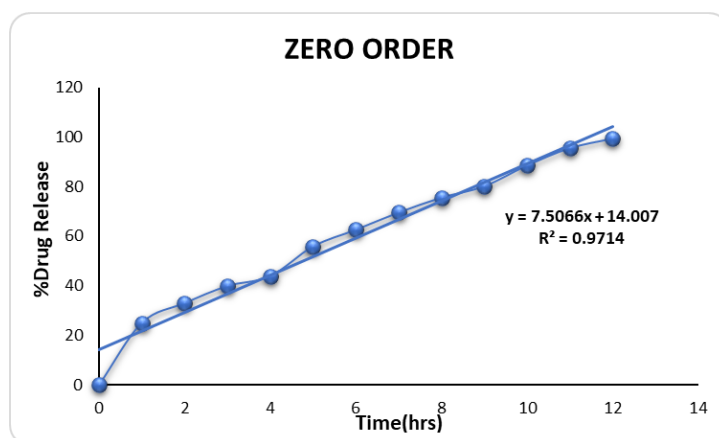


Figure.6 Zero Order

First Order Release Studies for Optimized Formulation:

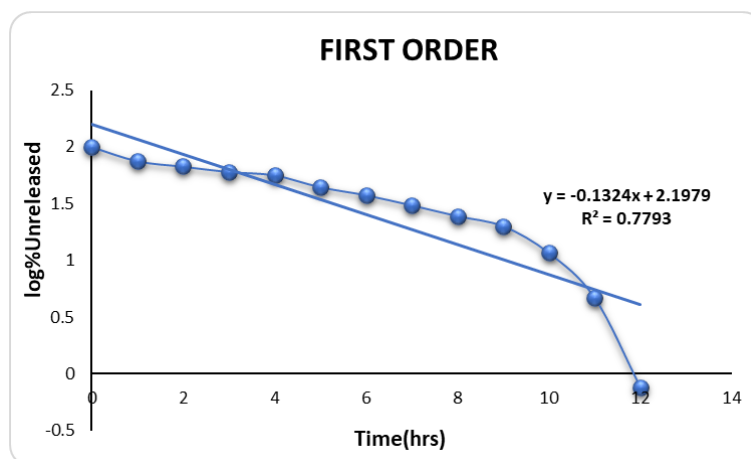
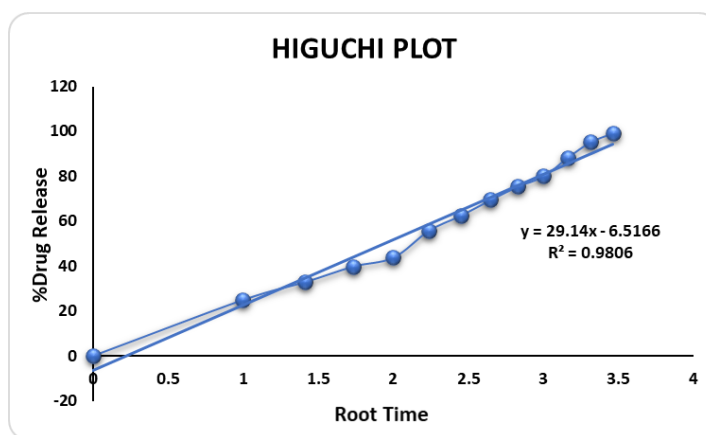
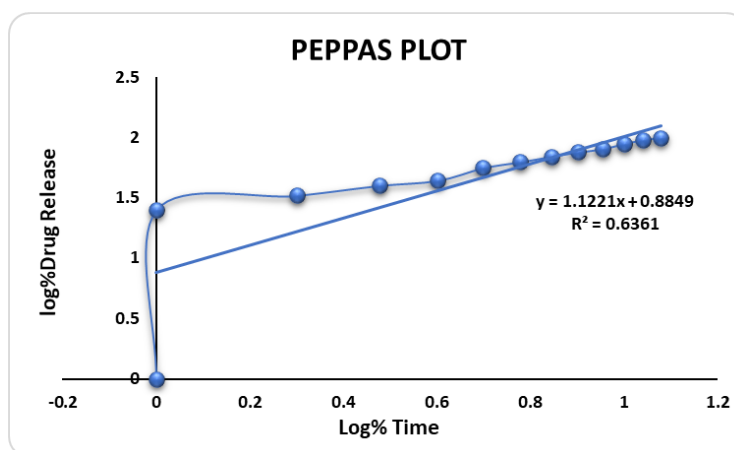


Figure.7 First Order

Higuchi Plot Release Studies for Optimized Formulation:**Figure.8 Higuchi****Peppas's Plot Release Studies for Optimized Formulation:****Figure.9 Peppas Plot****Discussion:**

The in-vitro dissolution data as log cum percent drug release versus log time were fitted to Peppas, values of the exponent 'n' was found to be in the range of 1.122 indicating that the drug release follows super case II transport mechanism and zero order release.

SUMMARY AND CONCLUSION**SUMMARY**

The present study is an attempt to develop floating tablets of Nizatidine, with different polymers which releases a therapeutic amount of Nizatidine to the proper site in the body and also to achieve and maintain the desired Nizatidine concentration. Direct compression method was used for formulation of floating tablets, also different types of polymers like PEO (Polyethylene oxide), Guar Gum, Xanthan gum, Sodium alginate were studied. These polymers were widely used gel forming polymers. The release rate could effectively be modified by varying the "polymer" concentration. By using Sodium alginate they gave optimum FLT as well as long acting effect. It was found that the tablet formulation retarded the drug release for 12h as desired. The results of the drug-excipients compatibility by FTIR studies revealed that there was no chemical interaction between the pure drug and excipients. The Pre compression parameters like bulk density, tapped density, Carr's index and angle of repose were determined. The final formulation showed acceptable flow properties. The post compression parameters like the thickness, hardness, friability, weight variation, content uniformity, FLT and TFT and *In vitro* release, were carried out and the values were found to be within IP limits. Thus it is summarized and concluded that Sodium alginate with 100mg can be successfully used in formulation of Nizatidine sustained release gastro retentive floating tablets which show the release of $99.24 \pm 1.45\%$ at the end of 12th hour.

CONCLUSION

From the compatibility studies, it is concluded that, PEO (Polyethylene oxide), Guar Gum, Xanthan gum, Sodium alginate, were compatible with drug Nizatidine and thus suitable for the formulation of Nizatidine floating tablets were fabricated by direct compression method. In-vitro buoyancy studies were performed for all the formulations, F1 to F12 by using 0.1 N HCl solution at 37°C. Tablet containing Sodium Alginate (F12) 100mg showed good buoyancy with very short lag time and long floatation time of more than 12 hrs in 0.1 N HCl. In-Vitro release study is performed for 12 hrs. Optimized formula containing Sodium alginate (F12) showed better release compare to other formulations and it followed zero order kinetics. The super case II transport mechanism was confirmed as the drug release mechanism from this formulation. From this study, it was concluded that Sodium alginate can be used in formulation of Nizatidine sustained release gastro retentive floating drug delivery system. Overall, this study concludes that viscosity of the polymer is a major factor affecting the drug release and floating properties of FDDS.

SCOPE FOR THE FUTURE STUDIES

The principle of FDDS can be adopted for drug acting locally in stomach. The work can be extended to the *In-vivo* studies to conclude *In-vitro* and *In-vivo* correlation Work can be extended to the *In-vivo* buoyancy studies in humans. The formulation of FDDS can be tried with different grades of Sodium Alginate and other swellable polymers. The work can be carried out to study the effect of other response parameters like bio adhesiveness, etc, on floating and release rate of drug. The work can be carried out to improve the physical stability of the dosage form like coating the tablet.

REFERENCES

1. Vinesh Kumar, Rakesh Kumar Sodavat, Garvendra Singh Rathore, Formulation and Evaluation of Gastroretentive Floating Tablets of Lovastatin Using Natural Polymers, Journal of Drug Delivery & Therapeutics. 2025; 15(7):71-79.
2. Dehghan MH, Khan FN. Gastroretentive drug delivery systems: A patent perspective. Int J Health Res. 2009;2:23–44.
3. Rocca JG, Omidian H, Shah K. Progress in gastroretentive drug delivery systems. Business briefing. Pharma Tech. 2003;5:152–6.
4. Mathur P, Saroha K, Syan N, Verma S, Kumar V. Floating drug delivery systems: An innovative acceptable approach in gastroretentive drug delivery. Arch Appl Sci Res. 2010;2:257–70. [Google Scholar]
5. Shah SH, Patel JK, Patel NV. Stomach specific floating drug delivery system: A review. Int J Pharm Tech Res. 2009;1:623–33.
6. Yeshavantha Kumar, F R Sheeba, Likitha B*, Dr. Shivanand mutta, H S Keerthy, Dr. Ashvini HM, Formulation and Evaluation of Floating Beads of Nizatidine, Volume 7, Issue 3 May-June 2022, pp: 449-457.
7. Mustafa C, Mustafa SK, “UV spectroscopic method for determination of the Dissolution profile of Rivaroxaban “ 2014, doi:10.14227/DT210414, P56-59.
8. Kaur L and Kumar S. “Solid Dispersions: A Promising Approach for Improving Dissolution Characteristics of a poorly soluble drug.” Int. J. Pharma. Res. 2011, 3 (1),1-7.
9. Ludescher J. Crystalline form of rivaroxaban dehydrate. European Patents EP 2590970 A1, 2011.
10. Savjini KT, Gajjar AK, and Savjini JK. “ Drug solubility: Importance and Enhancement techniques”. Int. Sch. Res.Net. 2012, doi:10.5402/2012/195727.
11. Halsas M, Ervasti P, Veski P, Jürjenson H, Marvola M. Biopharmaceutical evaluation of timecontrolled press-coated tablets containing polymers to adjust drug release. Eur J Drug Metabol Pharmacokinet., 1998;23: 190-196