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Formulation and Evaluation of Floating Tablets

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Abstract: *The present study was aimed at the formulation and evaluation of floating tablets of Meloxicam to achieve prolonged gastric residence and sustained drug release, thereby enhancing bioavailability. Preformulation studies were performed to characterize the drug, including melting point, solubility, UV, and FTIR analysis. Floating tablets were formulated by wet granulation technique using varying concentrations of HPMC (K4M, K15M, K100M), sodium bicarbonate as a gas-generating agent, and citric acid to optimize floating characteristics. Pre-compression parameters like bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose were determined, indicating acceptable flow properties. The prepared tablets were evaluated for weight variation, hardness, friability, drug content uniformity, in-vitro buoyancy (floating lag time and total floating time), swelling index, and in-vitro dissolution. The optimized formulation exhibited a floating lag time below 20 seconds, total floating time exceeding 12 hours, and sustained drug release up to 12 hours. Thus, the study successfully developed a floating drug delivery system of Meloxicam with desirable physicochemical and release properties.*

Keywords: Meloxicam, floating tablets, wet granulation, HPMC, gastroretentive, sustained release, in-vitro buoyancy

I. INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, and cost-effectiveness. However, one of the major challenges associated with conventional oral dosage forms is their limited gastric residence time, which can lead to incomplete drug release and reduced bioavailability of drugs that are primarily absorbed in the upper gastrointestinal tract (GIT). To overcome these limitations, gastroretentive drug delivery systems (GRDDS) have been developed to prolong the residence time of dosage forms in the stomach, thereby enhancing the absorption of drugs with narrow absorption windows.[1,2]

Floating drug delivery systems (FDDS), a subclass of GRDDS, are designed to remain buoyant on gastric fluids, enabling prolonged gastric retention and sustained drug release. These systems are particularly advantageous for drugs that are absorbed predominantly in the stomach or the proximal part of the small intestine, have local activity in the stomach, or are unstable in the intestinal or colonic environment.[3,4]

Meloxicam, a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class, is widely used in the management of osteoarthritis, rheumatoid arthritis, and other inflammatory conditions. It exhibits poor aqueous solubility and is mainly absorbed from the upper GIT. Thus, formulating Meloxicam as a floating dosage form can potentially enhance its bioavailability by maintaining it in the stomach for a prolonged period, allowing continuous drug release at the absorption site.[5,6]

Hydroxypropyl methylcellulose (HPMC) is a commonly used hydrophilic polymer in controlled-release formulations due to its ability to form a gel barrier upon hydration, thereby regulating drug release. The incorporation of gas-generating agents like sodium bicarbonate, along with acids such as citric acid, can further aid in maintaining tablet buoyancy by generating carbon dioxide upon contact with gastric fluid.[7,8]

The present study focuses on the formulation and evaluation of Meloxicam floating tablets using different grades and concentrations of HPMC to achieve sustained drug release and extended gastric retention. The research aims to investigate the influence of polymer type and effervescent agents on the physicochemical properties, buoyancy behavior, swelling characteristics, and in-vitro drug release profile of the prepared floating tablets.

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II. MATERIALS AND METHODS

The present study involved the preformulation and formulation development of Meloxicam tablets. The obtained sample of Meloxicam was first authenticated by evaluating its physical properties such as color, odor, and physical state. Preformulation studies included determination of melting point using the open capillary tube method to assess purity, solubility profiling in various solvents (water, alcohol, fatty oils), and compatibility studies. A UV spectrophotometric method was employed to prepare a standard calibration curve: stock solution of Meloxicam (10 mg in 100 ml of 0.1 N HCl) was serially diluted to obtain concentrations of 5, 10, 15, 20, and 25 µg/ml, and absorbance was measured at 313 nm using a Shimadzu 1800 UV/Vis spectrophotometer. The infrared spectrum of Meloxicam was recorded using an FTIR-4100s spectrophotometer by the KBr pellet method to confirm functional groups. For formulation development, three grades of hydroxypropyl methylcellulose (HPMC K4M, HPMC K15M, and HPMC K100M) were selected as matrix-forming polymers to prepare sustained-release tablet formulations. The formulations were designed by direct compression method, and the selection of excipients was based on their compatibility with Meloxicam as established in the preformulation studies.[9-11]

Preparation of Meloxicam Floating Tablets

Floating tablets of Meloxicam were prepared using the wet granulation technique. Accurately weighed quantities of Meloxicam, selected grades of HPMC polymer, and sodium bicarbonate were thoroughly mixed in a glass mortar and pestle to achieve uniform blending. Isopropyl alcohol was employed as the granulating fluid to form a cohesive mass, which was then passed through a #16 sieve to obtain wet granules. These granules were dried in a hot air oven at 45 °C until a constant weight was achieved, followed by sieving through a #40 mesh to ensure uniform particle size. The dried granules were lubricated with magnesium stearate and talc for about 4–5 minutes to enhance flow and compressibility. Finally, the lubricated granules were compressed into tablets using a Karnavati Mini press I tablet compression machine fitted with 13 mm flat round punches, producing tablets that complied with the desired specifications.[12-14]

Table 1: Composition of Meloxicam Floating Tablet

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Meloxicam	15	15	15	15	15	15	15	15	15
HPMC K100M	107.5	134.4	161.3	107.5	134.4	161.3	107.5	134.4	161.3
Sod. Bicarbonate	132.5	132.5	132.5	132.5	132.5	132.5	132.5	132.5	132.5
Citric Acid	13.4	13.4	13.4	26.9	26.9	26.9	40.3	40.3	40.3
PVP K30	60.3	60.3	60.3	60.3	60.3	60.3	60.3	60.3	60.3
Magnesium stearate	68.4	68.4	68.4	68.4	68.4	68.4	68.4	68.4	68.4
Talc	41.7	41.7	41.7	41.7	41.7	41.7	41.7	41.7	41.7
Total Wt. (mg)	500	500	500	500	500	500	500	500	500

The prepared granules for Meloxicam floating tablets were assessed for pre-compression parameters including bulk density, tapped density, Carr's Index, Hausner's Ratio, and angle of repose to evaluate flow properties and compressibility. Post-compression evaluation of the tablets involved examining general appearance (shape, color, texture, odor), measuring hardness using a Monsanto hardness tester, and checking weight variation by weighing 20 individual tablets to ensure compliance with pharmacopeial limits. Friability was determined by subjecting 20 tablets to 100 revolutions in a friabilator and calculating the percentage weight loss. Drug content was analyzed by powdering 20 tablets, dissolving an equivalent of 100 mg Meloxicam in 0.1 N HCl, and measuring absorbance at 216 nm. In-vitro buoyancy was assessed by recording the floating lag time (FLT) and total floating time (TFT) in 0.1 N HCl at 37 ± 0.5 °C. Swelling index was determined by weighing tablets at 1, 4, and 6 hours after immersion in the dissolution medium and calculating weight gain. Finally, in-vitro drug release was studied using a USP type II dissolution apparatus in 900 ml of 0.1 N HCl at 37 ± 0.5 °C and 75 rpm, with samples withdrawn hourly over 12 hours, analyzed at 313 nm, and cumulative drug release plotted versus time.[15-18]

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III. RESULT AND DISCUSSION

The pre-compression parameters (Table 2) indicated that the granules exhibited good to fair flowability and compressibility, essential for uniform die filling and tablet formation. The angle of repose values ranged between 250° to 300°, suggesting satisfactory flow properties. Carr's index and Hausner's ratio were within acceptable limits (< 22% and <1.25 respectively for most batches), confirming moderate compressibility and minimal interparticle friction. These findings ensured that the granules were suitable for consistent tablet compression without significant weight variation or capping.

The tablets passed the general appearance check, being uniform in shape, color, and free from visible defects. Weight variation results (Table 3) indicated all batches were within pharmacopeial limits, confirming uniformity of fill. The hardness ranged from 5.3 to 5.8 kg/cm² across all batches, suggesting adequate mechanical strength to withstand handling. Friability values were below 1%, ensuring resistance to abrasion and maintaining tablet integrity during packaging and transport.

Drug content uniformity across formulations ranged between 95.66% to 97.66%, indicating homogeneous drug distribution within the matrix. In-vitro buoyancy tests demonstrated excellent floating characteristics, with floating lag times between 10–18 seconds and total floating times exceeding 12 hours for all batches, attributed to optimal sodium bicarbonate and citric acid concentrations generating sufficient CO_2 for rapid buoyancy.

Swelling studies revealed that the tablets absorbed dissolution medium progressively, which facilitated gel formation and sustained release. The swelling index increased over time, supporting the slow erosion mechanism essential for prolonged drug release.

The in-vitro dissolution profiles confirmed that the floating tablets achieved sustained release over 12 hours. The variations in HPMC grades and concentrations impacted drug release rates, with higher viscosity polymers (HPMC K100M) showing slower drug release due to formation of a denser gel barrier, effectively controlling diffusion. This ensured a controlled drug release pattern suitable for reducing dosing frequency and enhancing patient compliance.

Table 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

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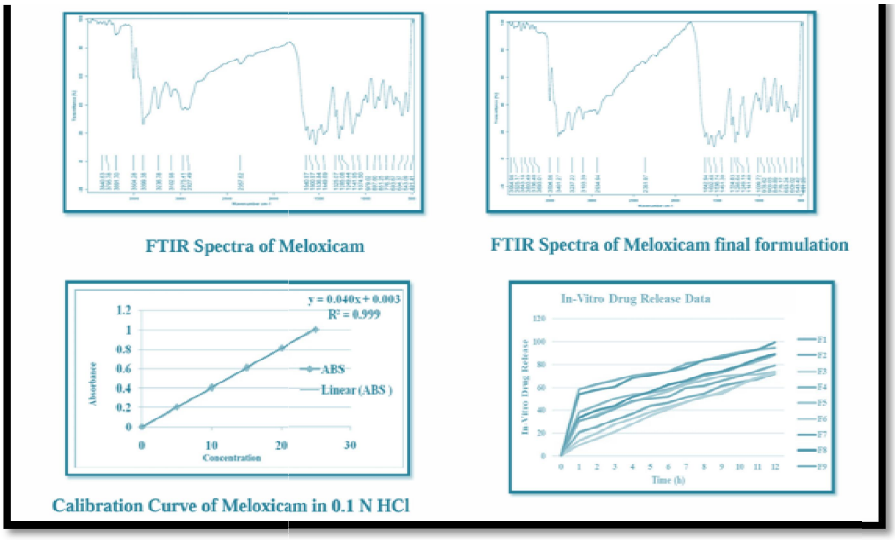
Table 3: Evaluation of tablet

Batch Code	Weight Variation (mg) ± SD	Drug Content Uniformity (%) ± SD	Floating Lag Time (seconds)	Floating (hours)	Hardness (kg/cm²) ± SD	Friability (%)
F1	365 ± 2.64	97.33 ± 1.15	14	> 12	5.3 ± 0.20	0.719
F2	385 ± 2.51	96.00 ± 1.73	17	> 12	5.4 ± 0.20	0.833
F3	405 ± 1.00	97.00 ± 1.00	16	> 12	5.8 ± 0.10	0.805
F4	375 ± 2.00	97.00 ± 1.00	15	> 12	5.7 ± 0.15	0.851
F5	395 ± 2.51	97.00 ± 1.73	18	> 12	5.8 ± 0.11	0.821
F6	435 ± 4.72	97.00 ± 2.64	15	> 12	5.8 ± 0.05	0.935
F7	385 ± 4.16	96.33 ± 1.15	10	> 12	5.6 ± 0.17	0.701
F8	405 ± 4.04	97.66 ± 2.30	15	> 12	5.7 ± 0.20	0.814
F9	425 ± 3.60	95.66 ± 2.08	16	> 12	5.7 ± 0.17	0.916



IV. CONCLUSION

The study successfully formulated and evaluated Meloxicam floating tablets using HPMC polymers of varying viscosities by wet granulation. The formulations demonstrated acceptable pre-compression and post-compression parameters, excellent buoyancy with rapid floating lag time and prolonged total floating duration, and sustained drug release over 12 hours. These results highlight the potential of the developed floating tablets as an effective gastroretentive system for Meloxicam, offering the promise of improved bioavailability and patient adherence. Future in-vivo studies can further validate the efficacy and gastric retention performance of this delivery system.

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