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Pharmaceutical Development and In-Vitro Evaluation of Gastro-Retentive Floating Tablets of Telmisartan

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ABSTRACT

Gastro-retentive drug delivery systems (GRDDS) have emerged as a promising approach to enhance the bioavailability of drugs exhibiting a narrow absorption window in the upper gastrointestinal tract. Telmisartan, an angiotensin II receptor antagonist with low aqueous solubility and variable oral bioavailability, is an ideal candidate for gastro-retentive formulation. The present research focuses on the pharmaceutical development and in-vitro evaluation of effervescent gastro-retentive floating tablets of Telmisartan prepared by direct compression technique. Floating tablets were formulated using hydrophilic polymers and gas-generating agents to achieve prolonged gastric residence time and sustained drug release. Pre-compression and post-compression parameters were evaluated to ensure acceptable flow, compressibility, mechanical strength, buoyancy, and drug content uniformity. In-vitro buoyancy and dissolution studies demonstrated rapid floating lag time, prolonged floating duration, and controlled drug release up to 12 hours. The study confirms that gastro-retentive floating tablets of Telmisartan can be successfully developed to enhance gastric retention and potentially improve bioavailability.

KEYWORDS: *Telmisartan, gastro-retentive drug delivery system, floating tablets, hypertension, sustained release.*

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1. INTRODUCTION

Oral drug delivery is the most commonly employed route of administration due to its simplicity, convenience, patient compliance, and cost-effectiveness compared to other routes of drug delivery (1).

Despite these advantages, conventional oral dosage forms often exhibit limitations such as unpredictable gastric emptying and variable gastrointestinal transit time, which can adversely affect drug absorption (2).

The gastric residence time of a dosage form is a critical factor influencing the bioavailability of drugs that are absorbed primarily from the stomach or the proximal region of the small intestine (3).

Rapid gastric emptying can result in incomplete drug release from the dosage form, leading to reduced therapeutic efficacy and increased variability in plasma drug concentration (4).

Gastro-retentive drug delivery systems (GRDDS) have been developed to address these challenges by prolonging the residence time of dosage forms in the stomach (5).

By retaining the dosage form in the gastric region for an extended duration, GRDDS enhance drug dissolution, absorption, and overall bioavailability (6).

These systems are particularly advantageous for drugs that have a narrow absorption window, poor solubility at intestinal pH, or instability in the alkaline environment of the lower gastrointestinal tract (7).

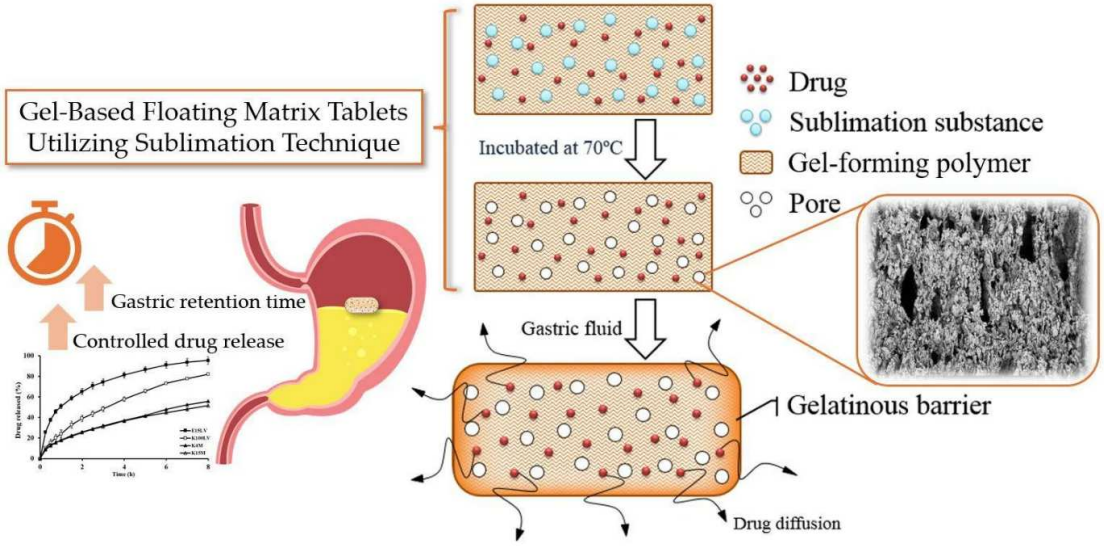


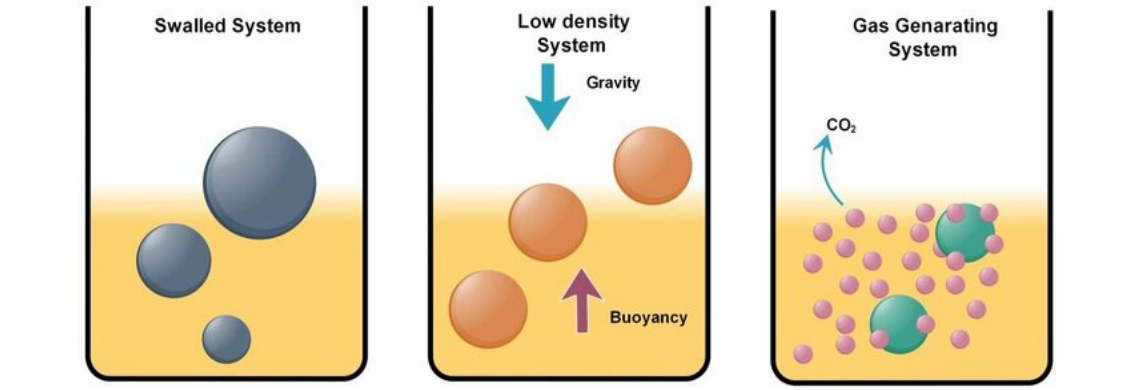
Figure 1. Floating Drug Delivery System (FDDS) in Stomach

Various strategies have been explored to achieve gastro-retention, including floating systems, bioadhesive systems, expandable systems, high-density systems, and raft-forming systems (8).

Among these approaches, floating drug delivery systems (FDDS) have gained considerable attention due to their ease of formulation and reliable gastric retention characteristics (9).

Floating drug delivery systems are designed to possess a bulk density lower than that of gastric fluid, allowing them to float on the stomach contents without interfering with gastric emptying (10).

Fig .2 Mechanism of Effervescent Floating Tablets



While floating on gastric fluid, the dosage form releases the drug in a controlled manner, thereby maintaining sustained plasma drug concentrations over an extended period (11).

Effervescent floating systems utilize gas-generating agents such as sodium bicarbonate, which react with gastric acid to produce carbon dioxide that becomes entrapped within the hydrated polymer matrix, resulting in buoyancy (12).

Non-effervescent floating systems rely on swellable polymers that form a gel barrier upon contact with gastric fluid, reducing tablet density and enabling prolonged flotation (13).

Hypertension is a chronic cardiovascular disorder characterized by persistently elevated arterial blood pressure and is a major risk factor for stroke, myocardial infarction, and renal failure (14).

Telmisartan is an angiotensin II receptor blocker widely prescribed for the management of hypertension due to its efficacy and favorable safety profile (15).

However, Telmisartan exhibits poor aqueous solubility and variable oral bioavailability, which can limit its therapeutic effectiveness (16).

Improving the gastric residence time of Telmisartan through a gastro-retentive floating tablet can enhance its dissolution and absorption in the upper gastrointestinal tract (17).

Therefore, the present study aims to develop and evaluate gastro-retentive floating tablets of Telmisartan using an effervescent approach to achieve sustained drug release and improved oral bioavailability (18).

2. LITERATURE REVIEW

Gastro-retentive drug delivery systems have been extensively explored as an effective approach to enhance the bioavailability of drugs with limited absorption windows in the upper gastrointestinal tract (19).

Sahu et al. reported the development of sustained-release effervescent floating tablets of levofloxacin using different polymer ratios and sodium bicarbonate–citric acid as gas-generating agents (20). Their study demonstrated prolonged floating behavior and sustained drug release up to 12 hours, confirming the effectiveness of effervescent floating systems.

Kumar et al. highlighted the potential of floating drug delivery systems for antihypertensive drugs and emphasized their role in improving gastric residence time and maintaining consistent plasma drug levels (21).

Rahman et al. reviewed recent advancements in gastro-retentive floating tablets and discussed formulation strategies such as polymer selection, tablet density optimization, and gas-generating systems to enhance gastric retention of antihypertensive drugs (22).

Gupta et al. formulated floating tablets of losartan potassium and evaluated their in-vitro buoyancy and drug release characteristics (23). The study showed that optimized formulations achieved rapid floating lag time and sustained drug release, demonstrating the applicability of FDDS for antihypertensive therapy.

Sharma et al. provided a comprehensive review on gastro-retentive floating tablets of antihypertensive drugs and concluded that floating systems significantly improve drug bioavailability and patient compliance (24).

Reddy et al. developed floating tablets of esomeprazole using sodium bicarbonate as a gas-forming agent and polymers such as HPMC K15M and chitosan (25). The optimized formulation showed sustained drug release for 12 hours and followed zero-order kinetics, indicating the importance of polymer selection in controlling release behavior.

Mohan et al. reviewed various floating drug delivery systems designed for hypertension management and highlighted the advantages of sustained drug release and reduced dosing frequency (26).

Jain et al. discussed emerging trends in gastro-retentive floating tablets, focusing on technological advancements such as direct compression techniques and novel polymer combinations to enhance tablet performance (27).

Zafar et al. formulated floating tablets of acyclovir using HPMC, sodium carboxymethyl cellulose, and carbopol (28). Their study confirmed good floating behavior and controlled drug release, while SEM analysis revealed surface morphology changes after dissolution.

Sharma et al. conducted in-vivo evaluation of gastro-retentive floating tablets containing valsartan and demonstrated improved bioavailability compared to conventional dosage forms (29).

Bhattacharjee et al. developed floating tablets of enalapril maleate and evaluated their in-vitro buoyancy and dissolution behavior (30). The results indicated sustained drug release and prolonged gastric retention.

Kaur et al. formulated gastro-retentive floating tablets of atenolol to overcome its poor absorption in the lower gastrointestinal tract (31). The study reported enhanced gastric retention and improved bioavailability.

Jain et al. prepared floating tablets of ciprofloxacin using HPMC K15M and HPMC K100M and reported extended drug release up to 12 hours with minimal floating lag time (32).

Ansari et al. developed gastro-retentive floating tablets of itopride hydrochloride using HPMC K15M and xanthan gum (33). The optimized formulation showed sustained drug release following zero-order kinetics and no drug–polymer interaction.

Yadav et al. reviewed gastro-retentive floating tablets as an ideal approach for antihypertensive drug delivery and emphasized their role in enhancing therapeutic efficacy and patient compliance (34).

Patel et al. formulated floating tablets of amlodipine besylate and reported prolonged floating duration and controlled drug release, confirming the suitability of FDDS for antihypertensive drugs (35).

Based on the literature survey, it is evident that gastro-retentive floating drug delivery systems are a promising approach for improving the bioavailability and therapeutic performance of antihypertensive drugs. However, limited studies have been reported on the formulation of gastro-retentive floating tablets of Telmisartan, thereby justifying the need for the present research.

3. DRUG PROFILE OF TELMISARTAN

Telmisartan is a potent antihypertensive agent belonging to the class of angiotensin II receptor blockers (ARBs) and is widely prescribed for the management of essential hypertension and cardiovascular risk reduction (36).

3.1. Chemical Profile

Telmisartan is chemically designated as **$C_{33}H_{30}N_4O_2$**, with a molecular weight of approximately **514.62 g/mol** (37).

The drug exhibits a highly lipophilic nature with a log P value of about **6.1**, which contributes to its poor aqueous solubility (38).

Telmisartan appears as a white to off-white crystalline powder and is practically insoluble in water but soluble in organic solvents such as methanol and ethanol (39).

3.2. Pharmacological Classification

Telmisartan belongs to the pharmacological class of **angiotensin II type-1 (AT_1) receptor antagonists**, which selectively inhibit the binding of angiotensin II to AT_1 receptors (40).

It is categorized under antihypertensive agents and is used either as monotherapy or in combination with other antihypertensive drugs (41).

3.3. Mechanism of Action

Telmisartan exerts its antihypertensive effect by selectively blocking the AT_1 receptor, thereby inhibiting the vasoconstrictive and aldosterone-secreting effects of angiotensin II (42).

By blocking the renin-angiotensin-aldosterone system (RAAS), Telmisartan causes vasodilation, reduces sodium and water retention, and ultimately lowers blood pressure (43).

Unlike angiotensin-converting enzyme (ACE) inhibitors, Telmisartan does not interfere with bradykinin metabolism, resulting in a lower incidence of cough and angioedema (44).

3.4. Pharmacokinetics

Telmisartan is well absorbed following oral administration, with an absolute bioavailability of approximately **33%**, which may vary depending on gastrointestinal conditions (45).

The drug exhibits extensive plasma protein binding (~99.7%), primarily to albumin, contributing to its prolonged duration of action (46).

Telmisartan undergoes minimal hepatic metabolism and is primarily metabolized by glucuronidation to an inactive metabolite (47).

The elimination half-life of Telmisartan is relatively long, ranging from **20 to 24 hours**, allowing for once-daily dosing (48).

Excretion occurs mainly via biliary elimination, with minimal renal excretion, making the drug suitable for patients with renal impairment (49).

3.5. Therapeutic Uses

Telmisartan is primarily indicated for the treatment of **essential hypertension**, either alone or in combination with other antihypertensive agents (50).

It is also used to reduce cardiovascular morbidity and mortality in patients at high risk of cardiovascular events (51).

Additionally, Telmisartan is beneficial in patients with diabetic nephropathy and left ventricular hypertrophy due to its renoprotective and cardioprotective properties (52).

3.6. Rationale for Selection of Telmisartan for Gastro-Retentive Floating Tablets

Despite its long half-life, Telmisartan exhibits poor aqueous solubility and variable oral bioavailability, which can limit its therapeutic effectiveness (53).

The drug shows better solubility in acidic pH, making it a suitable candidate for gastro-retentive drug delivery systems (54).

Formulating Telmisartan as a floating tablet can prolong gastric residence time, enhance drug dissolution in the stomach, and improve absorption in the upper gastrointestinal tract (55).

Therefore, Telmisartan is considered an ideal drug candidate for the development of gastro-retentive floating tablets aimed at improving bioavailability and therapeutic efficacy (56).

4. MATERIALS AND METHODS

4.1. Materials

Telmisartan was used as the active pharmaceutical ingredient (API) for the formulation of gastro-retentive floating tablets. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC) were employed as release-retarding agents to control drug release and maintain matrix integrity. Sodium bicarbonate was used as a gas-generating agent to impart buoyancy to the tablets. Microcrystalline cellulose (MCC) was used as a diluent to improve compressibility. Magnesium stearate and talc were used as lubricant and glidant, respectively. All chemicals and excipients used in the study were of analytical or pharmaceutical grade and were used as received.

4.2. Pre-Formulation Studies

Pre-formulation studies were carried out to characterize the physicochemical properties of Telmisartan and to evaluate its suitability for formulation into gastro-retentive floating tablets.

4.2.1. Physical Appearance

The physical appearance of Telmisartan was examined visually for color, odor, and texture. The

drug was observed under normal daylight conditions to assess uniformity and presence of any visible impurities.

4.2.2. Melting Point Determination

The melting point of Telmisartan was determined using the capillary tube method. A small quantity of drug was filled into a capillary tube sealed at one end and placed in a melting point apparatus. The temperature at which the drug started melting and completely melted was recorded to confirm purity.

4.2.3. Solubility Studies

Solubility studies of Telmisartan were conducted in distilled water, 0.1 N hydrochloric acid, phosphate buffer pH 6.8, and selected organic solvents. An excess amount of drug was added to each solvent and shaken continuously for 24 hours at room temperature. The solutions were filtered, and drug concentration was determined spectrophotometrically to assess solubility behavior.

4.2.4. UV Spectrophotometric Analysis

A UV-visible spectrophotometer was used to determine the λmax of Telmisartan. The drug was dissolved in 0.1 N hydrochloric acid, and the solution was scanned between 200–400 nm. A calibration curve was prepared by measuring absorbance of standard drug solutions at the determined λmax to enable quantitative analysis during drug content and dissolution studies.

4.2.5. Drug–Polymer Compatibility Studies

Fourier Transform Infrared (FTIR) spectroscopy was performed to study possible interactions between Telmisartan and selected polymers. FTIR spectra of pure drug, polymer, and physical mixtures were recorded in the range of 4000–400 cm^{-1}. The spectra were analyzed for any significant shifts or disappearance of characteristic peaks.

4.3. Formulation Development of Floating Tablets

Gastro-retentive floating tablets of Telmisartan were prepared using the **direct compression method**. Different batches were formulated by varying the concentration of hydrophilic polymers while keeping the drug content constant.

All ingredients were accurately weighed and passed through a #60 mesh sieve. The drug and polymers were blended thoroughly in a mortar to ensure uniform mixing. Sodium bicarbonate was added to the blend and mixed uniformly. Finally, magnesium stearate and talc were added and blended gently to avoid over-lubrication. The resulting powder blend was compressed into tablets using a rotary tablet compression machine equipped with flat-faced punches.

4.4. Evaluation of Powder Blend (Pre-Compression Parameters)

4.4.1. Angle of Repose

The angle of repose was determined using the fixed funnel method. The powder blend was allowed to flow freely through a funnel onto a flat surface. The height and radius of the powder heap were measured, and the angle of repose was calculated to assess flow properties.

4.4.2. Bulk Density

Bulk density was determined by gently pouring a known weight of powder into a graduated cylinder and measuring the initial volume occupied. Bulk density was calculated as the ratio of mass to bulk volume.

4.4.3. Tapped Density

Tapped density was measured by tapping the graduated cylinder containing the powder blend using a tapped density apparatus until a constant volume was obtained. The tapped density was calculated as mass divided by tapped volume.

4.4.4. Carr's Index

Carr's compressibility index was calculated using bulk and tapped density values to assess compressibility and flow behavior of the powder blend.

4.4.5. Hausner's Ratio

Hausner's ratio was calculated as the ratio of tapped density to bulk density and used as an indicator of flow properties.

4.5. Evaluation of Floating Tablets (Post-Compression Parameters)

4.5.1. Weight Variation

Twenty tablets from each batch were randomly selected and weighed individually. The average weight was calculated and compared with individual tablet weights to assess weight variation.

4.5.2. Thickness

Tablet thickness was measured using a Vernier caliper to ensure uniformity of tablet dimensions.

4.5.3. Hardness

Tablet hardness was determined using a Monsanto hardness tester. The force required to break the tablet diametrically was recorded.

4.5.4. Friability

Friability was evaluated using a Roche friabilator. A known number of tablets were rotated at 25 rpm for 4 minutes. Tablets were weighed before and after the test, and percentage friability was calculated.

4.5.5. Drug Content Uniformity

Drug content uniformity was determined by crushing tablets and dissolving an accurately weighed quantity

equivalent to one tablet in 0.1 N HCl. The solution was filtered, diluted, and analyzed spectrophotometrically.

4.6. In-Vitro Buoyancy Studies

4.6.1. Floating Lag Time

Floating lag time was determined by placing a tablet in a beaker containing 0.1 N HCl at 37 ± 0.5 °C. The time taken for the tablet to rise to the surface was recorded.

4.6.2. Total Floating Time

The duration for which the tablet remained continuously floating on the surface of the dissolution medium was recorded as total floating time.

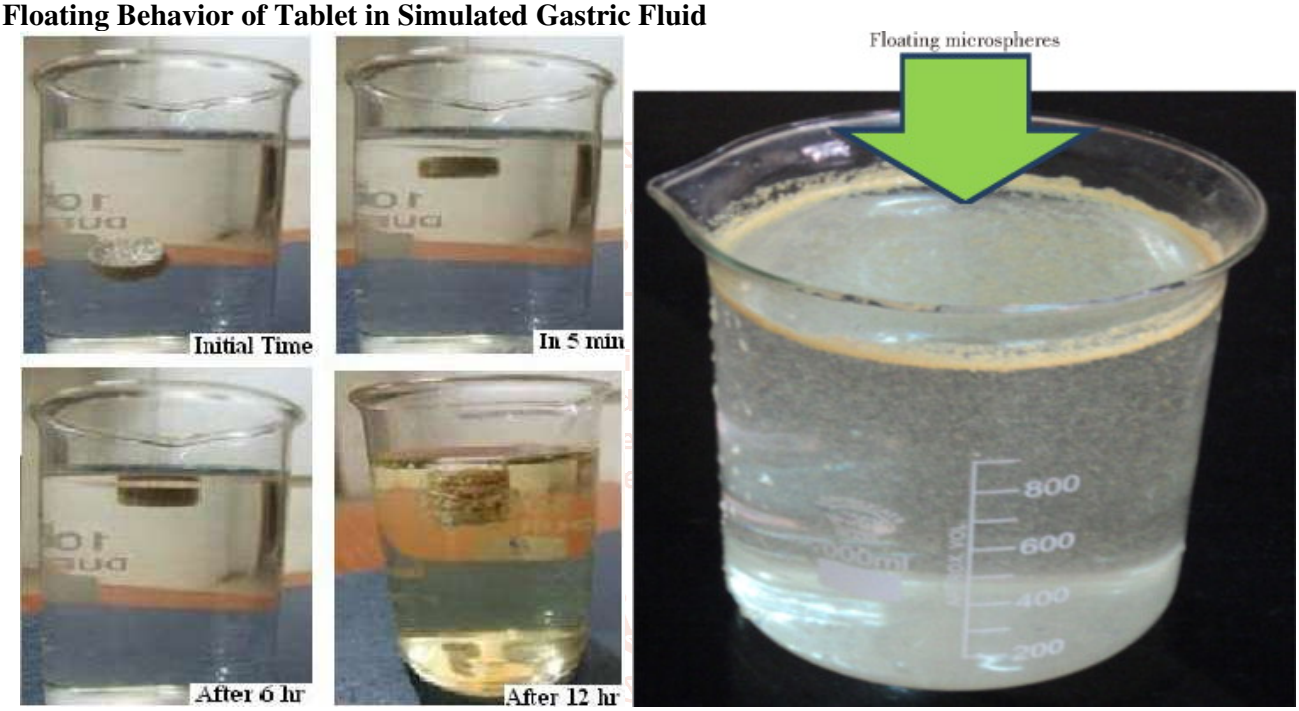
4.7. In-Vitro Dissolution Studies

In-vitro dissolution studies were performed using USP type II (paddle) dissolution apparatus. The dissolution medium consisted of 900 mL of 0.1 N HCl maintained at 37 ± 0.5 °C with a paddle speed of 50 rpm. Samples were withdrawn at predetermined time intervals, filtered, and analyzed spectrophotometrically. An equal volume of fresh medium was replaced to maintain sink conditions.

4.8. Stability Studies

Stability studies of the optimized formulation were carried out according to ICH guidelines. Tablets were stored at accelerated conditions (40 ± 2 °C / 75 ± 5% RH) and evaluated periodically for physical appearance, drug content, buoyancy, and dissolution behavior.

Floating Behavior of Tablet in Simulated Gastric Fluid



5. RESULTS AND DISCUSSION

5.1. Pre-formulation Studies

5.1.1. Physical Appearance

Telmisartan was observed as a white to off-white crystalline powder with no visible impurities. The drug was free flowing and odorless, indicating acceptable physical characteristics for further formulation development.

5.1.2. Melting Point

The melting point of Telmisartan was found to be within the reported range, confirming the purity and identity of the drug. No deviation from standard values was observed, indicating absence of degradation or adulteration.

5.1.3. Solubility Studies

Solubility studies revealed that Telmisartan exhibited very poor solubility in distilled water and phosphate buffer pH 6.8, whereas comparatively higher solubility was observed in acidic medium (0.1 N HCl). This pH-dependent solubility behavior supports the selection of a gastro-retentive drug delivery system, as prolonged gastric retention in acidic environment can enhance drug dissolution and absorption.

5.1.4. UV Spectrophotometric Analysis

The UV spectrophotometric scan of Telmisartan in 0.1 N HCl showed a distinct absorption maximum (λmax), which was used for quantitative estimation during drug content and dissolution studies. The calibration curve obeyed Beer-Lambert's law within the selected concentration range, indicating linearity and suitability of the method for analysis.

5.1.5. Drug–Polymer Compatibility Studies (FTIR)

FTIR spectra of pure Telmisartan showed characteristic peaks corresponding to functional

groups such as aromatic rings, carboxyl groups, and nitrogen-containing moieties. The FTIR spectra of physical mixtures of drug and polymers exhibited all characteristic peaks of Telmisartan without significant shifting, disappearance, or formation of new peaks. This indicates the absence of chemical interaction between the drug and excipients, confirming compatibility and stability of the formulation components.

5.2. Evaluation of Powder Blend (Pre-Compression Parameters)

The pre-compression parameters of all formulation batches showed satisfactory results.

The angle of repose values indicated good flow properties of the powder blend, which is essential for uniform die filling during compression. Bulk density and tapped density values were found to be within acceptable limits, reflecting good packing characteristics. Carr's index and Hausner's ratio values further confirmed good compressibility and flow behavior of the blends.

The acceptable pre-compression characteristics ensured that the blends were suitable for tablet manufacturing by direct compression technique.

5.3. Evaluation of Floating Tablets (Post-Compression Parameters)

5.3.1. Weight Variation

All formulated batches complied with pharmacopoeial limits for weight variation. The low variation in tablet weight indicates uniform die filling and proper mixing of formulation components.

5.3.2. Thickness

Tablet thickness was found to be uniform across all batches, indicating consistent compression force and uniform tablet dimensions.

5.3.3. Hardness

The hardness of tablets was found to be within the desired range, ensuring sufficient mechanical strength to withstand handling, packaging, and transportation without compromising drug release.

5.3.4. Friability

Friability values of all formulations were less than 1%, indicating good mechanical resistance and acceptable tablet integrity. Low friability confirms that the tablets can withstand abrasion during handling.

5.3.5. Drug Content Uniformity

Drug content analysis revealed uniform distribution of Telmisartan in all tablet formulations. The drug content was found to be within acceptable limits, confirming accuracy of formulation and effectiveness of blending process.

5.4. In-Vitro Buoyancy Studies

5.4.1. Floating Lag Time

Floating lag time was observed to be minimal for all formulations due to the presence of sodium bicarbonate as a gas-generating agent. The rapid generation of carbon dioxide upon contact with acidic medium resulted in quick tablet buoyancy.

5.4.2. Total Floating Time

All formulations remained buoyant for more than 12 hours in 0.1 N HCl, indicating effective floating behavior. The prolonged floating duration can be attributed to the formation of a stable gel layer by hydrophilic polymers, which entrapped the generated gas and maintained tablet density below that of gastric fluid.

5.5. In-Vitro Dissolution Studies

The in-vitro dissolution studies demonstrated sustained drug release from floating tablets over a period of 12 hours.

Initial drug release was controlled, followed by a gradual and sustained release pattern. This release behavior can be attributed to hydration and swelling of hydrophilic polymers, forming a gel barrier that controlled the diffusion of drug molecules.

Formulations containing higher polymer concentration showed slower drug release, indicating polymer-dependent release kinetics. The sustained release profile is advantageous for maintaining therapeutic drug levels and reducing dosing frequency.

5.6. Drug Release Kinetics

The release profile of Telmisartan from floating tablets suggests that drug release was governed by a combination of diffusion and polymer matrix erosion mechanisms. The hydrophilic polymer matrix swelled upon contact with dissolution medium, allowing gradual diffusion of drug molecules.

Such controlled release behavior is desirable for antihypertensive therapy, as it helps maintain consistent plasma drug concentration and minimizes fluctuations associated with immediate-release dosage forms.

5.7. Overall Discussion

The results of the present study demonstrate that gastro-retentive floating tablets of Telmisartan can be successfully formulated using the direct compression method. Pre-compression and post-compression parameters confirmed acceptable flow, compressibility, mechanical strength, and uniformity.

The rapid floating lag time and prolonged floating duration confirm the effectiveness of the effervescent floating system. Sustained drug release observed

during dissolution studies supports the potential of the developed formulation to improve gastric residence time and enhance bioavailability.

Overall, the study establishes gastro-retentive floating drug delivery as a promising approach for improving the therapeutic performance of Telmisartan.

6. CONCLUSION

The present investigation was undertaken to design, formulate, and evaluate gastro-retentive floating tablets of Telmisartan with the objective of enhancing gastric residence time and achieving sustained drug release. Telmisartan was selected as a suitable drug candidate due to its poor aqueous solubility, pH-dependent solubility profile, and therapeutic requirement for prolonged drug release in the management of hypertension.

Pre-formulation studies provided essential information regarding the physicochemical characteristics of the drug and confirmed its compatibility with the selected excipients. The absence of any significant drug–polymer interaction, as confirmed by FTIR studies, ensured formulation stability and integrity throughout the development process.

Floating tablets were successfully formulated using the direct compression technique, which is a simple, economical, and scalable manufacturing method. The prepared formulations exhibited acceptable pre-compression parameters, indicating good flow and compressibility of the powder blends, which facilitated uniform tablet compression.

Post-compression evaluation demonstrated that all tablet batches complied with pharmacopeial limits for weight variation, hardness, friability, thickness, and drug content uniformity, confirming the mechanical strength and quality of the tablets. These results indicate that the developed formulation is robust and suitable for routine handling and packaging.

In-vitro buoyancy studies revealed a rapid floating lag time and prolonged floating duration exceeding 12 hours, confirming the effectiveness of the effervescent floating system. The generation and entrapment of carbon dioxide within the hydrated polymer matrix played a crucial role in maintaining tablet buoyancy and gastric retention.

In-vitro dissolution studies showed a controlled and sustained release of Telmisartan over an extended period. The drug release behavior was influenced by the type and concentration of hydrophilic polymers, which regulated matrix swelling, gel formation, and drug diffusion. This sustained release profile is advantageous in minimizing fluctuations in plasma drug concentration and reducing dosing frequency.

Overall, the results of the study demonstrate that gastro-retentive floating tablets represent a promising and effective drug delivery system for Telmisartan. The developed formulation has the potential to enhance oral bioavailability, improve therapeutic efficacy, and increase patient compliance in the long-term management of hypertension.

However, further studies such as in-vivo pharmacokinetic evaluation, bioavailability studies, and long-term stability testing are recommended to establish a definitive in-vitro–in-vivo correlation and confirm the clinical performance of the developed gastro-retentive formulation.

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