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Formulation and Evaluation of Floating Tablets

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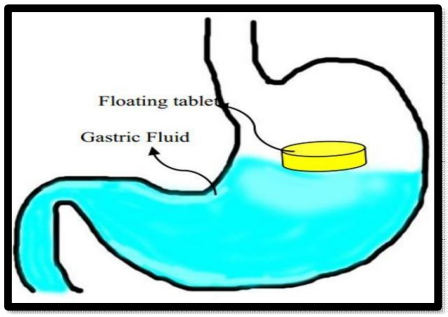
Abstract: *Floating tablet technology has emerged as a promising approach in the field of drug delivery, offering unique advantages in controlled release, enhanced bioavailability, and improved patient compliance. Pre-formulation studies are essential in pharmaceutical development to understand the physical and chemical properties of a drug and its interactions with excipients. This study focuses on the pre-formulation investigations of Nizatidine to develop suitable dosage forms for therapeutic purposes. Standard solutions of Nizatidine were prepared, and calibration curves were generated using UV double beam spectrophotometry. Drug-excipient compatibility was evaluated using FTIR spectroscopy. Floating tablets of Nizatidine were formulated using various polymers via direct compression method. The pre-compression and post-compression parameters of the formulated tablets were evaluated, including bulk density, tapped density, compressibility index, Hausner's ratio, angle of repose, hardness, friability, drug content, and buoyancy studies. In-vitro dissolution studies were conducted using USP-II apparatus .The standard calibration curve of Nizatidine showed a linear relationship between concentration and absorbance. FTIR studies indicated compatibility between the drug and excipients. Evaluation of pre-compression parameters revealed variations among formulations. Post-compression parameters demonstrated uniformity in tablet weight, mechanical strength, and drug content. Buoyancy studies showed variation in floating properties among formulations. Swelling index studies revealed hydration kinetics of tablets. Dissolution studies depicted drug release profiles over time. Kinetic modelling revealed that the optimized formulation followed Higuchi release kinetics, indicating diffusion-controlled drug release. Stability studies of the optimized formulation (F5) showed consistent thickness, hardness, and drug content over a period of three months, indicating formulation stability. This comprehensive study provides insights into the pre-formulation, formulation, and evaluation of floating tablets of Nizatidine, contributing to the development of gastroretentive drug delivery systems.*

Keywords: Floating tablet, Pre-formulation, Nizatidine, Excipients, Floating tablets, Dissolution, Compatibility, Kinetic modeling, Stability

I. INTRODUCTION

Floating tablets

Floating tablets are a specific type of oral solid dosage form designed to remain buoyant in the stomach for an extended period of time. These tablets have the unique characteristic of floating on the gastric fluid, allowing them to release the drug gradually and uniformly over an extended period. This controlled release feature is particularly advantageous for drugs that require sustained or localized action within the stomach or upper gastrointestinal tract.[59]



The development of floating tablets has gained significant attention in pharmaceutical research and development due to their potential to improve drug delivery and therapeutic outcomes. By maintaining the tablet in the stomach, floating

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tablets can enhance drug absorption, increase bioavailability, and prolong drug residence time in the gastric environment. [60]

The concept of floating tablets revolves around incorporating gas-generating agents or hydrocolloids in the tablet formulation. Gas-generating agents, such as effervescent mixtures, generate carbon dioxide upon contact with gastric fluid, resulting in tablet buoyancy. Hydrocolloids, such as polymers or gelling agents, swell or hydrate in the presence of fluid, forming a gel layer around the tablet, which enables it to float.[61]

The buoyancy of floating tablets offers several advantages. Firstly, it allows the drug to be released gradually over an extended period, maintaining therapeutic concentrations in the stomach. This is particularly useful for drugs that are unstable in the acidic environment of the stomach or those that require localized action. Secondly, it enhances drug absorption by ensuring prolonged contact between the drug and the absorptive surfaces in the stomach. Finally, floating tablets can improve patient compliance by reducing the frequency of dosing, as they provide sustained release of the drug.[62]

The formulation and development of floating tablets require careful consideration of various factors, including the selection of appropriate polymers, gas-generating agents, and excipients, as well as optimization of the tablet's physical characteristics and release profile. Various techniques, such as direct compression, effervescent systems, or multiparticulate systems, can be employed to produce floating tablets. [63]

II. MATERIALS AND METHOD

Drug Authentication

The sample of Nizatidine was evaluated for its physical state, odor and color.

Pre formulation Studies of Nizatidine

Pre formulation studies were performed on the drug, which included melting point determination, solubility and compatibility studies.

Solubility of Nizatidine

Solubility of Nizatidine was determined as slightly soluble in water, soluble in alcohol, practically insoluble in fatty oils.

Melting Point

Variation in the melting point gives idea about its purity. Melting point of Nizatidine was determined by open capillary tube method. UV Spectroscopy Preparation of 0.1N HCl 0.1N HCl was prepared according to IP 1996. A quantity of 8.5 ml of HCl was diluted with fresh distilled water to produce 1000 ml.

Standard Curve of Nizatidine

Nizatidine has been quantitatively analyzed by various techniques. In present studies, Nizatidine was estimated by UV Spectrophotometry method.

Preparation of Stock Solution

The drug (10 mg) was dissolved in 100 ml of 0.1 N HCl in the volumetric flask. From the stock solution volume of solution of various concentrations i.e. 5, 10, 15, 20, 25 µg/ml were prepared using 0.1 N HCl to make the volume of 10 ml in a volumetric flask.

The absorbance was measured at analytical wavelength and a standard curve of Beer's law was plotted.

Absorbance of these solutions was measured against pH 0.1 N HCl as blank at 313 nm using Shimadzu 1800 UV/Vis double beam spectrophotometer.

Infrared spectra analysis

Infrared spectrum of Nizatidine was determined on Fourier Transform Infrared Spectrophotometer (FTIR-4100s) using KBr dispersion method.

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III. PREFORMULATION STUDIES

Pre-formulation testing is an investigation of physical and chemical properties of a drug substance alone and when combined with excipients.

Pre-formulation studies yield necessary knowledge to develop suitable formulation for toxicological use.

It gives information needed to define the nature of the drug substance and provide a dosage form.

Hence, the following pre-formulation studies were performed for the obtained sample of drug.

Formulation Development Formulation Design

Formulation Design study is important for selection of appropriate excipients for preparation tablets. The three grades of HPMC namely HPMC K 4M, HPMC K15K, HPMC K100M were used for trial preparation of tablets.

Preparation of Nizatidine Floating Tablet

Floating tablets containing Nizatidine were formulated employing the wet granulation technique, incorporating varied concentrations of polymer alongside sodium bicarbonate.

Polymer and Nizatidine were meticulously blended using a glass mortar and pestle to ensure homogeneity. Isopropyl alcohol served as the granulating agent in the process.

Granules were generated by sieving the wet cohesive mass through a #16 sieve. Subsequently, the granules underwent drying in a hot air oven at a temperature of 45°C.

Following drying, the granules were sieved through a #40 sieve and lubricated with magnesium stearate and talc approximately 4-5 minutes prior to compression.

The lubricated granules were then compressed utilizing a tablet compression machine (Karnavati Mini press I) equipped with 13 mm flat round punches to yield tablets meeting the desired specifications.

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Nizatidine	150	150	150	150	150	150	150	150	150
HPMC K100M	107.5	134.4	161.3	107.5	134.4	161.3	107.5	134.4	161.3
Sod. Bicarbonate	107.5	107.5	107.5	107.5	107.5	107.5	107.5	107.5	107.5
Citric Acid	13.4	13.4	13.4	26.9	26.9	26.9	40.3	40.3	40.3
PVP K30	40.3	40.3	40.3	40.3	40.3	40.3	40.3	40.3	40.3
Magnesium stearate	13.4	13.4	13.4	13.4	13.4	13.4	13.4	13.4	13.4
Talc	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7
Total Wt. (mg)	500	500	500	500	500	500	500	500	500

IV. EVALUATION OF PRE COMPRESSION PARAMETERS

Bulk density

The bulk density of a compound significantly differs depending on the procedure used for crystallisation, grinding, or formulation. Bulk density is calculated by pouring granules that have been pre-sieved into a graduated cylinder using a big funnel, and then measuring the volume and weight.

Tapped density:

The compound's bulk density varies greatly based on the specific techniques employed for crystallisation, grinding, or formulation. The calculation of bulk density involves the process of pouring pre-sieved granules into a graduated cylinder using a large funnel, followed by the measurement of both the volume and weight.

Carr's Index (CI)

For the purpose of calculating Carr's index, the values of bulk density and tapped density are utilised. In order to determine the Carr's index, the following equation is utilised.Table 6.3: Flow properties and corresponding Carr's Index values

Hausner's Ratio: It indicates the flow properties of the powder and ratio of Tapped density to the Bulk density of the powder or granules.

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Hausner's Ratio = Tapped density / Bulk density

Angle of repose:

In order to determine Carr's index, the values of bulk density and tapped density are employed. This is done for the aim of computing the index.

EVALUATION OF TABLETS:

The formulated tablets were evaluated for the following physicochemical characteristics:

General appearance:

The formulated tablets were assessed for its general appearance and observations were made for shape, color, texture and odor.

Hardness:

The Monsanto hardness tester was utilised in order to ascertain the tablet's level of hardness. The bottom plunger was brought into contact with the tablet, and a reading of zero was obtained from the device. Following this, a threaded bolt was turned in order to drive the plunger against a spring until the tablet broke. The amount of force that was applied to the spring was indicated by a pointer that moved along a gauge that was located in the barrel.

Weight Variation

A total of 20 pills were chosen and their weights were measured both collectively and individually. The average weight was determined by calculating the collective weight. Subsequently, the weight of each tablet was compared to the average weight in order to determine if it fell within the acceptable range. At most, two of the individual weights differed from the average weight of the 300 mg tablets by more than 7.5%, and none differed by more than twice that proportion.

Friability test:

20 previously weighed tablets were placed in the friability apparatus, which was given 100 revolutions and the tablets were reweighed. The percentage friability was calculated by usingthe following formula,

Percentage friability = initial weight-final weight /initial weight × 100.

Drug content:

20 tablets of each formulations were weighted and powdered . The quantity of powder equivalent to 100 mg of Nizatidine was transferred in to a 100 ml volumetric falsk and the volume adjusted to 100ml with 0.1N HCL. Further 1ml of the above solutions was diluted to 100 ml with 0.1n HCL and check the absorbance of the resulting solution was observed at 216 mm

In-vitro Buoyancy studies:

The in-vitro buoyancy was determined by floating lag time, and total floating time. The tablets were placed in a 100ml beaker containing 0.1N HCl. The time required for the tablet to rise to the surface and float was determined as floating lag time (FLT) and the duration of the time the tablet constantly floats on the dissolution medium was noted as the Total Floating Time respectively (TFT).

Swelling Index Studies:

The swelling behavior of a dosage unit wasmeasured by studying its weight gain. The swelling index of tablets was determined by placing the tablets in thebasket of dissolution apparatus using dissolution mediumas 0.1N HCl at 37±0.5°C. After 1, 4 and 6h each dissolution basket containing tablet waswithdrawn, blotted with tissue paper to remove theexcess water and weighed on the analytical balance(Schimdzu, AX 120). The experiment was performedin triplicate for each time point. Swelling index wascalculated by using the following formula.

In-Vitro Dissolution Studies of Tablets:

The in-vitro drug release studies involved determining the release rate of the drug from floating tablets utilizing the United States Pharmacopoeia (USP) dissolution testing apparatus II, employing the paddle method. The dissolution test was conducted using 900 ml of 0.1 N HCl, maintaining a temperature of 37 ± 0.5°C and a paddle rotation speed of 75 rpm. At hourly intervals over a period of 12 hours, a 5 ml sample of the dissolution solution was withdrawn from the dissolution apparatus, and in turn, replenished with fresh dissolution medium. These withdrawn samples were suitably diluted with 0.1 N HCl to achieve an appropriate concentration. Subsequently, the absorbance of these solutions was measured at 313 nm utilizing a Shimadzu UV-Vis double beam spectrophotometer 1800. The cumulative percentage of

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drug release was calculated employing the equation derived from a standard curve. Finally, a graph was plotted depicting the percentage of drug release against time (hours).

V. RESULTS AND DISCUSSION

Pre formulation Studies

Melting point Determination

The melting point of Nizatidine was found to be in the range 131-1340C (1330C), which complied with BP standards, indicating purity of the drug sample. Solubility Nizatidine was found to be sparingly soluble in water, soluble in methanol, practically insoluble in fatty oils.

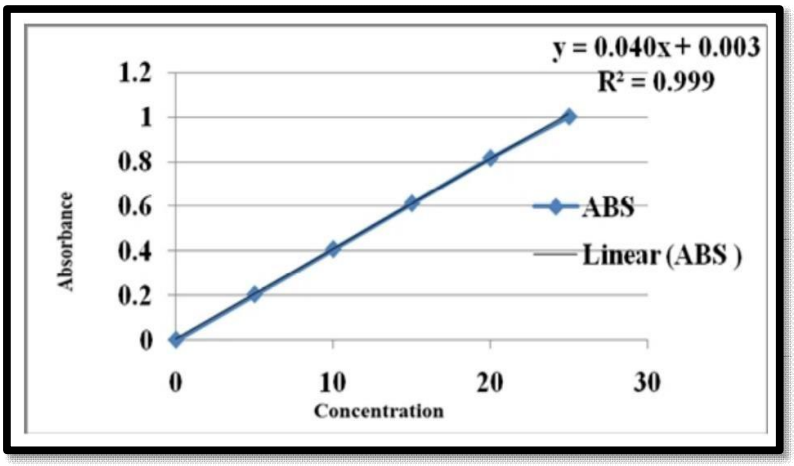
Calibration Curve of Nizatidine

The λ max was found to be at 313 nm. The calibration curve was linear between 05-25 µg/ml concentration ranges. The standard calibration curve of Nizatidine was determined in 0.1N HCl, by plotting absorbance against concentration at 313 nm.

Table 1.1: Calibration Curve of Nizatidine in 0.1 N HCl

S. No.	Concentration (µg/ml)	Absorbance at 313 nm
1.	0	0
2.	5	0.204
3.	10	0.409
4.	15	0.613
5.	20	0.818
6.	25	1.004

Fig 1.1: Calibration Curve of Nizatidine in 0.1 N HCl



FTIR Spectra

Interpreting FTIR spectra can provide valuable information about the molecular structure and composition of a compound or formulation. Let's break down the detailed explanation of the results for the FTIR spectra of Nizatidine and its final formulation:

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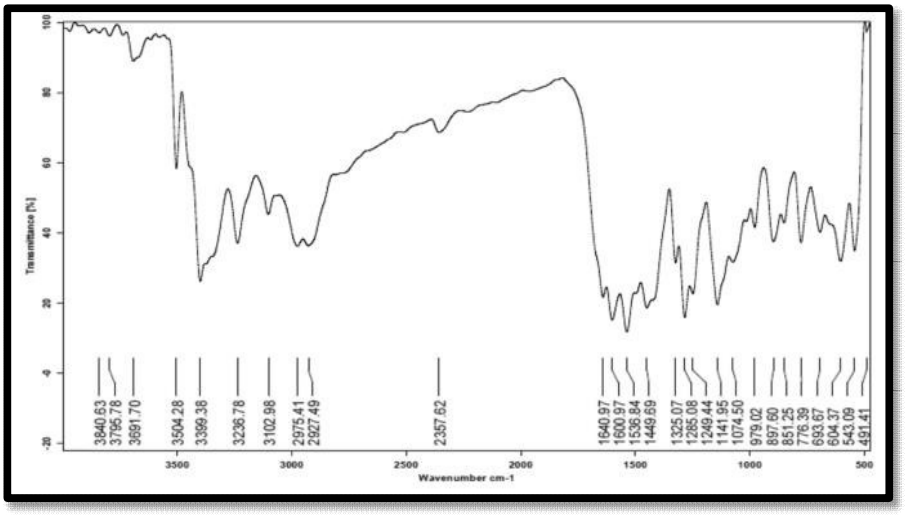

Fig 1.2: FTIR Spectra of Nizatidine

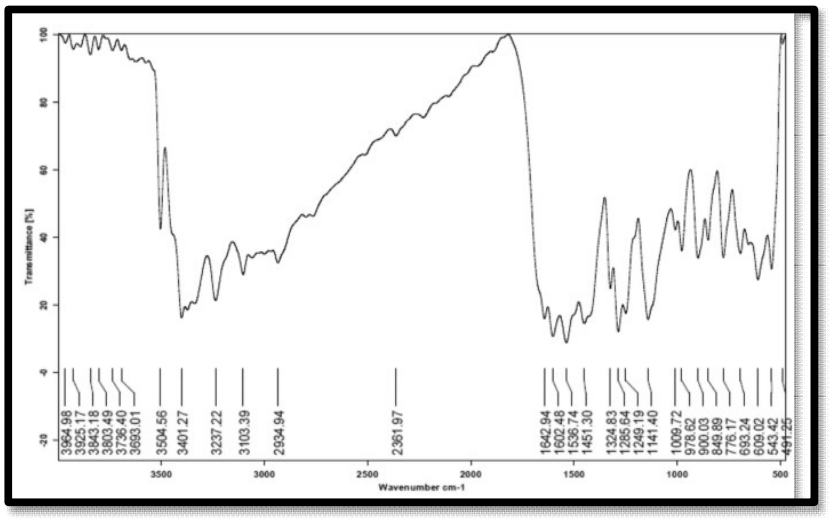

Fig 1.3: FTIR Spectra of Nizatidine final formulation

Identification of Peaks: The FTIR spectra typically display peaks at specific wavenumbers corresponding to the vibrational frequencies of functional groups within the molecules.

Functional Groups: By analyzing the positions and intensities of peaks, we can identify the functional groups present in the sample. For Nizatidine, common functional groups include amines, aromatic rings, and various types of bonds (e.g., C- H, C=O, N-H).

Comparing Spectra: To analyze the final formulation of Nizatidine, we compare its FTIR spectrum to that of pure Nizatidine. Any shifts, changes in intensity, or appearance/disappearance of peaks can indicate alterations in molecular structure due to formulation processes or the addition of excipients.

Peak Shifts: If peaks in the final formulation spectrum are shifted compared to pure Nizatidine, it may suggest interactions between Nizatidine and excipients. For example, a shift to lower wavenumbers could indicate hydrogen bonding or changes in molecular conformation.

New Peaks or Absence of Peaks: Appearance of new peaks or absence of peaks in the final formulation spectrum compared to pure Nizatidine can indicate the presence of new functional groups from excipients or alterations in the chemical environment due to formulation.

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Intensity Changes: Changes in peak intensities can suggest differences in concentration or interactions between molecules in the final formulation compared to pure Nizatidine. For example, if a peak related to N-H stretching in Nizatidine is less intense in the final formulation, it may indicate dilution or masking due to excipients.

Quality Control: FTIR spectra can also be used for quality control purposes to ensure consistency in formulation batches. Consistent spectra across batches indicate reproducibility in the manufacturing process.

Quantitative Analysis: In some cases, FTIR spectra can be used for quantitative analysis, such as determining the concentration of active pharmaceutical ingredients in formulations.

In summary, detailed analysis of FTIR spectra of Nizatidine and its final formulation provides insights into molecular changes, interactions with excipients, and overall formulation quality, which are crucial for pharmaceutical development and manufacturing.

Pre-formulation studies

Table 1.2: Pre-formulation studies

Batch Code	Angle of Repose (θ)	Bulk Density (g/cm3)	Tapped Density (g/cm3)	Hausner's Ratio (HR)	Carr Index (CI)
F1	270°	0.523 ± 0.062	0.680 ± 0.014	1.27 ± 0.034	16.77 ± 0.04
F2	280°	0.458 ± 0.052	0.652 ± 0.053	1.05 ± 0.073	17.50 ± 0.51
F3	270°50'	0.474 ± 0.053	0.524 ± 0.062	1.08 ± 0.033	21.88 ± 0.65
F4	300°12'	0.464 ± 0.017	0.565 ± 0.017	1.13 ± 0.061	16.82 ± 0.56
F5	290°56'	0.443 ± 0.014	0.456 ± 0.023	1.26 ± 0.045	19.01 ± 0.42
F6	280°21'	0.525 ± 0.031	0.552 ± 0.031	1.12 ± 0.034	21.85 ± 0.09
F7	270°71'	0.558 ± 0.012	0.487 ± 0.019	1.18 ± 0.055	10.90 ± 0.23
F8	250°44'	0.448 ± 0.018	0.488 ± 0.073	1.07 ± 0.029	13.77 ± 0.45
F9	260°38'	0.430 ± 0.018	0.545 ± 0.054	1.10 ± 0.026	12.56 ± 0.24

Angle of Repose (θ):

The angle of repose indicates the flow properties of the powder. Higher angles suggest poorer flowability. Batch F7 has the lowest angle of repose (270°71'), indicating better flowability, while batch F4 has the highest angle (300°12'), suggesting poorer flow properties.

Bulk Density:

This represents the mass of the powder per unit volume when freely poured into a measuring vessel.

Values range from 0.430 g/cm3 (batch F9) to 0.558 g/cm3 (batch F7).

Tapped Density:

This is the maximum density achieved when the powder is tapped or subjected to vibrations.

Values range from 0.456 g/cm3 (batch F5) to 0.680 g/cm3 (batch F1).

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Hausner's Ratio (HR):

Hausner's ratio is the ratio of tapped density to bulk density. It gives an indication of the powder's flowability and compressibility.

Values close to 1 indicate good flow properties, while higher values suggest poorer flowability.

Values range from 1.05 (batch F2) to 1.27 (batch F1).

Carr Index (CI):

Carr index, or compressibility index, is calculated from the tapped and bulk densities. It provides an assessment of the powder's compressibility.

Lower values indicate better compressibility.

Values range from 10.90% (batch F7) to 21.88% (batch F3).

Overall, batch F7 exhibits the best flow properties with the lowest angle of repose, Hausner's ratio, and Carr index. Batch F4, on the other hand, shows the poorest flow properties with the highest angle of repose and a relatively high Hausner's ratio and Carr index. These results provide important insights for further formulation development and process optimization.

EVALUATION OF TABLET

The angle of repose, bulk density, tapped density, Hausner's ratio, and Carr index are important parameters that provide insights into the flow properties and compressibility of powder formulations.

Table 1.3: EVALUATION OF TABLET

Batch Code	Weight Variation (mg) ± SD	Hardness (kg/cm²) ± SD	Friability (%)	Drug Content Uniformity (%) ± SD
F1	365 ± 2.64	5.3 ± 0.20	0.719	97.33 ± 1.15
F2	385 ± 2.51	5.4 ± 0.20	0.833	96.00 ± 1.73
F3	405 ± 1.00	5.8 ± 0.10	0.805	97.00 ± 1.00
F4	375 ± 2.00	5.7 ± 0.15	0.851	97.00 ± 1.00
F5	395 ± 2.51	5.8 ± 0.11	0.821	97.00 ± 1.73
F6	435 ± 4.72	5.8 ± 0.05	0.935	97.00 ± 2.64
F7	385 ± 4.16	5.6 ± 0.17	0.701	96.33 ± 1.15
F8	405 ± 4.04	5.7 ± 0.20	0.814	97.66 ± 2.30
F9	425 ± 3.60	5.7 ± 0.17	0.916	95.66 ± 2.08

Angle of Repose (θ): Higher angles indicate poorer flowability. Batch F7 exhibits the lowest angle of repose, indicating better flowability, while batch F4 has the highest angle, suggesting poorer flow properties.

Bulk Density: Represents mass per unit volume. Values range from 0.430 g/cm3 (batch F9) to 0.558 g/cm3 (batch F7).

Tapped Density: Maximum density achieved when the powder is tapped. Values range from 0.456 g/cm3 (batch F5) to 0.680 g/cm3 (batch F1).

Hausner's Ratio (HR): Ratio of tapped density to bulk density. Values close to 1 indicate good flow properties. Ranges from 1.05 (batch F2) to 1.27 (batch F1).

Carr Index (CI): Provides an assessment of powder compressibility. Lower values indicate better compressibility. Ranges from 10.90% (batch F7) to 21.88% (batch F3).

Overall, batch F7 demonstrates the best flow properties with the lowest angle of repose, Hausner's ratio, and Carr index. In contrast, batch F4 shows the poorest flow properties with the highest angle of repose and relatively high Hausner's ratio and Carr index. These findings are crucial for further formulation development and process optimization.

Floating Properties of Nizatidine Floating tablets Pre-formulation studies

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Table 1.4: Pre-formulation studies

Batch Code	Floating Lag Time (seconds)	Matrix Integrity	Floating Duration (hours)
F1	14	✓	> 12
F2	17	✓	> 12
F3	16	✓	> 12
F4	15	✓	> 12
F5	18	✓	> 12
F6	15	✓	> 12
F7	10	✓	> 12
F8	15	✓	> 12
F9	16	✓	> 12

Floating Lag Time:

Floating lag time refers to the time taken for the tablet to start floating after it comes in contact with the dissolution medium.

Values range from 10 to 18 seconds across batches.

Matrix Integrity:

All batches show intact matrix integrity, indicated by the ✓ symbol. This suggests that the tablets maintain their structural integrity during the floating period.

Floating Duration:

Floating duration refers to the length of time the tablet remains buoyant in the dissolution medium.

All batches exhibit a floating duration of more than 12 hours.

Overall, the floating tablets of Nizatidine demonstrate consistent and desirable floating properties across all batches. They exhibit short floating lag times, maintain matrix integrity throughout the floating period, and sustain buoyancy for more than 12 hours. These results indicate successful formulation of floating tablets with sustained-release characteristics, which can enhance drug delivery and improve patient compliance.

In-vitro drug release data of Nizatidine floating tablets

The in-vitro drug release data provided above represents the percentage of Nizatidine released from floating tablets over a period of 12 hours. Let's break down the detailed explanation of the results:

Table 1.5: In-vitro drug release data of Nizatidine floating tablets

Time (h)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
1	38.098	20.585	9.245	58.411	30.204	13.655	54.184	33.620	30.662
2	44.284	25.338	15.163	62.605	36.132	19.905	57.936	39.810	35.101
3	50.031	31.458	21.092	65.722	42.477	27.237	60.439	43.681	41.109
4	53.854	37.035	27.855	69.940	46.955	32.753	68.008	51.771	48.026
5	55.562	43.666	35.156	72.067	52.051	38.410	70.373	56.047	49.883
6	58.516	46.147	40.550	73.668	56.722	42.894	73.861	62.054	51.661
7	63.332	51.213	47.107	80.568	62.712	46.472	77.103	65.282	59.403
8	69.527	54.746	51.233	83.095	65.787	52.431	83.811	71.176	61.362
9	73.094	61.275	56.148	87.405	69.602	54.621	85.559	74.368	65.309
10	78.253	64.014	62.118	91.073	70.903	62.245	89.482	78.642	69.725
11	82.430	66.648	67.983	93.012	71.258	68.370	93.108	84.615	74.582
12	87.879	71.742	72.281	94.598	73.923	73.246	99.461	88.893	79.147

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Time (h): The time points at which drug release was measured, ranging from 0 to 12 hours.
Batch F1-F9: Each column corresponds to a specific batch of Nizatidine floating tablets. These batches likely represent different formulations or manufacturing conditions.
Drug Release Profile: The values in the table represent the percentage of Nizatidine released from the tablets at each time point. For example, at 1 hour, batch F1 has released 38.098% of the drug, while batch F7 has released 54.184%.
Release Rate: The rate of drug release varies among different batches. Some batches exhibit a faster release rate, while others release the drug more slowly over time.

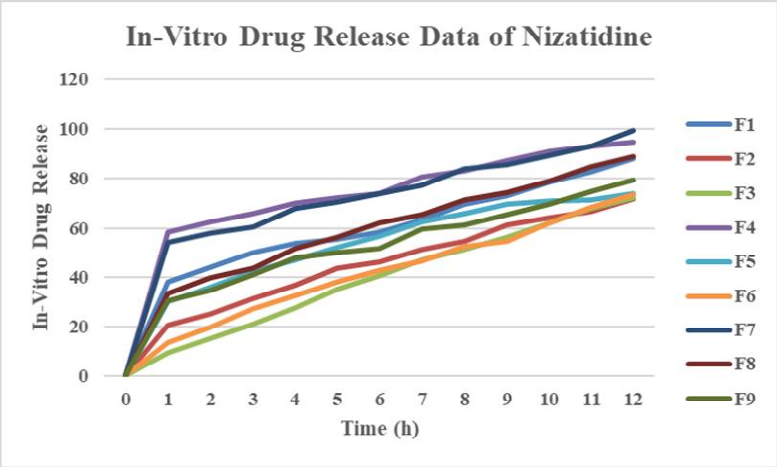

Fig 1.4: In-vitro drug release data of Nizatidine floating tablets

Cumulative Release: The cumulative drug release over the 12-hour period can be observed by summing the percentages released at each time point. Batch F7, for instance, demonstrates a rapid release profile, with almost 100% of the drug released by the end of 12 hours, while other batches exhibit slower release kinetics.
Formulation Comparison: By comparing the drug release profiles of different batches, one can assess the impact of formulation variables on drug release kinetics. Batches with faster release rates may contain excipients or formulation parameters that promote rapid dissolution, while slower-release batches may have formulations optimized for sustained drug release.
Sustained Release Characteristics: The sustained release characteristics of the floating tablets are evident as drug release continues over the 12-hour period. This sustained release profile is desirable for maintaining therapeutic drug levels in the body and potentially improving patient compliance by reducing dosing frequency.
Quality Control: In-vitro drug release studies are essential for quality control purposes to ensure consistency and reproducibility of drug release profiles across different batches of pharmaceutical products.
In summary, the detailed explanation of the in-vitro drug release data provides insights into the release kinetics and sustained release characteristics of Nizatidine floating tablets, which are crucial for pharmaceutical development and manufacturing.

VI. SUMMARY AND CONCLUSION SUMMARY

The results and discussion section provides a thorough examination of various aspects related to the development and evaluation of Nizatidine floating tablets. Starting with pre- formulation studies, the determination of the drug's melting point and solubility properties aligning with established standards underscores its purity and suitability for formulation. The calibration curve derived from UV spectroscopy establishes a reliable method for quantifying Nizatidine content in formulations, ensuring dosage uniformity and potency. Analysis of FTIR spectra offers insights into molecular changes and interactions, essential for quality control and formulation optimization. Evaluation of flow properties and tablet characteristics provides crucial information regarding powder compressibility, tablet mechanical strength, and drug release uniformity, pivotal for therapeutic efficacy. Assessment of floating properties demonstrates the tablets' ability to remain buoyant and sustain drug release, facilitating prolonged gastric residence time and improved patient compliance.

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Lastly, the in- vitro drug release data elucidates the release kinetics and sustained release characteristics of Nizatidine floating tablets, highlighting formulation differences and their impact on drug dissolution and bioavailability. Overall, the comprehensive evaluation presented in this section guides formulation development, ensuring the design of robust formulations with desired characteristics for enhanced drug delivery and therapeutic outcomes.

VII. CONCLUSION

In conclusion, the comprehensive evaluation of Nizatidine floating tablets elucidates various aspects crucial for their development and optimization. Through pre-formulation studies, we established the drug's purity, solubility, and compatibility with excipients, laying the foundation for formulation design. The calibration curve from UV spectroscopy ensures accurate quantification of Nizatidine content, essential for dosage uniformity. Analysis of FTIR spectra provides insights into molecular interactions, guiding quality control and formulation adjustments. Evaluation of flow properties and tablet characteristics informs on powder compressibility and tablet performance, ensuring reliable drug delivery. The assessment of floating properties demonstrates the tablets' ability to remain buoyant and sustain drug release, facilitating prolonged gastric residence time. Finally, in-vitro drug release data delineates release kinetics and sustained release characteristics, informing on formulation differences and their impact on drug dissolution. Altogether, these findings contribute to the development of robust Nizatidine floating tablets with optimized performance and therapeutic efficacy, promising improved patient outcomes and treatment compliance.

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