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Formulation and Development of Floating Tablets of Nizatidine

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A B S T R A C T

This study focused on the development and evaluation of floating tablets of Nizatidine designed to prolong gastric retention and achieve sustained drug release. A UV-Visible spectrophotometric method was validated for drug quantification using 0.1N HCl as the solvent with absorbance measured at 242 nm, showing excellent linearity and precision within 2 to 10 µg/ml concentration range. The pre-compression evaluation of powder blends revealed consistent bulk and tapped densities, favorable flow and compressibility properties as indicated by Carr's index, Hausner ratio, and angle of repose, suitable for direct compression.Post-compression studies confirmed tablet formulations met pharmacopeial requirements for hardness, friability, drug content, thickness, and weight uniformity, ensuring mechanical robustness and dosage accuracy. In vitro buoyancy tests demonstrated rapid floating onset and maintained buoyancy up to 12 hours with matrix integrity intact. The dissolution profile highlighted efficient, sustained drug release, with the optimal formulation displaying a release mechanism consistent with diffusion-controlled, non-Fickian behavior, as supported by kinetic modeling. Overall, the research successfully formulated gastroretentive Nizatidine floating tablets with enhanced gastric residence, controlled release characteristics, and potential for improved therapeutic efficacy and patient adherence.

Keywords: Nizatidine, floating tablets, gastroretentive drug delivery, UV spectrophotometry, sustained release, direct compression, drug release kinetics.

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C O N T E N T S

1. Introduction

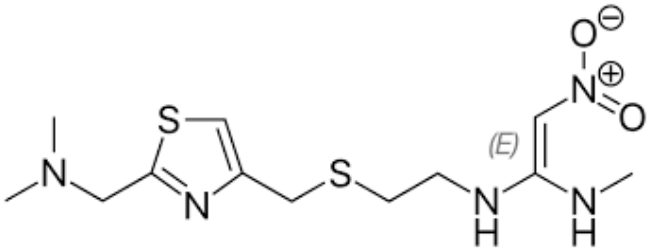

Fig.1: Nizatidine

Molecular Formula: $C_{12}H_{21}N_5O_2S_2$
Molecular Weight: 331.46 g/mol
IUPAC Name: N-[2-[[[2-[(dimethylamino)methyl]-4-thiazolyl]methyl]thio]ethyl]-N′-methyl-2-nitro-1,1-ethenediamine
ChemSpider ID: 3102
Density: ~1.25 g/cm³ (predicted)
Boiling Point: ~478 °C (predicted)
Melting Point: 130–132 °C
Vapour Pressure: Very low; not commonly reported

Flash Point: Not readily available; low volatility
Refractive Index: Not typically measured for solids
Polar Surface Area: Not specified, but moderate due to polar groups
LogP (Octanol/Water): Estimated ~0.4 (hydrophilic)
Generic Name: Nizatidine
Brand Names: Axid, Tazac, Nizaxid
Drug Category: H_2-receptor antagonist (antiulcer agent)
Indications: Treatment of active duodenal ulcers, gastric ulcers, GERD, and conditions with excessive stomach acid
Pharmacology: Blocks histamine H_2 receptors on gastric parietal cells, reducing acid secretion
Potency: Comparable to ranitidine; more potent than cimetidine
Tolerability: Generally well-tolerated; fewer CNS side effects than cimetidine
Contraindications: Hypersensitivity to nizatidine or other H_2 blockers
Adverse Effects: Headache, diarrhea, fatigue, dizziness; rare liver enzyme elevations
Availability: Oral capsules and solutions; widely available by prescription Would you like to compare it with oth

2. Materials and Methods

Table.1: Chemical and Manufactures

S.N	Chemical	Manufactures
1	Nizatidine	Supplied by Pharma Train
2	Hpmc k 100m	Colorcon
3	Eudragit rs 100	Colorcon
4	Xanthum gum	Colorcon
5	Pvp k 30	SD Fine Chemicals, Mumbai
6	Sodium bicarbonate	SD Fine Chemicals, Mumbai
7	Mcc	SD Fine Chemicals, Mumbai
8	Talc	SD Fine Chemicals, Mumbai
9	Magnesium stearate	SD Fine Chemicals, Mumbai
10	Nizatidine	Supplied by Pharma Train
11	Hpmc k 100m	Colorcon

Table.2: List of Equipment

S.N	Name of The Equipment	Model
1	Electronic Weighing Balance	SCALE-TEC
2	Friabilator	Roche Friabilator, Electrolab, Mumbai.
3	Compression Machine	CMD(CADMACH)
4	Tablet Hardness Tester	Pfizer Hardness Tester, Mumbai
5	UV	LABINDIAUV 3000+
6	Dissolution Apparatus	Electrolab TDT-08L
7	Verniercallipers	CD-6”CS

Analytical Method Development
Preparation of 0.1 N Hydrochloric Acid (pH 1.2): 8.5 ml of concentrate hydrochloric acid was taken and diluted with distilled water up to 1000 ml.
Determination of λ_{max} of Nizatidine in 0.1N HCL:
Procedure:
Working standard: 100mg of Nizatidine was weighed and dissolved in 10ml methanol and then make up to a volume of 100ml with 0.1N HCL it gives 1000µg/ml concentrated stock solution.
Dilution 1: From the working standard solution 10ml was diluted to 100ml with 0.1N HCL it will give 100µg/ml concentrated solution.
Dilution 2: From the dilution-1, 10ml was diluted to 100ml with 0.1N HCL it will give 10µg/ml concentrated solution.
This solution was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted. The corresponding wavelength having highest absorbance is noted as λ_{max}
Construction of calibration curve of Nizatidine in 0.1N HCL:
Working standard: 100mg of Nizatidinewas weighed and dissolved in 10ml methanol and then made up to a volume of 100ml with0.1N HCL it gives1000µg/ml concentrated stock solution.
Dilution 1: From the working standard solution 10ml was diluted to 100ml with 0.1NHCL it will give 100µg/ml concentrated solution.
From dilution-1, take 0.2, 0.4, 0.6, 0.8 and 1ml of solution and was diluted up to mark in 10ml volumetric flask to obtain 2, 4, 6, 8 and 10µg/ml concentrated solutions. This solutions absorbance was noted at $\lambda_{max=242}$
III. Formulation of gastro retentive floating tablets by direct compression method
Processing steps involved in direct compression method: The matrix tablets were prepared by following the General Methodology as given below:

- All ingredients (except magnesium stearate and talc) were weighed accurately and co sifted by passing through #40 sieve, blended in a Poly Bag for 5 min
- The above blendwere lubricated with # 60 Sieve passed Magnesium stearate & talc.
- The final blend was then compressed into tablets using 16 station tablet compression machine with an average hardness of 5.0 -6.0kg/cm^2, by using 8mm to 10mm die

Assay Procedure.
Ten tablets were weighed and powdered, a quantity of powder equivalent to 100 mg of Nizatidine was transferred to a 100 ml volumetric flask and 10 ml methanol is added. The drug is extracted in methanol by vigorously shaking the Stoppard flask for 15 minutes. Then the volume is adjusted to the mark with 0.1N HCL and the liquid is filtered. From prepared solution take 1ml solution in 100ml volumetric flask and make up to mark with 0.1 N HCL. The Nizatidine content was determined by measuring the absorbance at 242 nm after appropriate dilution. The drug content was calculated using the standard calibration curve. The mean percent drug content was calculated as an average of three determinations.

Calculate the quantity in mg of Nizatidine in the portion taken by the formula

Assay = test absorbance/standard absorbance*standard concentration/sample concentration*purity of drug/100*100

In vitro Buoyancy studies:

The in vitro buoyancy was determined as per the method described by Rosa et al.

a. **Floating Lag Time (FLT):** A tablet was placed in a 100 ml beaker containing 0.1N HCl. The time required for the tablet to rise to the surface and float was determined as the Floating Lag Time (FLT).
b. **Total Floating Time (TFT):** A tablet was placed in a 100 ml beaker containing 0.1N HCl. The duration of time up to which the tablet constantly floats on the dissolution medium was noted as the Total Floating Time (TFT).
c. **Matrix integrity:** During the period of TFT the swelled matrix tablets were observed for integrity. For 12 hrs

In vitro Dissolution Study:

900 ml of 0.1N HCl was placed in the vessel and the USP-II apparatus (Paddle method) was assembled. The medium was allowed to equilibrate to temperature of $37^0C \pm 0.5^0C$. A tablet was placed in the vessel and was covered; the apparatus was operated up to 12 hrs at 50 rpm. At definite time intervals, 5 ml of dissolution medium was withdrawn; filtered and again replaced with 5 ml of fresh medium to maintain sink conditions. Suitable dilutions were done with dissolution medium, were analysed spectrophotometrically at λ_{max} =279 nm using a UV-spectrophotometer (Lab India).

Table 3: Dissolution parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	0.1N HCl.
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	1,2, 3, 4,6,8,10,12hrs
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	242 nm

In-vitro Release Kinetics Studies:

The analysis of drug release mechanism from a pharmaceutical dosage form is important but complicated process and is practically evident in the case of matrix systems. The order of drug release from FDDS was described by using zero order kinetics or first order kinetics. The mechanism of drug release from FDDS was studied by using Higuchi equation and the Peppa's-Korsemeyer equation.

Zero Order Release Kinetics:

It defines a linear relationship between the fractions of drug released versus time.

$$Q=k_0t.$$

Where, Q is the fraction of drug released at time t and $k_o$is the zero order release rate constant. A plot of the fraction of drug released against time will be linear if the release obeys zero order release kinetics.

First Order Release Kinetics:

Wagner assuming that the exposed surface area of a tablet decreased exponentially with time during dissolution process suggested that the drug release from most of the slow release tablets could be described adequately by the first-order kinetics. The equation that describes first order kinetics is

$$\textbf{Log C= Log } C_o\textbf{-kt/2.303}$$

Where C is the amount of drug dissolved at time t,

C_o is the amount of drug dissolved at t=0 and

k is the first order rate constant.

A graph of log cumulative of log % drug remaining Vs time yields a straight line. Will be linear if the release obeys the first order release kinetics.

Higuchi equation:

It defines a linear dependence of the active fraction released per unit of surface (Q) and the square root of time.

$$Q=K_2t^{1/2}$$

Where K_2 is release rate constant. A plot of the fraction of drug released against square root of time will be linear if the release obeys Higuchi equation. This equation describes drug release as a diffusion process based on the Fick's law, square root time dependent[20].

Peppa's-Korsemeyer equation (Power Law):

In order to define a model, which would represent a better fit for the formulation, dissolution data was further analysed by Peppa's-Korsemeyer equation (Power Law).

$Mt/ \mathbf{M}_\infty = K.t^n$

Where, Mt is the amount of drug released at time t

M_α is the amount released at time α,

M_t/M_α is the fraction of drug released at time t,

K is the kinetic constant and n is the diffusion exponent.

To characterize the mechanism for both solvent penetration and drug release n can be used as abstracted . A plot between log drug release upto 60% against log of time will be linear if the release obeys Peppa's-Korsemeyer equation and the slope of this plot represents "n" value[21].the kinetic data of the formulations were included. Nature of release of the drug from the designed tablets was inferred based on the correlation coefficients obtained from the plots of the kinetic models. The data were processed for regression analysis using MS EXCEL

Table 4: Drug release kinetics mechanism

Diffusion exponent(n)	Mechanism
0.45	Fickian diffusion
0.45 < n <0.89	Anomalous (Non-Fickian) diffusion
0.89	Case II transport
n > 0.89	Super Case II transport

3. Results and Dicussion

Construction of Standard calibration curve of Nizatidine in 0.1N HCL: The absorbance of the solution was measured at 242nm, using UV spectrometer with 0.1N HCl as blank. The values are shown in table no12. A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer's law in the concentration range 2 to 10 µg/ml.

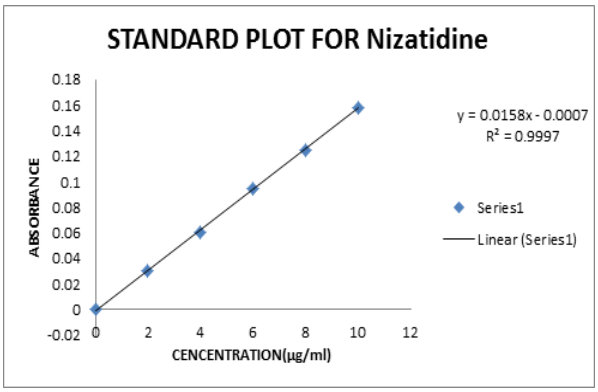

Fig.2:: Standard calibration curve of Nizatidine in 0.1N Hcl at λMax = 242nm

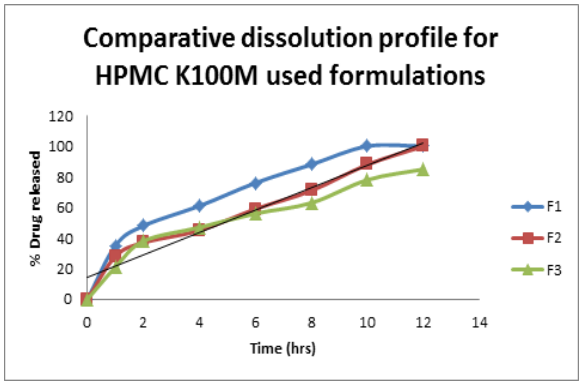

Fig.3: Comparative dissolution profile for HPMC K100M used formulations

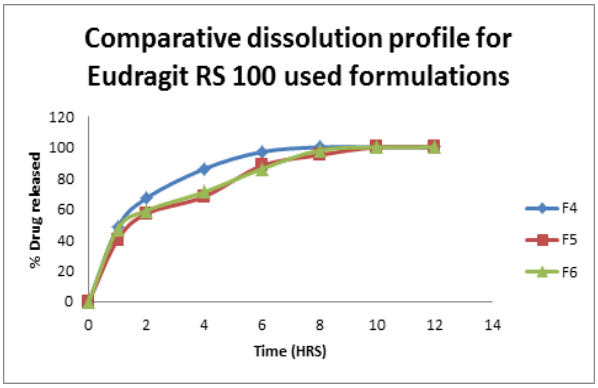

Fig.4: Comparative dissolution profile for Eudragit RS100 used formulations

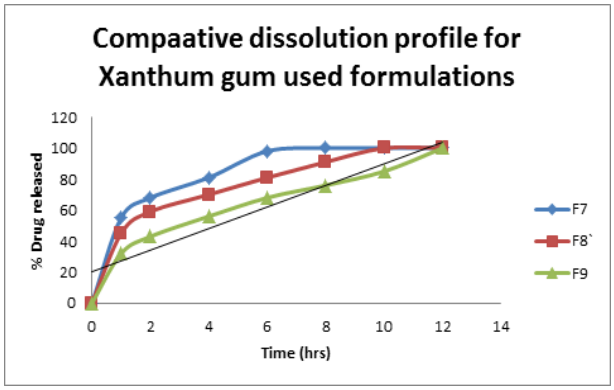

Fig.5: Comparative dissolution profile for Xanthum gum used formulations

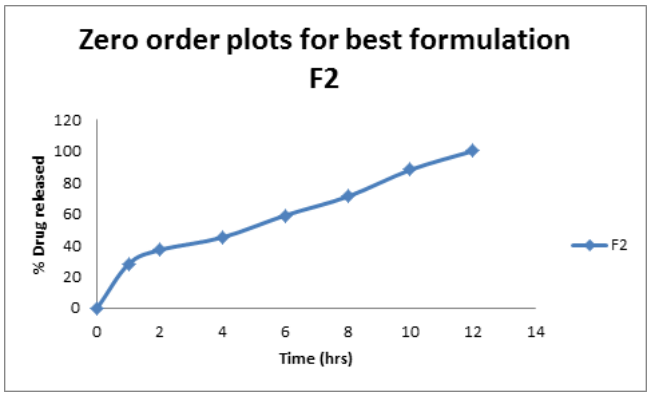

Fig.6: Zero order plot for best formulation F2

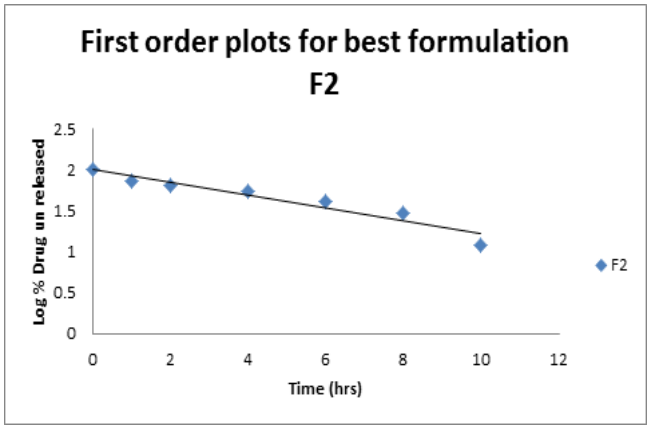

Fig.7: First order plot for best formulation F2

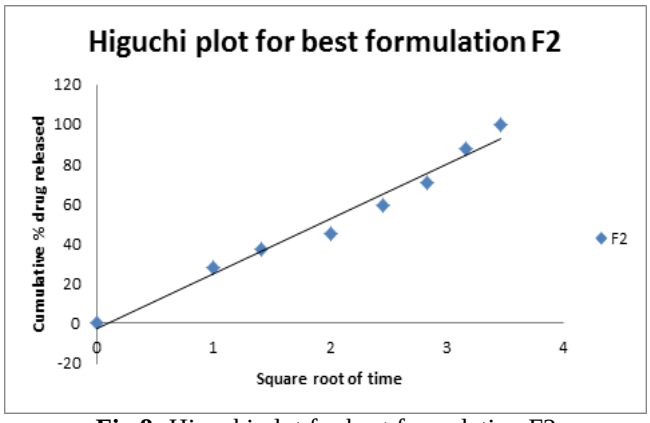

Fig.8: Higuchi plot for best formulation F2

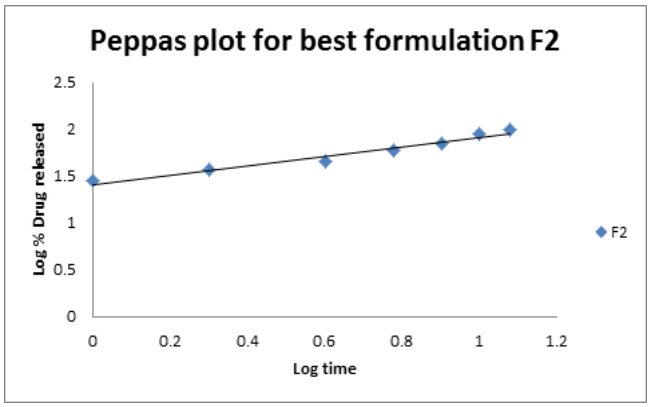

Fig.9: Korsmayerspepas plot for best formulation F2

Table 5: Standard Calibration graph values of Nizatidine in 0.1N Hcl at λ_{Max} = 242 nm

Conc.(µg / ml)	Absorbance at λ_{Max} = 242 nm
0	0
2	0.031
4	0.061
6	0.095
8	0.125
10	0.158

Table 6: Pre compression studies of Nizatidine Floating tablets

Formulation Code	Bulk density (Kg/cm^3)	Tapped density (Kg/cm^3)	Cars index	Hausners ratio	Angle of repose (˚)
F1	0.40	0.48	16	1.2	12.73
F2	0.41	0.50	13.0	1.5	11.29
F3	0.50	0.58	13	1.16	11.58
F4	0.39	0.47	17.0	1.56	12.23
F5	0.37	0.41	9.75	1.1	12.35
F6	0.43	0.52	17.3	1.41	11.62
F7	0.44	0.50	12	1.1	9.92
F8	0.41	0.45	8.8	1.0	11.85
F9	0.39	0.48	18	1.23	11.96

Table 7: Post compression studies of Nizatidine floating tablets

Formulation Code	% weight variation	Thickness (mm)	% Friability	% Drug Content	Hardness (Kg/cm^2)
F1	pass	5.06±0.11	0.142	101.3 ±1.2	5.56 ±0.057
F2	pass	5.06±0.15	0.151	102.3 ±1.7	5.03 ±0.115
F3	pass	5.03±0.057	0.62	100.1 ±1.2	5.01 ±0.1
F4	pass	5.1±0.1	0.154	100.7 ±1.1	5.63 ±0.05
F5	pass	5.03±0.05	0.132	99.6±1.5	5.63 ±0.03
F6	pass	5.03±0.15	0.143	98.9 ±2.3	5.5 ±0.05
F7	pass	4.93±0.05	0.110	100.2± 1.7	5.7 ±0.1
F8	pass	5.1±0.1	0.133	100.5± 1.4	5.53 ±0.04
F9	pass	5.02±0.2	0.13	99.2±1.1	5.69 ±0.05

*Test for Friability was performed on singlebatch of 20 tablets

Table 8: In vitro Buoyancy Studies of Nizatidine floating tablets

Formulation Code	Floating lag time(sec) n = 3	Total floating time n = 3	Matrix Integrity upto 12 hrs. n = 3
F1	20 ± 0.51	Up to 12	+
F2	40 ± 0.21	Up to 12	+
F3	80 ± 0.61	Up to 12	+
F4	20 ± 0.71	Up to 10	-
F5	30 ± 0.81	Up to 12	+
F6	35 ± 0.51	Up to 12	+
F7	24 ± 0.31	Up to 10	-
F8	20 ± 0.81	Up to 12	+
F9	36 ± 0.71	Up to 12	+

Table 9: In-vitro Dissolution results for formulation trails

Time (hrs)	% Drug released								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8`**	**F9**
0	0	**0**	0	0	0	0	0	0	0
1	35	**28**	21	48	40	47	55	45	32
2	48	**37**	38	67	57	59	68	59	43
4	61	**45**	47	86	68	71	81	70	56
6	76	**59**	56	97	88	86	98	81	68

8	88	**71**	63	100	95	98	100	91	76
10	100	**88**	78	100	100	100	100	100	85
12	100	**100**	85	100	100	100	100	100	100

4. Conclusion

A UV-Visible spectrophotometric method was developed and validated for the quantification of Nizatidine in 0.1N HCl, with absorbance measured at 242 nm. The standard calibration curve demonstrated an excellent linear relationship within the concentration range of 2 to 10 µg/ml, with a regression value of 0.9997, confirming the method's precision and reliability for routine analysis. Pre-compression studies of the tablet blends revealed consistent bulk and tapped densities, favorable Carr's index and Hausner ratios, and acceptable angles of repose, all indicative of good flow properties and compressibility suitable for direct compression. Post-compression evaluation confirmed that all Nizatidine floating tablet formulations complied with pharmacopeial standards for hardness, friability, drug content, thickness, and weight variation. The tablets exhibited sufficient mechanical strength and consistent drug dosing. In vitro buoyancy studies demonstrated satisfactory floating lag times and total floating durations up to 12 hours, with matrix integrity maintained during this period. Dissolution studies showed efficient and sustained drug release, with the F2 formulation achieving the most favorable release profile, supported by strong correlation with drug release kinetics models such as zero-order, first-order, and Higuchi, indicating a diffusion-controlled mechanism with non-fickian anomalous transport. Overall, the study successfully formulated robust, controlled-release Nizatidine floating tablets with improved gastric retention and drug release properties, enhancing potential therapeutic effectiveness and patient compliance.

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