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Formulation and Evaluation of Acyclovir Floating Matrix Tablets for Sustained Gastro-Retention

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Abstract:

Acyclovir is a commonly prescribed antiviral drug; however, its therapeutic effectiveness after oral administration is restricted by poor bioavailability and rapid gastric emptying. The present investigation focused on the development and assessment of gastro-retentive floating matrix tablets of acyclovir designed to prolong gastric residence time and provide sustained drug delivery. The formulations were prepared using hydrophilic release-retarding polymers, namely HPMC K100M and xanthan gum, along with sodium bicarbonate as an effervescent agent to impart buoyancy. Pre-compression evaluation of the powder mixtures demonstrated satisfactory micromeritic properties, indicating good flow and compressibility characteristics. Parameters such as Hausner's ratio (1.024–1.306), Carr's compressibility index (9.27–11.84%), and angle of repose (26.24°–26.83°) confirmed the suitability of the blends for direct compression. Post-compression analysis showed that all prepared tablets complied with official pharmacopeial limits for physical quality attributes, including uniformity of weight, tablet hardness (4.2–4.7 kg/cm²), friability below 0.3%, swelling behavior, and drug content ranging from 96.79% to 99.57%. Buoyancy testing demonstrated floating lag times between 4.3 and 5.1 minutes, while most formulations remained buoyant for more than 10 hours, indicating effective gastro-retentive performance. In vitro dissolution studies confirmed prolonged drug release over a period of 12 hours, with formulations containing higher concentrations of HPMC K100M exhibiting a slower and more controlled release pattern. Compatibility and stability investigations using FTIR and UV spectroscopy revealed no significant interaction between acyclovir and the selected excipients. Overall, the developed floating matrix tablets demonstrated effective gastro-retentive and sustained-release characteristics, suggesting their potential to improve the oral bioavailability of acyclovir and enhance patient adherence through reduced dosing frequency.

Keywords: Acyclovir, floating matrix tablets, gastro-retentive drug delivery, HPMC K100M, xanthan gum, sustained release.

Introduction

Acyclovir is commonly administered through the oral route, which continues to be the preferred method of drug delivery because of its simplicity, convenience, affordability, and high level of patient acceptance. Nevertheless, conventional oral dosage forms frequently fail to maintain consistent therapeutic drug levels for prolonged periods, leading to rapid drug elimination, repeated dosing requirements, and variations in plasma concentration. Such fluctuations may compromise therapeutic effectiveness and patient adherence to treatment. In response to these challenges, sustained-release drug delivery systems, particularly matrix tablets, have gained considerable attention as an effective means of providing controlled drug release over extended durations.[1–3]

Acyclovir is a synthetic antiviral agent belonging to the class of guanine analogs and is widely prescribed for the management of infections caused by herpes simplex virus (HSV) and varicella-zoster virus (VZV). Although clinically effective, the drug exhibits several pharmacokinetic disadvantages, including limited oral bioavailability of approximately 15–30%, a relatively short elimination half-life of about 2.5–3.3 hours, and the necessity for multiple daily administrations. Frequent dosing schedules may reduce patient compliance and increase the likelihood of inconsistent therapeutic exposure, thereby limiting the overall effectiveness of therapy. Consequently, the development of a sustained-release oral formulation of acyclovir has become an important pharmaceutical objective to enhance therapeutic performance while reducing dosing frequency.[4–5]

Among various controlled-release approaches, matrix tablet systems are considered one of the most practical and reliable techniques for prolonged drug delivery. In these systems, the active pharmaceutical ingredient is uniformly incorporated within a polymeric network, allowing gradual drug release through mechanisms such as diffusion, matrix swelling, erosion, or their combined effects. The characteristics of the polymers employed greatly influence the release behavior, mechanical strength, and stability of the formulation. Both hydrophilic and hydrophobic polymers, including hydroxypropyl methylcellulose (HPMC), carbopol, sodium alginate, guar gum, and ethyl cellulose, have been extensively utilized to design sustained-release matrix systems. By varying the type and concentration of polymers, the release profile of the drug can be effectively modified to meet specific therapeutic requirements.[6–8]

Recent pharmaceutical research has increasingly focused on polymer-based sustained-release formulations for drugs characterized by short biological half-lives and inadequate bioavailability. Incorporating acyclovir into a matrix-based controlled-release system may help maintain prolonged plasma drug concentrations, improve therapeutic consistency, and minimize the need for repeated administration. Furthermore, comparative evaluation of different polymers provides valuable insight into selecting the most suitable formulation capable of achieving controlled release while maintaining acceptable physicochemical tablet properties.

In view of these considerations, the present investigation was undertaken to design and evaluate sustained-release matrix tablets of acyclovir using various polymers. The study was intended to achieve prolonged drug release, enhance oral bioavailability, and improve patient compliance. The prepared formulations were subjected to comprehensive pre-compression and post-

compression evaluations, along with in vitro dissolution studies and release kinetic analysis to elucidate the mechanism governing drug release. The outcomes of this research may contribute to the development of an efficient and reliable controlled-release oral dosage form of acyclovir.

Materials and Methods

Equipment and Apparatus

Various pharmaceutical instruments were employed during the formulation and evaluation of the floating matrix tablets of Acyclovir. Accurate weighing of ingredients was carried out using an analytical balance. Tablet compression was performed with the help of a rotary tablet compression machine. Drug characterization and analytical investigations were conducted using UV–Visible and FTIR spectrophotometers. In vitro dissolution studies were carried out using a USP Type II dissolution apparatus. A bulk density apparatus was utilized for micromeritic analysis of powder blends. Tablet friability was evaluated using a friabilator, whereas crushing strength was determined using a Monsanto hardness tester.

Materials and Chemicals

Acyclovir was selected as the model antiviral drug for the study. Hydroxypropyl methylcellulose (HPMC K100M) and xanthan gum were incorporated as matrix-forming polymers to regulate drug release.

Microcrystalline cellulose (MCC) served as the filler material. Sodium bicarbonate was included as a gas-forming agent to impart floating characteristics to the tablets. Polyvinylpyrrolidone (PVP K30) was used as a binding agent, while talc and magnesium stearate functioned as glidant and lubricant, respectively. All chemicals, reagents, and solvents used throughout the investigation were of analytical grade quality.

Drug Characterization Studies

Identification of Drug

The identity of acyclovir was verified through Fourier Transform Infrared (FTIR) spectroscopy and UV spectrophotometric analysis. For FTIR analysis, potassium bromide (KBr) was first dried at 60 °C for one hour and then thoroughly blended with the drug sample. The prepared mixture was subjected to infrared spectral analysis to identify the characteristic functional group peaks corresponding to acyclovir.

For UV spectroscopic identification, a 100 ppm solution of the drug was prepared in pH 1.2 buffer solution and scanned over a wavelength range of 200–400 nm. The wavelength corresponding to maximum absorbance (λmax) was recorded and compared with reported reference values.[9–11]

Solubility Analysis

The solubility behavior of acyclovir was investigated in different solvents including distilled water, methanol, acetonitrile, and pH 1.2 buffer. Excess quantities of the drug were separately added to 5 mL of each solvent in tightly sealed vials and maintained at room temperature for 24 hours to attain equilibrium solubility. Following equilibration, the samples were filtered using Whatman No. 41 filter paper. The filtrates were suitably diluted and analyzed spectrophotometrically at 253 nm to determine the drug concentration.[12]

Determination of Melting Point

The melting point of acyclovir was determined by the capillary tube method. A small amount of drug powder was filled into a capillary tube, which was attached to a thermometer and placed in a Thiele's tube containing liquid paraffin. The paraffin bath was heated gradually, and the temperature at which the drug sample completely liquefied

was noted as the melting point of the drug.[13]

Preformulation Evaluation

Micromeritic properties of the drug and powder blends were evaluated prior to tablet compression to assess their flow and compressibility characteristics. Bulk density was determined by introducing a previously sieved sample into a graduated measuring cylinder and recording the unsettled volume. Tapped density was measured after mechanically tapping the cylinder approximately 1000 times until a constant volume was obtained. The angle of repose was evaluated using the fixed funnel technique and calculated using the relation:

$$\theta = \tan^{-1}\left(\frac{h}{r}\right)$$

Where h represents the height and r represents the radius of the powder heap.

Hausner's ratio was calculated as the ratio of tapped density to bulk density, while Carr's compressibility index was determined using the following equation:

$$\text{Carr's Index} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100$$

The obtained values were interpreted according to standard micromeritic flow property classifications.[14–17]

Preparation of Floating Matrix Tablets

Floating matrix tablets of Acyclovir were formulated by employing the wet granulation method. Precisely weighed quantities of all formulation ingredients, excluding the lubricant and glidant, were blended uniformly in a polyethylene bag for approximately 10 minutes and subsequently passed through sieve number 60 to ensure uniform particle size distribution. Granulation of the powder mixture was carried out using a binding solution prepared from PVP K30 dissolved in isopropyl alcohol.

The resulting wet mass was screened through sieve number 12 to produce granules, which were then dried in a hot air oven at 75 °C for a period of 2 hours. After drying, the granules were passed through sieve number 18 to obtain uniformly sized particles. Magnesium stearate and talc were finally incorporated into the dried granules as lubricant and glidant, respectively. The lubricated granules were compressed into tablets using 8 mm flat-faced punches fitted to a rotary tablet compression machine. A total of twelve formulations (F1–F12) were developed by altering the proportions of xanthan gum and HPMC K100M while maintaining a constant tablet weight of 250 mg for all batches.[18–20]

Evaluation of Floating Matrix Tablets[21–23]

The prepared floating tablets were subjected to a series of physicochemical and performance evaluations to determine their quality and suitability for sustained-release delivery.

Weight Variation Test

Twenty tablets were randomly selected from each formulation batch and weighed individually. The mean tablet weight was calculated, and the percentage deviation of individual tablets from the average weight was determined in accordance with official Indian Pharmacopoeial specifications.

Tablet Hardness: The crushing strength of the tablets was assessed using a Monsanto hardness tester. The hardness values were expressed in kg/cm² to evaluate the mechanical integrity of the tablets.

Friability Study

Friability testing was performed using a Roche friabilator to assess the resistance of tablets to abrasion during handling. Twenty

tablets were initially weighed and rotated at 25 rpm for 4 minutes. After completion of the test, the tablets were reweighed and the percentage weight loss was calculated.

Swelling Behavior

Swelling studies were carried out by immersing tablets in 100 mL of pH 1.2 hydrochloric acid maintained at 37 ± 0.5 °C for 8 hours. At specified time intervals, tablets were removed, gently blotted to eliminate excess surface liquid, and weighed. The swelling index was calculated using the following equation:

$$\text{Swelling Index} = \frac{W_t - W_0}{W_0} \times 100$$

Where $W_t$represents the weight of the swollen tablet at time t and W_0denotes the initial tablet weight.

In Vitro Buoyancy Evaluation

Floating characteristics of the tablets were investigated in 100 mL of pH 1.2 hydrochloric acid maintained at 37 ± 0.5 °C. The floating lag time (FLT), defined as the time required for the tablet to rise to the surface, and the total floating time (TFT), indicating the duration for which the tablet remained buoyant, were recorded.

In Vitro Drug Release Study

Dissolution studies were conducted using a USP Type II paddle dissolution apparatus containing 900 mL of 0.1 N hydrochloric acid maintained at 37 ± 0.5 °C. The paddle rotation speed was adjusted to 75 rpm. At predetermined intervals, 5 mL samples were withdrawn and replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The collected samples were filtered and analyzed spectrophotometrically at 253 nm using a UV–Visible spectrophotometer. Drug release data obtained from dissolution studies were further subjected to kinetic modeling to elucidate the mechanism of drug release.

Results and Discussion

Drug Characterization

The authenticity and purity of acyclovir were confirmed through FTIR and UV spectroscopic investigations.

The FTIR spectrum exhibited distinct characteristic peaks corresponding to the functional groups present in the drug molecule. A broad absorption band observed at 3220.20 cm^{-1} was attributed to hydroxyl (–OH) stretching vibrations, while the peak at 3545.22 cm^{-1} indicated aromatic C=C stretching. The absorption peak at 2842.41 cm^{-1} corresponded to C–H stretching vibrations, whereas the characteristic amide carbonyl (C=O) stretching peak appeared at 1700.54 cm^{-1}. The observed spectral peaks closely matched the standard reference spectrum of acyclovir, thereby confirming the identity and purity of the drug.

UV spectroscopic analysis further supported drug identification by showing a well-defined absorption maximum (λmax) at 253 nm, which was in agreement with the reported standard value for acyclovir. These findings verified the suitability of the drug for subsequent formulation studies.

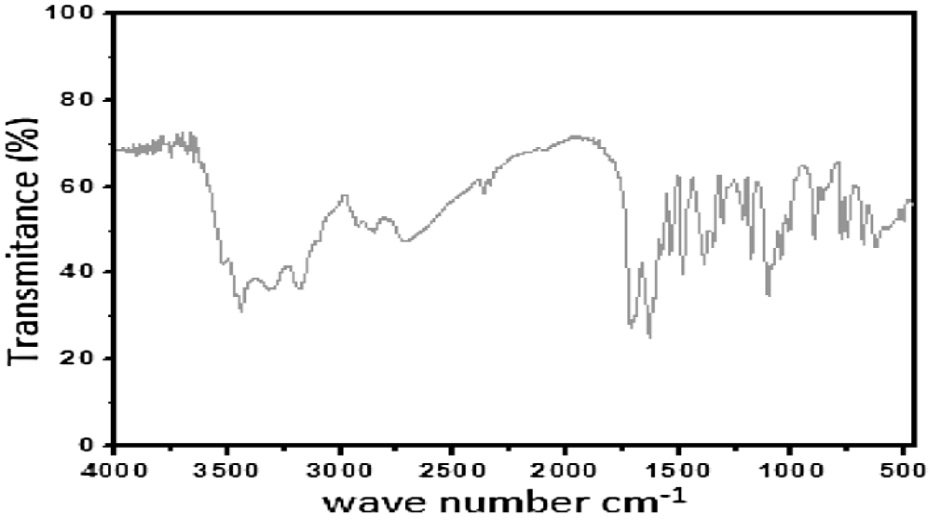

Figure 1: IR Spectra of Acyclovir

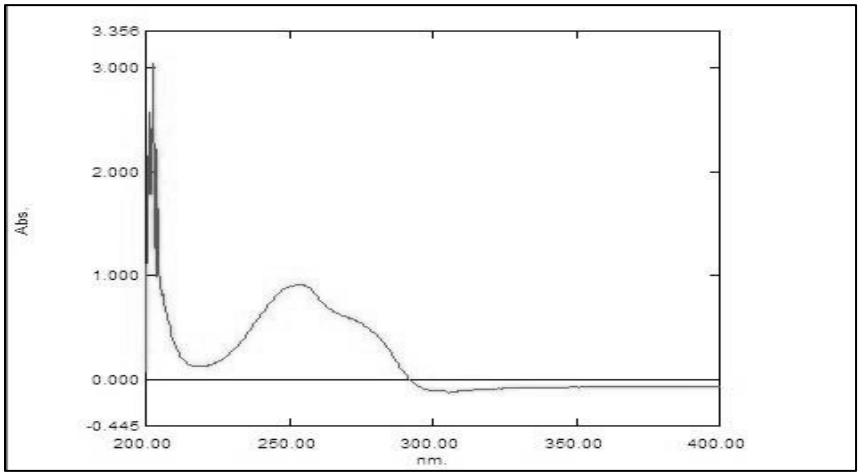

Figure 2: UV Spectra of Acyclovir

The solubility studies showed that acyclovir exhibited pH-dependent solubility. It was freely soluble in methanol, soluble in pH 1.2 buffer, slightly soluble in water and pH 6.8 buffer, and very slightly soluble in alcohol.

This indicates that the drug dissolves more readily under acidic conditions, making it suitable for gastro-retentive formulations. The melting point was determined by capillary method and found to be 256.3 °C, which matched the reported value, further confirming the drug's purity.

Preformulation Studies: The powder blends intended for tablet compression were evaluated for micromeritic properties. The angle of repose values ranged from 26.24° to 26.83°, which is indicative of excellent flow characteristics.

The bulk density ranged between 0.507–0.587 g/mL, while the tapped density varied between 0.545–0.597 g/mL.

The Carr's index values were observed between 9.27–11.84, and Hausner's ratio values ranged from 1.024–1.306, both suggesting good flowability and compressibility. These findings confirmed that the powder blends were suitable for direct compression after granulation.

Table 1: Preformulation parameters for powder blend

Batch	Bulk Density (gm/mL)	Tap Density (gm/mL)	Carr's Index	Hausner's Ratio	Angle of Repose
F1	0.511±0.055	0.545±0.042	10.63±0.46	1.153±0.66	26.27±0.15
F2	0.501±0.034	0.534±0.064	11.53±0.75	1.149±0.82	26.37±0.13
F3	0.529±0.012	0.573±0.047	10.75±0.30	1.306±0.51	26.82±0.26
F4	0.535±0.067	0.545±0.015	9.93±0.21	1.274±0.26	26.72±0.57
F5	0.549±0.052	0.593±0.039	10.74±0.82	1.062±0.17	26.43±0.27
F6	0.525±0.035	0.548±0.022	11.07±0.34	1.044±0.24	26.43±0.23
F7	0.535±0.028	0.569±0.015	10.13±0.46	1.024±0.14	26.34±0.74
F8	0.553±0.024	0.585±0.034	10.32±0.32	1.064±0.35	26.31±0.24
F9	0.587±0.046	0.597±0.065	11.84±0.76	1.083±0.13	26.62±0.21
F10	0.558±0.074	0.587±0.043	10.34±0.45	1.057±0.23	26.74±0.74
F11	0.527±0.036	0.545±0.066	9.27±0.85	1.057±0.15	26.24±0.45
F12	0.507±0.035	0.576±0.084	10.25±0.45	1.035±0.19	26.83±0.23

Physicochemical Evaluation of Tablets:

All twelve batches of acyclovir floating matrix tablets were evaluated for weight variation, hardness, friability, swelling index, floating lag time, floating duration, and drug content. The weight variation of tablets remained within pharmacopeial limits (±5% for tablets >250 mg), confirming uniformity. Hardness values ranged from 4.2–4.7 kg/cm², which were adequate to withstand handling stresses while ensuring proper drug release. Friability was less than 1% for all batches, demonstrating sufficient mechanical strength.

Table 2: Physio-chemical evaluation of Tablet

Batch	Hardness (Kg/cm^2)	Friability (%)	Weight Variation	Swelling Index 12 hr	Floating Lag Time (min)	Floating Time	Drug Content (%)
F1	4.4±0.03	0.22±0.46	251±5.35	97.24±0.567	4.3±0.13	>10 hr	99.28±0.24
F2	4.6±0.04	0.22±0.04	250±3.35	93.46±0.723	4.9±0.12	>10 hr	98.36±0.23
F3	4.5±0.01	0.23±0.07	249±3.62	96.53±1.353	5.0±0.24	>10 hr	98.31±0.13
F4	4.4±0.08	0.24±0.01	252±7.95	93.64±1.134	5.1±0.14	>10 hr	99.35±0.34
F5	4.5±0.06	0.23±0.02	252±1.35	96.23±0.327	4.6±0.17	>8 hr	99.10±0.14
F6	4.2±0.02	0.25±0.08	250±1.13	95.75±0.875	4.7±0.24	>10 hr	97.24±0.24
F7	4.6±0.03	0.27±0.04	253±1.42	96.89±0.754	4.7±0.35	>10 hr	96.79±0.26
F8	4.3±0.07	0.28±0.06	252±1.24	92.12±0.346	4.9±0.14	>10 hr	98.67±0.12
F9	4.2±0.04	0.23±0.03	254±1.64	91.35±0.156	4.8±0.24	>10 hr	98.86±0.19
F10	4.7±0.05	0.27±0.05	251±1.43	94.42±0.535	4.7±0.13	>10 hr	99.15±0.26
F11	4.4±0.03	0.29±0.06	250±1.13	96.65±0.764	4.6±0.15	>10 hr	99.57±0.25
F12	4.2±0.01	0.25±0.04	253±1.64	94.34±0.963	4.4±0.27	>10 hr	97.35±0.22

The swelling index, measured after 12 hours, ranged between 91.35% and 97.24%, indicating good swelling capacity of the hydrophilic polymers, which is essential for

controlled drug release. Floating lag time (FLT) was found between 4.3–5.1 minutes across batches, while all formulations maintained buoyancy for more than 10 hours (except F5, which floated for >8 hours). This confirmed the effectiveness of sodium bicarbonate as a gas-generating agent in imparting buoyancy to the dosage form. Drug content was uniform among all batches, ranging from 96.79% to 99.57%, which falls within the acceptable pharmacopeial limits.

In Vitro Drug Release Studies

The in vitro dissolution studies were conducted in 0.1 N HCl (pH 1.2) for 12 hours, and the release profiles varied among different batches depending on the polymer concentration and composition. The initial drug release (at 1 hour) ranged from 20.12% (F3) to 36.94% (F5), while cumulative release at 12 hours varied between 92.55% (F9) and 96.55% (F5). Formulation F5, containing a higher proportion of xanthan gum, exhibited rapid drug release, achieving nearly complete release (96.55%) by 8 hours.

On the other hand, formulations F3, F9, and F12 demonstrated a more sustained release pattern, with approximately 93–95% release at 12 hours, indicating the efficiency of HPMC K100M in controlling drug release.

Overall, the release profile showed that a combination of xanthan gum and HPMC K100M could be optimized to achieve prolonged drug release over 12 hours while maintaining tablet buoyancy.

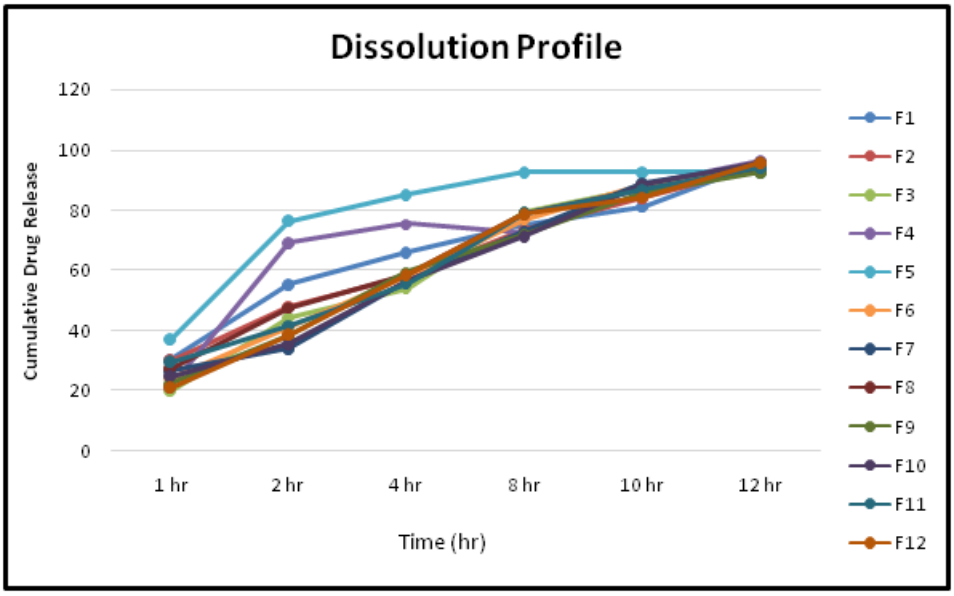

Figure 3: Dissolution Profile

Discussion

The results confirmed that acyclovir could be successfully formulated into floating matrix tablets using hydrophilic polymers such as xanthan gum and HPMC K100M in combination with sodium bicarbonate as a gas-generating agent. The preformulation data established the suitability of the powder blends for compression, while the physicochemical evaluations demonstrated that the tablets met pharmacopeial quality standards. The swelling and buoyancy studies revealed that the tablets could expand adequately and float for extended periods, making them suitable for gastro-retentive delivery. Drug release studies highlighted the importance of polymer concentration in modulating release rates.

Formulations with higher HPMC content showed sustained release, whereas formulations with higher xanthan gum content exhibited faster release. Among the tested formulations, F3, F9, and F12 demonstrated an optimal balance between buoyancy and sustained release, making them promising candidates for further optimization. These findings suggest that the developed floating matrix tablets can improve the bioavailability of acyclovir by prolonging gastric residence time and maintaining therapeutic plasma concentrations for extended periods. This may reduce dosing frequency, enhance patient compliance, and ultimately improve therapeutic outcomes in the treatment of viral infections such as herpes simplex and varicella-zoster.

Conclusion

The study successfully developed acyclovir floating matrix tablets capable of sustained release and prolonged gastric retention. Preformulation evaluation confirmed that the powder blends had suitable flow and compressibility properties for tablet compression.

The prepared tablets exhibited acceptable physicochemical characteristics, including hardness, friability, weight uniformity, swelling index, and high drug content, complying with pharmacopeial standards. In vitro buoyancy studies demonstrated rapid floating onset and extended floating duration, while dissolution studies confirmed sustained drug release over 12 hours. Formulations containing higher HPMC K100M concentrations provided controlled release, whereas xanthan gum promoted faster drug release. FTIR and UV spectroscopic studies confirmed drug–excipient compatibility, ensuring formulation stability. Overall, the optimized floating matrix tablets of acyclovir are promising for enhancing gastric residence time, improving bioavailability, and reducing dosing frequency, thereby offering better therapeutic outcomes and patient compliance in antiviral therapy.

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