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Formulation and Evaluation of Gastroretentive Floating Tablet Dosage Form

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ABSTRACT:

The study aimed to formulate an oral floating tablet of Moxifloxacin using gum Karaya and HPMC K100M via wet granulation. The optimized batch released the drug slowly and completely for 12 hours, allowing the tablet to remain in floating condition throughout dissolution. This increased the residence time of Moxifloxacin HCl in the stomach, thereby increasing its bioavailability. The drug identification confirmed the purity of Moxifloxacin hydrochloride, and FTIR spectra analysis revealed no interaction between the drug, polymer, and excipients. Micromeritic studies indicated excellent flow properties of the granules, producing tablets with optimum hardness, consistent average weight, and low friability. The in vitro buoyancy study found that Gum Karaya tablets had good gel strength, stable, persistent buoyancy, and good matrix integrity up to 12 hours. Batch F5 was selected as an optimized formulation due to its best results in terms of in vitro buoyancy, good matrix integrity, and sustained drug release. All formulations passed standard pharmacopeial tests, confirming acceptable flow properties and tablet characteristics.

Keywords: Granulation, beam spectrophotometer, compressibility, bioavailability, etc.

Introduction

Oral drug delivery is preferred due to ease of administration, patient compliance, & formulation flexibility. Most available systems progress from immediate release to site-specific delivery. An ideal system should deliver the active drug directly to the target site. Gastro retentive controlled release formulations offer a solution to the problem of prolonged gastric residence time, allowing drugs to exit the stomach with gastric fluids and have the entire small intestine available for absorption. This could be beneficial for enhanced drug therapy for stomach conditions like peptic ulcer. However, designing controlled release systems for better absorption and enhanced bioavailability faces difficulties, such as confined dosage forms in the desired area of the gastrointestinal tract. Improved bioavailability and therapeutic efficacy of drugs, potential dose reduction, constant therapeutic levels, minimized resistance risk, and increased patient compliance can be achieved through prolonged dosing.

Material and Method

Preformulation study- The study evaluated Moxifloxacin's physical state, odour, and color. The melting point, a crucial parameter for determining drug purity, was determined using the capillary method. The mean melting point was considered the drug's melting point. The λ max was determined by transferring 10.0 mg of Moxifloxacin to a 100 mL volumetric flask, dissolved in distilled water, and scanned in the 200-400 nm UV spectrophotometer using water as a blank. The standard curve of Moxifloxacin was also determined in 0.1N HCl and water. The FTIR analysis was conducted to determine any possible interaction between the drug and excipients used. The Fourier transform infrared spectrophotometer (Jasco-V-530 model) was used to analyze the IR absorption spectrum of Moxifloxacin. The spectral analysis showed the compatibility of ingredients in the formulations. The study concluded that Moxifloxacin's purity was determined through various methods, including the capillary method and FTIR analysis.

Formulation of moxifloxacin floating tablets- The study focuses on the preparation of Moxifloxacin floating tablets (dose 400 mg) using a wet granulation method. The ingredients were sifted, mixed, and diluted before being passed through a sieve to form granules. The granules were dried in a hot air oven, mixed with lubricants, and compressed using a Tablet press. The granules were evaluated for their flow and compressibility before compression.

Table 1: Composition of Moxifloxacin Gastroretentive Floating Tablets

Ingredient (mg)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Moxifloxacin	**400**	**400**	**400**	**400**	**400**	**400**	**400**	**400**	**400**
Gum Karaya	**160**	**140**	**120**	**100**	**80**	**60**	**40**	**20**	**-**

HPMC K100M	**-**	**20**	**40**	**60**	**80**	**100**	**120**	**140**	**160**
Sodium Bicarbonate	**130**	**130**	**130**	**130**	**130**	**130**	**130**	**130**	**130**
Citric Acid	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Magnesium Stearate	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Talc	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Total Tablet Weight	**720**	**720**	**720**	**720**	**720**	**720**	**720**	**720**	**720**

Result and Discussion

Moxifloxacin, a white crystalline powder with characteristic odor, has a melting point of 238-242°C and a prominent FT-IR spectrum with characteristic peaks at the principal position. The principal peaks in the Moxifloxacin sample were found to correspond to the functional group, confirming its presence in the spectrum. The λ max, determined to be 294 nm, was crucial for drug characterization. The calibration curve for Moxifloxacin in water was determined using a double beam spectrophotometer (Jasco V630) and absorbance values at various concentrations.

Evaluation of granules: Granulation characteristics are crucial for formulation scientists and are widely measured. Bulk density, which influences compressibility, porosity, and dissolution, depends on particle size, shape, and adhesion. Moxifloxacin floating tablets have a good packing capacity, with a density influenced by particle packing and changing as the powder consolidates. The degree of consolidation is unique to the powder. The study found that a Carr's index below 15% indicates good flow characteristics, while a Hausners ratio of low range indicates good flow ability. The angle of repose, suitable for particles >150µm, was within the range of 20.8±0.13 to 27.43±0.12, indicating good flowability of the granules.

Table 2: Evaluation of Moxifloxacin floating tablets

Batch code	Average weight (mg)	Thickness (mm)	Diameter (mm)	Hardness (Kg/cm^2)	Friability (%)	Drug content (%)
F1	**717±0.79**	**4.59±0.03**	**14.07±0.07**	**4.69±0.22**	**0.89±0.02**	**97.73±0.31**
F2	**720±0.85**	**4.95±0.07**	**14.01±0.02**	**4.73±0.39**	**0.52±0.06**	**98.52±0.20**
F3	**718±0.99**	**4.61±0.04**	**14.09±0.02**	**4.60±0.23**	**0.93±0.01**	**98.90±0.14**
F4	**720±1.12**	**4.30±0.07**	**14.02±0.05**	**4.35±0.10**	**0.82±0.02**	**98.63±0.22**
F5	**719±0.12**	**4.43±0.08**	**14.07±0.06**	**4.40±0.13**	**0.49±0.05**	**99.73±0.17**
F6	**718±1.14**	**4.78±0.05**	**14.02±0.02**	**4.53±0.21**	**0.51±0.03**	**97.53±0.29**
F7	**717±1.21**	**4.92±0.02**	**14.08±0.07**	**4.39±0.17**	**0.86±0.09**	**101.18±0.1**
F8	**721±0.84**	**4.65±0.04**	**14.07±0.08**	**4.33±0.35**	**0.67±0.03**	**99.43±0.27**
F9	**717±1.14**	**4.68±0.05**	**14.03±0.02**	**4.55±0.21**	**0.57±0.03**	**98.50±0.29**

All readings are average ±(SD)

The study evaluated tablet formulations for thickness, diameter, and hardness, revealing consistent particle size and uniform behavior during compression. Thickness ranged from 4.30± 0.07mm to 4.95±0.07mm, while hardness ranged from 4.39 ± 0.17 to 4.73±0.39 Kg/cm2. Tablets had good tensile strength, allowing them to withstand handling stress without breaking. Friability was less than 1%, ensuring tablets can withstand mechanical impacts during packing, transportation, and processing operations. The average weight ranged from 717±0.79 to 721±0.84 mg, and the drug content

was in the range of 97.53 ± 0.29 to 1.0 ± 0.12, indicating good content uniformity in the prepared formulation.

Dissolution Studies: The study found that drug release from the matrix is influenced by polymer swelling, drug diffusion, and matrix erosion. Tablets ascended to upper dissolution vessels and remained floated until release studies were completed.

Stability study: Stability studies were conducted according to ICH guidelines to check the quality, efficacy, and safety of formulations. Results showed no significant changes in physical properties after accelerated stability studies for 30, 60, and 90 days, indicating no degradation during storage.

Table 3: Evaluation of optimized formulation F5 after stability period

Parameters	**Period**			
	Before	**After 30 days**	**After 60 days**	**After 90 days**
Thickness (mm)	**4.43±0.08**	**4.43±0.03**	**4.42±0.10**	**4.42±0.02**
Diameter (mm)	**13.07±0.06**	**13.07±0.02**	**13.07±0.01**	**12.98±0.08**
Hardness (Kg/cm^2)	**4.40±0.13**	**4.41±0.15**	**4.40±0.18**	**4.40±0.10**
Floating lag time (s)	**58**	**58**	**59**	**59**
Floating time (h)	**>12**	**>12**	**>12**	**> 12**
Drug content	**99.77±0.17**	**99.73±0.17**	**99.12±0.57**	**98.45±0.89**
Drug release after 12 h	**99.17**	**98.75**	**98.75**	**97.98**

Conclusion

Gastro retentive floating tablets of Moxifloxacin were effectively formulated using Gum Karaya and HPMC K100M via wet granulation. Batch F5 showed optimal floating lag time (< 60 sec), total floating time (>12 hrs), and sustained drug release (99.17% in 12 hrs). All formulations passed standard pharmacopeial tests, confirming acceptable flow properties and tablet characteristics. Optimized batch remained stable under accelerated conditions and exhibited high swelling index, confirming Gastroretentive potential.

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