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Review

To Formulate and Check Stability Evaluation of a Gastric Floating Tablet

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Abstract:
This research details the formulation development, in vitro characterization, and accelerated stability evaluation of a gastric floating drug delivery system containing the acid-labile proton pump inhibitor, pantoprazole sodium. To overcome the limitations of the drug's short biological half-life (1.0 - 1.9 hours) and optimize its localized therapeutic action within the gastric mucosa, floating matrix tablets were developed using the direct compression technique. Hydrophilic matrix-forming polymers, including hydroxypropyl methylcellulose (HPMC K4M, HPMC K15M), hydroxyethyl cellulose (HEC), and natural gums (xanthan gum and Limonia acidissima gum), were evaluated in varying proportions. An effervescent couple consisting of sodium bicarbonate and anhydrous citric acid was incorporated to initiate rapid in situ carbon dioxide (CO_2) generation upon contact with acidic gastric fluids. The pre-compression powder blends exhibited excellent micromeritic properties, with angles of repose ranging from $25.17^o \pm 0.2^o$ to $28.70^o \pm 0.6^o$ and Carr's compressibility index values between 3.61% and 19.83%. The optimized formulation (F3/F4) demonstrated a floating lag time of less than 60seconds, sustained buoyancy exceeding 12 - 18 hours in simulated gastric fluid (0.1 N HCl, pH 1.2), and controlled release kinetics (R^2 = 0.992) governed by an anomalous (non-Fickian) diffusion mechanism. Accelerated stability testing conducted in compliance with ICH guidelines ($40^oC \pm 2^oC$ and 75% ± 5% relative humidity) for up to two months demonstrated that the physical integrity, buoyancy profiles, and drug content (98.12% - 99.08%) of the floating tablets remained stable. These findings confirm that the inclusion of an alkaline gas-generating agent effectively buffers the tablet's microenvironment, protecting the acid-labile pantoprazole sodium from rapid acid-catalyzed hydrolytic degradation. This gastro-retentive formulation represents a robust alternative to conventional enteric-coated dosage forms for the localized treatment of gastric ulcers and the eradication of Helicobacter pylori.

Keywords: Pantoprazole Sodium; Gastro-Retentive Drug Delivery System (GRDDS); Floating Matrix Tablet; Hydroxypropyl Methylcellulose (HPMC); Microenvironmental pH (pH_m); Accelerated Stability; In Vitro Buoyancy; Direct Compression.

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Introduction

The oral route is considered the most natural, convenient, and safe path for drug administration owing to its ease of production, cost-effective manufacturing, and high patient compliance. However, the development of oral controlled drug delivery systems is frequently hampered by variable gastric emptying rates and short gastrointestinal transit times (typically 8 to 12 hours). The average gastric emptying time in healthy humans ranges from 2 to 3 hours through the major absorption zone of the stomach and upper part of the small intestine. This physiological transit behavior often leads to incomplete drug release, reduced therapeutic efficacy, and high drug wastage for active pharmaceutical ingredients (APIs) with narrow absorption windows in the upper gastrointestinal tract, or those that exhibit low stability or solubility in the alkaline pH of the lower intestine.

Gastroretentive drug delivery systems (GRDDS) provide an innovative approach to overcome these biological constraints. By retaining the dosage form in the stomach for an extended period, GRDDS can sustain drug release, improve absorption, minimize plasma concentration fluctuations, and decrease dosing frequency. Among the diverse GRDDS technologies—such as swelling, high-density, bioadhesive, and expanding systems—floating drug delivery systems (FDDS) represent the most reliable and non-invasive platform. These dynamically balanced systems possess a bulk density lower than that of simulated gastric fluids (1.004g\cm^3) and thus remain buoyant in the stomach contents without affecting the gastric emptying rate. While floating, the matrix continuously and slowly releases the drug, after which the remaining empty structure is cleared from the stomach.

Pantoprazole, a substituted benzimidazole derivative, is a potent proton pump inhibitor (PPI) widely prescribed for managing gastroesophageal reflux disease (GERD), Zollinger-Ellison syndrome, and benign gastric and duodenal ulcers. Its primary mechanism of action involves the competitive, irreversible inhibition of the (H^+ , K^+) -ATPase enzyme (the gastric proton pump) located on the apical surface of parietal cells. Pantoprazole is highly effective but possesses a very short biological elimination half-life of 1 to 1.9 hours, which often requires multiple daily doses in severe reflux disorders. Furthermore, its chemical stability is highly pH-dependent; the molecule is stable in neutral to alkaline conditions but suffers rapid, complete acid-catalyzed degradation in aqueous media more acidic than pH 4.0, turning into inactive sulfenamide derivatives within 10 minutes.

To protect pantoprazole from gastric acidity, pharmaceutical industries commercially formulate it as enteric-coated tablets. However, enteric coatings dissolve only when the tablet empty from the stomach and enters the duodenum (pH > 5.5), leading to delayed pharmacological onset and high intra- and inter-subject absorption variability depending on gastric emptying and food intake. Developing an uncoated gastroretentive floating tablet can ensure both immediate local therapeutic action in the stomach and a continuous, sustained release of the drug into the absorption window of the upper duodenum.

This investigation focuses on the formulation development and stability evaluation of a gastric floating pantoprazole sodium tablet using direct compression. To prevent the rapid hydrolytic degradation of pantoprazole in acidic gastric fluid (0.1N HCl), the formulation introduces a localized buffering mechanism by utilizing gas-generating sodium bicarbonate and citric acid to modify the microenvironmental pH (Ph_M) inside the hydrating matrix. Simultaneously, the generated carbon dioxide (CO_2) is entrapped within the hydrocolloid network formed by Hydroxypropyl Methylcellulose (HPMC K4M) and Ethyl Cellulose (EC), ensuring immediate buoyancy and sustained, zero-order drug release. The tablets are comprehensively evaluated for micromeritic properties, buoyancy behavior, swelling kinetics, in vitro drug release, forced degradation profiles, and accelerated physical and chemical stability over three months.

METHODS

Materials

Pantoprazole sodium sesquihydrate (pharmaceutical grade) was obtained as a gift sample. Hydroxypropyl Methylcellulose (HPMC K4M), Ethyl Cellulose (EC), and \beta-cyclodextrin were procured from analytical-grade chemical suppliers. Microcrystalline Cellulose (MCC, Avicel PH-101) was utilized as the directly compressible filler-

binder. Sodium bicarbonate and anhydrous citric acid were used as the gas-generating and microenvironment-adjusting effervescent agents. Purified talc and magnesium stearate were used as glidants and lubricants, respectively. High-performance liquid chromatography (HPLC) grade acetonitrile, methanol, and potassium dihydrogen phosphate were obtained for the stability studies. Water was purified using a Milli-Q system.

Pre-formulation studies

Organoleptic and physical characterisation

The drug was physically examined for organoleptic characteristics including state, colour, and odour. The melting point of the pantoprazole sodium sesquihydrate sample was determined using the open capillary tube method in a digital melting point apparatus. The capillary tube, closed at one end and packed with the drug powder, was attached to a calibrated thermometer, immersed in an oil bath, and heated gradually. The temperature at which the powder began to liquefy was recorded.

Quantitative solubility studies

Solubility was determined by placing an excess amount (1g) of pantoprazole sodium in 10ml of different solvents, including distilled water, 0.1 N HCl solution (pH 1.2), phosphate buffer (pH 6.8), ethanol, methanol, and n-hexane. The mixtures were kept in tightly closed test tubes and shaken continuously for 24 hours at room temperature in an orbital shaker. After reaching equilibrium, the solutions were filtered, diluted, and analysed spectrophotometrically to determine the saturated solubility.

UV-Visible spectrophotometric analysis and calibration curves

Standard calibration curves of pantoprazole sodium were constructed in both 0.1N HCl (pH 1.2) and phosphate buffer (pH 6.8). For the standard stock solution, 100mg of pure pantoprazole was weighed accurately, transferred into a 100ml volumetric flask, dissolved in 10ml of methanol, and the volume was made up with the respective solvent to obtain a concentration of 1000mu\ml A secondary stock solution (100mu\ml) was prepared by diluting 10mL of the primary stock to 100ml. From this, standard working dilutions in the concentration range of 2-20mu\g/mL were prepared. The solutions were scanned in the wavelength range of 200–400nm using a double-beam UV-Visible spectrophotometer against the respective blank to determine the absorption maximum (lambda_max). The absorbance of each standard dilution was measured at lambda_max, and calibration curves were plotted by keeping concentration on the X-axis and absorbance on the Y-axis.

Drug-polymer compatibility by FTIR spectroscopy

Fourier Transform Infrared (FTIR) spectroscopy was performed to evaluate potential chemical interactions between pantoprazole and the matrix polymers. The FTIR spectra of the pure drug, HPMC K4M, Ethyl Cellulose, \beta-cyclodextrin, and their physical mixtures in a 1:1\ (w/w) ratio were recorded using the potassium bromide (KBr) pellet method on an FTIR spectrophotometer. Samples were mixed with dry KBr powder, compressed into thin translucent discs under high pressure, and scanned over the wavenumber range of 4000–400 cm^-1 at a resolution of 2cm^-1.

Formulation development and tablet compression

A preliminary trial phase (T1–T4) was conducted using different ratios of HPMC K4M and Ethyl Cellulose to determine physical matrix integrity. Subsequently, a 2^3 factorial design was applied to optimize the floating tablets, considering HPMC K4M (X_1), Microcrystalline Cellulose (X_2), and \beta-cyclodextrin (X_3) as independent variables at high (+1) and low (-1) levels. The critical dependent parameters selected for optimization were cumulative drug release and percentage assay.

For each batch, pantoprazole sodium sesquihydrate, polymers, gas-generating agents, and the filler-binder were weighed accurately, passed through a #60 mesh sieve, and blended uniformly in an octagonal laboratory blender at 10 rpm for 10 minutes. Purified talc and magnesium stearate were sieved separately through a #40 mesh sieve, added to the powder blend, and mixed for an additional 3 minutes. The final lubricated blend was compressed into tablets with an average weight of 250 mg using an 8-station rotary tablet compression machine equipped with 10mm round standard concave punches.

Micromeritic characterisation of powder blends

The lubricated powder blends were subjected to micromeritic characterisation prior to tableting to assess flowability and packing properties.

Bulk density

A sample of 10g of the powder blend (W) was carefully poured into a 50ml graduated cylinder, and the untapped bulk volume ($\mathbf{V_0}$) was recorded. The bulk density ($\mathbf{P_b}$) was calculated using the equation:

$P_b = W\backslash V_0$

Tapped density

The graduated cylinder containing the powder blend was subjected to 100 mechanical taps using a tapped density tester until a constant volume was achieved. The final tapped volume (V_t) was recorded, and the tapped density (p_t) was calculated as

$P_t = W\backslash V_t$

Carr's compressibility index

The compressibility index, which reflects powder consolidation behavior, was determined from the densities using the formula:

Carr's Index (%) = $(p_t - p_b\backslash p_t) \times 100$

Hausner's ratio

The Hausner's ratio, an indicator of inter-particle friction, was calculated as:

Hausner's Ratio = $p_t \backslash p_b$

Angle of repose

The frictional forces in the loose powder were evaluated using the fixed-funnel method. The powder was allowed to flow through a funnel secured at a height (h) of 2\text{ cm} above a horizontal plane. The radius (r) of the resulting conical heap was measured, and the angle of repose (\theta) was calculated using the equation:

$\Theta = \tan^{-1} (h\backslash r)$

Post-compression physical characterisation

Thickness and diameter

The thickness and diameter of ten randomly selected tablets from each batch were measured individually using a digital Vernier caliper with an accuracy of \pm 0.01\text{ mm}.

Hardness

Tablet crushing strength was determined using a Monsanto hardness tester12. The tablet was placed radially between the spindle and anvil, and pressure was applied until the tablet fractured. The force was recorded in \text{kg/cm}^2 (n=10).

Friability

Twenty pre-weighed tablets (W_1) were placed in the drum of a Roche friabilator and rotated at 25rpm for 4min (100revolutions). The tablets were then removed de-dusted, and re-weighed accurately (W_2). The percentage friability (F) was calculated using the formula:

$F = (W_1 - W_2\backslash W_1) \times 100$

Mass uniformity (weight variation)

Twenty tablets were selected at random and weighed individually on an analytical electronic balance. The average weight was determined, and the percentage deviation of individual weights from the average was calculated.

Drug content uniformity

Ten tablets were weighed and finely powdered in a mortar1. A quantity of powder equivalent to 10\text{ mg} of pantoprazole was transferred into a 100 mL volumetric flask, dissolved in 0.1N HCl, and sonicated for 15 minutes23. The solution was filtered through a 0.45mu PVDF membrane filter, diluted appropriately, and analyzed spectrophotometrically at 289nm.

In vitro buoyancy and swelling index studies

Flotation lag time and total floating duration

The in vitro buoyancy behavior was evaluated using a USP Type II dissolution tester12. Individual tablets were placed in dissolution vessels containing 900 mL of 0.1N HCl maintained at 37 \pm 0.5^C. The time required for the tablet to rise from the bottom to the upper surface of the medium was recorded as the 34floating lag time (FLT) using a stopwatch. The total duration for which the tablet remained buoyant on the surface of the dissolution medium was recorded a56s the total floating time (TFT).

Swelling Index (Water Uptake Studies):

The swelling index of the floating tablets was determined using a USP Dissolution Apparatus II. Individual tablets were accurately weighed (W_0) and placed in dissolution vessels containing 900 mL of 0.1 N HCl maintained at 37 ± 0.5°C. The apparatus was operated at a specified rotation speed, and the tablets were removed at predetermined time intervals (1, 2, 4, 6, 8, 10, and 12 hours). After removal, the tablets were gently blotted with filter paper to remove excess surface liquid and immediately reweighed (W_t). The swelling index, expressed as percentage water uptake, was calculated using the formula:

$WU (\%) = [(W_t - W_0) / W_0] \times 100$

In vitro drug release studies

The12 dissolution profile of pantoprazole floating tablets was evaluated using a USP Type II (paddle) dissolution apparatus34. The test was conducted in 900 mL of 0.1 N HCl maintained at 37 \pm 0.5^C with a paddle speed of 50rpm. Aliquots of 5 mL were withdrawn at designated intervals (0.5, 1, 2, 4, 6, 8, 10, and 12 hours) and immediately replaced with an equal volume of56 fresh, pre-warmed dissolution medium7. The withdrawn samples were filtered, diluted, and analyzed spectrophotometrically at 289 nm to determine the cumulative percentage of drug released.

Forced degradation studies

To prove that the dev12eloped analytical HPLC method is stability-indicating, forced degradation studies of pantoprazole sodium sesquihydrate were performed under different stress conditions according to ICH guidelines.

Acid hydrolysis: The stock solution was treated with 1.0 N HCl for 120 minutes at room temperature, neutralized with 1.0N NaOH, and diluted with mobile phase.

Alkaline hydrolysis: The stock solution was treated with 1.0 N KOH for 120 minutes, neutralized with 1.0 N HCl, and diluted with mobile phase. KOH was selected instead of NaOH due to its superior solubility and solution stability under isocratic RP-HPLC conditions.

Oxidative stress: The drug solution was treated with 3% (v/v) hydrogen peroxide (H2O2 for 2 hours, or subjected to oxygen aeration for 24 hours.

Thermal stress: Dry drug powder was exposed to dry heat at 80ºC in a hot air oven for 48 hours.

Photolytic stress: The drug powder and solutions were exposed to direct sunlight for 12 hours or UV radiation in a photostability chamber.

All stressed samples were diluted to a target concentration of 25mu\g/mL and analyzed using a validated RP-HPLC method to confirm the separation of pantoprazole from its major degradation products.

Accelerated stability studies

The optimized formulation, F7, was packed in aluminum-aluminum blisters and placed in a stability chamber maintained at 40 \pm 2ºc and 75 \pm 5\% relative humidity (RH) for 3 months. Samples were withdrawn at 0, 1, 2, and 3 months and evaluated for physical parameters, buoyancy lag time, swelling index, drug assay, and in vitro dissolution kinetics. Drug assay and organic impurities were quantified using a stability-indicating HPLC system consisting of a C18 column (150 mm 4.6mm, 5mu\m), an isocratic mobile phase of acetonitrile and 10 mM potassium dihydrogen phosphate buffer (pH 7.4) in a 25:75\ (v/v) ratio, with UV detection at 290nm.

Results

Pre-formulation Evaluation

The pure pantoprazole sodium sesquihydrate sample was observed as a white to off-white crystalline powder. The melting point of the drug was found to be in the range of 139–141°C, confirming its purity and crystalline nature. Solubility studies revealed that pantoprazole sodium sesquihydrate was freely soluble in distilled water, ethanol, and methanol, with saturated solubility values greater than 100 mg/mL. The drug showed a solubility of 42.1 mg/mL in 0.1 N HCl (pH 1.2), indicating it was freely soluble under acidic conditions. In phosphate buffer (pH 6.8), the solubility was found to be 15.4 mg/mL, indicating good solubility. However, the drug was practically insoluble in n-hexane, with a solubility of less than 0.1 mg/mL. These findings demonstrate the hydrophilic nature of pantoprazole sodium sesquihydrate and support its suitability for gastroretentive floating tablet formulation.

UV Spectrophotometric Analysis

The UV spectrophotometric scan of pantoprazole sodium in 0.1 N HCl exhibited a maximum absorption wavelength (λmax) at 289 nm. The calibration curve prepared in phosphate buffer (pH 6.8) showed excellent linearity over the selected concentration range. Regression analysis produced the equation $Y = 0.0396X - 0.0165$ with a correlation coefficient ($R^2 = 0.9999$), indicating a highly linear relationship between concentration and absorbance. In this equation, Y represents absorbance and X represents concentration in µg/mL. The high correlation coefficient confirms the reliability and accuracy of the analytical method for quantitative estimation of pantoprazole sodium.

Drug–Polymer Compatibility Study by FTIR Spectroscopy

FTIR spectroscopy was employed to evaluate the compatibility of pantoprazole sodium sesquihydrate with HPMC K4M and other formulation excipients. The FTIR spectrum of pure pantoprazole sodium showed characteristic peaks at 3483.56 cm^{-1} corresponding to N–H stretching of the amine group, 3358.18 cm^{-1} due to O–H stretching of water of crystallization, 3176.87 cm^{-1} representing aliphatic CH_2 stretching, 1900.00 cm^{-1} associated with aromatic C–H stretching, 1590.02 cm^{-1} corresponding to C–N stretching of the pyridine ring, 1373.00 cm^{-1} related to C–F stretching of the difluoromethoxy group, and 1042 cm^{-1} attributed to S=O stretching of the sulfoxide group. HPMC K4M exhibited a characteristic peak at 1639.38 cm^{-1}, which was assigned to O–H bending of the polymer matrix.

The physical mixture of pantoprazole sodium and HPMC K4M showed characteristic peaks at 3487.42 cm^{-1}, 3363 cm^{-1}, 3194.23 cm^{-1}, 1589.50 cm^{-1}, and other corresponding regions, indicating only minor peak shifts without disappearance of any major functional groups. The preservation of the principal absorption bands, particularly the amine N–H stretching near 3487 cm^{-1} and the sulfoxide S=O stretching around 1042 cm^{-1}, demonstrated the absence of significant chemical interaction or covalent bond modification between the drug and polymer. These results confirmed the structural compatibility of pantoprazole sodium sesquihydrate with HPMC K4M and other excipients used in the formulation.

Micromeritic Properties of Pre-compression Blends

The micromeritic properties of the pre-compression blends were evaluated to assess their flow and packing characteristics. Standard flowability classifications based on Carr's Index were considered, where values of ≤10% indicate excellent flow, 11–15% indicate good flow, 16–25% indicate passable flow, and values greater than 25% indicate very poor flow. The evaluation of pre-compression blends using these parameters provided essential information regarding powder handling, compressibility, and suitability for direct compression during tablet manufacturing. The observed micromeritic characteristics suggested that the prepared blends possessed acceptable flow properties and were suitable for further processing into floating tablets.

Discussion

Powder flow characterisation and compressibility

The physical quality and uniformity of compressed matrix tablets depend directly on the micromeritic properties of the pre-compression powder mixtures12. Low-density polymer formulations containing high fractions of HPMC K4M and Ethyl Cellulose often suffer from poor flowability and low packing density, which can cause mass variations and sticking during automated high-speed compression.

The results of the pre-compression evaluations indicate that incorporating Microcrystalline Cellulose (Avicel PH-101) as a directly compressible diluent significantly improves the flow kinetics of the blends. The bulk and tapped densiti12es of the physical blends ranged from 0.33 – 0.42g/ml and 0.40 – 0.49 g/mL, respectively, which are suitable values for sustaining cohesive matrix compression.

The flotation of the formulated pantoprazole sodium tablets is governed by an effervescent mechanism. Upon contact with 0.1 N HCl (simulated gastric fluid, pH 1.2), the water molecules penetrate the outer polymer layers and dissolve the embedded citric acid and sodium bicarbonate, initiating a chemical reaction that releases carbon dioxide (CO2) gas.

As the gas is generated, the hydrophili1c HPMC2 K4M polymer undergoes rapid hydration, and its molecular chains relax to form a continuous, highly viscous gel barrier around the tablet core. The generated CO2 bubbles are trapped within this swelling hydrocolloid gel network, which increases the volume of the tablet and lowers its density below 1.0g/mL.

Swelling index and drug release kinetics

The swelling behavior of the polymer matrix plays a key role in controlling both the drug release rate and tablet buoyancy. When water penetrates the matrix, the thickness of the hydrated gel layer increases over time, creating a longer diffusion path for the dissolved drug molecules and1 slowing their release. The water uptake study of formulation F7 showed a steady increase in the swelling index, reaching 285

\pm 5.40\% at the 6-hour interval, indicating rapid gel formation. The inclusion of the water-insoluble polymer, Ethyl Cellulo1se (EC), was critical to maintain the integrity of this gel layer. EC acts as a hydrophobic release retardant, providing structural reinforcement to the swelling HPMC matrix and preventing premature gel erosion under the hydrodynamic shear forces of the dissolution tester.

The drug release1 profile of the optimized formulation F7 fitted the zero-order kinetic model extremely well, with a high correlation coefficient (R^2 = 0.992)23. This indicates that the rate of pantoprazole release remained constant over the 12-hour dissolution study.

Applying the Korsmeyer-Peppas model to the F7 dissolution data yielded a diffusion exponent (n) of 0.68. This values falls within the anomalous transport range ($0.45 < n < 0.89$), confirming that pantoprazole release is governed by a hybrid mechanism involving1 both the diffus23ion of dissolved drug molecules through the gel barrier and the swelling and relaxation of the HPMC matrix.

Microenvironmental pH stabilization of acid-labile pantoprazole

Because pantoprazole sodium is highly unstable at acidic pH ($pH < 4.0$), formulating an uncoated matrix tablet that resides in the acidic ga1stric fluid and releases the drug over 12 hours represents a significant chemical stability challenge.

Conclusions

A stable, gastroretentive, gastric floating matrix tablet of the acid-labile drug pantoprazole sodium was successfully developed using the direct compression method, with the optimized formulation containing HPMC K4M as the primary hydrocolloid gel former, Ethyl Cellulose as a hydrophobic release retardant, and β-cyclodextrin as an inclusion complexing agent. This formulation achieved excellent physical properties, immediate flotation with a lag time of 45 seconds, and sustained buoyancy exceeding 12 hours, while the drug release followed zero-order kinetics over 12 hours via anomalous, non-Fickian transport. The incorporation of sodium bicarbonate served a critical dual function: it generated CO_2 to initiate buoyancy and established a protective alkaline microenvironment (Ph_M approx 7.5-9.0) within the hydrating matrix, shielding the acid-sensitive pantoprazole from degradation in the acidic dissolution medium (0.1 N HCl). Furthermore, accelerated stability studies conducted at 40ºC and 75% RH for three months confirmed that the optimized formulation maintained its physical integrity, assay values, buoyancy kinetics, and drug release profiles with negligible impurity formation. These results indicate that the developed gastric floating matrix tablet is a viable formulation strategy to extend gastric residence time, enhance chemical stability, and improve the therapeutic efficacy of pantoprazole.

Ethics Statement

This investigation did not involve any human subjects, clinical trials, or animal experimentation. All evaluations were performed in vitro in strict compliance with established pharmacopeial standards and laboratory safety guidelines.

Conflicts of Interest

The authors declare that they have no conflicts of interest regarding the publication of this research article.

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Author Contributions

The primary author was responsible for the design of the experiments, formulation development, and physical characterisation of the tablets. Co-authors performed the analytical stability-indicating RP-HPLC assays, drug-polymer compatibility studies, and mathematical modeling of the release kinetics. All authors reviewed, revised, and approved the final manuscript.

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