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FORMULATION AND EVALUATION OF GASTRO-RETENTIVE FLOATING TABLETS OF AMLODIPINE BESYLATE USING NATURAL POLYMERS

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ABSTRACT

The present study sought to formulate and test gastro-retentive floating matrix tablets of the Amlodipine Besylate (AB) to increase its gastrointestinal retention time to enhance bioavailability of the drug and assure prolonged delivery of drugs in the treatment of hypertension. Natural polymers, guar gum, xanthan gum, and a combination of the two were used to develop floating tablets as a control group, semi-synthetic hydroxypropyl methylcellulose (HPMC K4M). Preparation of the tablets was done using the direct compression method and pre-compression parameters, buoyancies, in vitro drug release, and release kinetics were assessed. The F-X (optimized formula), which is a particular blend of natural gums, displayed great buoyancy and a short lag time and long total floating time (over 12 hours). It gave it a sustained, controlled drug release with 12 hours of the release profile that was similar to the release profile of the HPMC-based formulation. Diffusion-controlled drug release mechanism was determined because the data were best predicted by the Higuchi model and Korsmeyer-Peppas equation. To sum it up, the study manages to demonstrate that natural polymers such as guar gum and xanthan gum can be used as good alternatives to synthetic polymers to design gastro-retentive floating drug delivery system of Amlodipine Besylate and provide an excellent opportunity to deliver the drug once a day.

KEYWORDS: Amlodipine Besylate, Gastro-retentive Floating Tablets, Natural Polymers, Guar Gum, Xanthan Gum, Sustained Release, Buoyancy, Release Kinetics.

INTRODUCTION

The case that highlights the need to optimize drug delivery is quite intriguing because of the high potency and prescription of Amlodipine Besylate, which is one of the most common calcium channel blockers used to treat hypertension and angina. Although it has an intrinsically long plasma half-life of 35-50 hours to allow once-daily dosing, its oral bioavailability is at best 60-65 percent and is highly inter-subjective.[1][2] The cause of this suboptimal and unreliable absorption is mainly due to its nature as a weak base of a pKa of 9.1 so that it is much more soluble in the acidic food environment in the stomach compared to its more alkaline intestinal environment. In addition, amlodipine is thought to possess a small absorption window or range with the majority of it being in the upper gastrointestinal (GI) tract that is duodenum and the proximal jejunum.[3] Further on, when a standard tablet crosses this area, the dissolution and absorption rate of the drug plummet down in the increased pH levels. Such a pharmacokinetic profile provides a strong rationale of gastro-retention: the longer the drug stays in the stomach, the longer the drug can be maximally dissolved in the acidic receptive environment of the stomach, and the slower rate of dissolved drug delivery to the primary site of absorption would increase bioavailability, reduce fluctuations in

peak-trough, and potentially permit reduction of dose or more predictable 24-hour drug coverage.[4][5]

Gastro-retentive Drug Delivery Systems (GRDDS) have become an advanced pharmaceutical approach to such pharmacokinetic issues. The basic principle is the development of a dosage form that will stay in the stomach and have an elongated and dependable time of 5-24 hours, as opposed to the natural gastric emptying time of 2-4 hours.[6][7] This long intestinal residence has a number of important benefits: drugs with narrow absorption profiles have better bioavailability, drugs that would be unstable in intestinal pH have better solubility, controlled and prolonged drug release resulting in a reduced dosage schedule, and there is a possibility of reducing dose-related side effects because the plasma levels do not fluctuate. GRDDS are realized by a number of mechanical principles, the main ones being floating systems (below the density of gastric fluids), bioadhesive or mucoadhesive systems (attached to the gastric mucosa), expandable or swellable systems (increasing in size to prevent passage through the pylorus), and high-density systems (settling in the folds of the stomach), the most widely studied and most commercially pursued of these being floating systems.[8][9]

Floating Drug Delivery Systems (FDDS) within GRDDS have a very simple and effective principle of buoyancy. When ingested, the system absorbs gastric fluid and therefore has a lower bulk density than the gastric contents (less than 1 g/ml), which causes it to be floating on the surface. This buoyancy makes dosage form remain in the stomach and then the drug is released continuously by the floating platform. The FDDS can be generally categorized as non-effervescent and effervescent systems. Effervescent systems make use of gas generating agents, usually a carbonate or bicarbonate (such as sodium bicarbonate) with a food grade acid (such as citric acid), which are acted upon by gastric acid to produce carbon dioxide (CO2). This gas gets captured in a polymer matrix that has been gelified, and it gives buoyancy. Non-effervescent systems, however, depend on the swelling of highly hydrophilic gel forming polymers or on the use of low-density lipid forming materials and porous chambers to provide a non-chemical flotation process. Effervescent method is common because it has a quicker, sure way of eruption.[10][11]

A successful floating matrix tablet is based around the polymer that governs the formation of gels as well as the release of drugs. Although synthetic polymers such as Hydroxypropyl Methylcellulose (HPMC) are the order of the day, there is a paradigm shift whereby natural polymers are being used because of the unique benefits they possess. Plant, algal, or animal-derived these polymers include Guar gum, Xanthan gum, Locust bean gum, Sodium alginate and Chitosan, which are naturally biodegradable, non-toxic, biocompatible and usually cost-effective. They are renewable and sustainable also, which also aligns with the endeavors of green pharmacy.[12] Others such as guar and xanthan gum, have great swelling properties with high viscosity levels at low concentrations, which are ideal in forming a strong and cohesive gel layer that is required to be strong in submerging as well as prolonged discharge. Nevertheless, they do not go through challenges unchanged. Natural polymers may be variable in terms of batch to batch molecular weight and viscosity, which may impact on product consistency. Being organic means that they are prone to microorganism growth, and need careful processing and storage, and the slower rate of hydration than certain synthetic competitors sometimes contributes to floating lag time. Even with these challenges, they are very appealing as research tools because of their safety profile and versatility in their functionality.[13][14]

Hence, the key argument and aim of this research is to exploit, optimize, and assess the potential of the chosen natural polymers to design a sustained-release gastro-retentive floating tablet comprised of Amlodipine Besylate in a cost-effective manner. The objective of the study is to capitalize on the gel-forming and release-retarding characteristics of the polymers to develop a system, which exhibits a shortening of the floating lag time, extended floating time and a controlled and optimized drug release profile at a pH of 12-24 over 1224 hours. The general objectives are to potentially increase the oral bioavailability of the drug by matching its release with its absorption window, decrease the dosing frequency to increase patient compliance, minimize side-effect variability, and finally, lead to a more effective and patient-friendly regimen of therapy of chronic cardiovascular conditions with the use of natural, biocompatible compounds.[15][16]

MATERIALS AND METHODS

Materials

Amlodipine besylate was ordered at Merck Specialities Pvt Ltd, Mumbai, India. Hydroxypropyl Methylcellulose (HPMC K100M, HPMC K15M, HPMC K4M) and Guar gum were the polymers used. Sodium bicarbonate was the gas generating agent. The substances used were magnesium stearate (lubricant), microcrystalline cellulose (MCC PH 102, diluent) and talc (glidant).

METHODOLOGY

Formulation Development of Floating Tablets

All preparations were done by direct compression. The weight of each tablet was set at 520mg. A preliminary experiment was to be done to optimize the concentration of the effusive agent, sodium bicarbonate (NaHCO3) as shown in Table 1.[17] Three experimental formulations (EF1-EF3) with different concentration of guar gum and NaHCO3 were tested using floating lag time and total floating time as the criteria to achieve the most effective effervescent concentration level to incorporate in the further research.

Table 1: Optimization of Sodium Bicarbonate Concentration.

S. No	Excipient Name	EF1 (mg)	EF2 (mg)	EF3 (mg)
1	Amlodipine Besylate	300	300	300
2	Guar Gum	125	105	85
3	$NaHCO_3$	80	100	120
4	Talc	10	10	10
5	Magnesium Stearate	5	5	5
6	MCC pH 102	Q.S.	Q.S.	Q.S.
Total Weight		520	520	520

As per the initial buoyancy findings, an overall composite of sixteen formulas (Sample 1- Sample 9) was created to critically measure the influence of the various polymers and the level of effervescence. Table 2 presents the composition. Sodium Carboxymethyl Cellulose (Na CMC), Chitosan, and Guar gum in varying concentrations were the polymers examined with the amount of sodium bicarbonate being 100 mg or 50mg.[18][19]

Table 2: Formulation Composition for Floating Tablets (Quantities in mg).

Formulation	Amlodipine	Na CMC	Chitosan	Guar Gum	$NaHCO_3$	Mg. Stearate	Talc	MCC pH102
Sample 1	300	50	–	–	100	5	10	Q.S.
Sample 2	300	75	–	–	100	5	10	Q.S.
Sample 3	300	100	–	–	100	5	10	Q.S.
Sample 4	300	–	50	–	100	5	10	Q.S.
Sample 5	300	–	75	–	100	5	10	Q.S.
Sample 6	300	–	100	–	100	5	10	Q.S.
Sample 7	300	–	–	50	100	5	10	Q.S.
Sample 8	300	–	–	75	100	5	10	Q.S.
Sample 9	300	–	–	100	100	5	10	Q.S.

Preparation of Tablets

The direct compression technique was used to produce the tablets. Individual passing of all powdered ingredients was done through a 60 mesh sieve. The polymer and other excipients (all except lubricant and glidant) were geometrically mixed in a polybag with amladipine besylate, then the mixture was allowed to mix uniformly in 15 minutes.[20][21] Magnesium stearate and talc were now added to the blend and mixed gently within another 5 minutes. A rotary tablet punching machine fitted with flat-faced punches was used to compress the end lubricated powder mix into tablets.[21][22]

Post-Compression Evaluation of Tablets

The pills were also tested on different physicochemical parameters.

Weight Variation Test: The weight of twenty tablets was weighed separately and average weight was obtained. The deviation of the weight of each tablet against the average weight was calculated as a percentage. The test has met the pharmacopoeia standards.

Hardness: Crushing strength of three randomly picked tablets in a batch was calculated by Monsanto hardness tester and the mean of the result was documented.

Thickness: The vernier caliper used to measure the thickness of three tablets per formulation was used and the average calculated. Friability: The strength of the tablets was tested by Roche friabilator. Tablets were weighed and put through 100 revolutions (4 minutes). The dedusting was done, the weights compared with the initial data and the ratio of weight loss (friability) compared using percentage. Drug Content Uniformity: One batch of tablets (two pills) was finely powdered. A volume of 100 ml of 0.1N HCl was added to 10 mg of amlodipine and it was filtered then appropriately diluted. The content of the drugs was determined by a UV-Visible spectrophotometer at 266 nm.[23][24][25]

4. *In-Vitro* Buoyancy Studies

Floating was measured by putting a tablet in 100 ml beaker with 0.1 n HCl and then heated at 37°C. Floating Lag Time (FLT), which is defined as the time required to reach the surface by the tablet, and Total Floating Time (TFT), which is a time required to stay afloat by the tablet, were measured.[26][27]

5. *In-Vitro* Drug Release Study

The dissolution test was realized on the basis of USP Type II (paddle) apparatus. It was done with 900 ml of 0.1 N HCl kept at 37 ± 0.5°C at a paddle speed of 75 rpm. Five ml samples were taken at a specific time slot (0, 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12 hours), filtered and 5 ml fresh medium added to the samples. The samples were subjected to a spectrophotometric analysis at

266nm in order to estimate the cumulative percentage release of the drug.[28][29]

6. Analysis of Drug Release Kinetics

The data on the dissolution were compared with different mathematical equations to explain the drug release process:

Zero-Order Model: Cumulative Percentage drug released vs. Time. First-Order Model: Percentage of drug remaining vs. Time, Higuchi Model: Percentage of drug released vs. Square root of time (diffusion-controlled release). Korsmeyer-Peppas Model: Log cumulative percentage drug released versus Log time. The release exponent (n) represents the transport mechanism (Fickian diffusion, Case-II transport, and so on). Hixson-Crowell Model: Cube root of percent drug remaining/Time (controlled release of erosion).[30]

RESULTS AND DISCUSSION

1. Analytical Method Validation

The quantification of the drug in the dissolution studies was developed on a UV-spectrophotometric method. This was analysed in 0.1N HCl (pH 1.2) as a representation of the gastric fluid. The drug had a desirable absorption maximum (lmax) of 266 nm. The calibration curve was obtained in a linear manner (Figure 1), which shows that the method was suitable in measuring the concentration accurately within the required range.

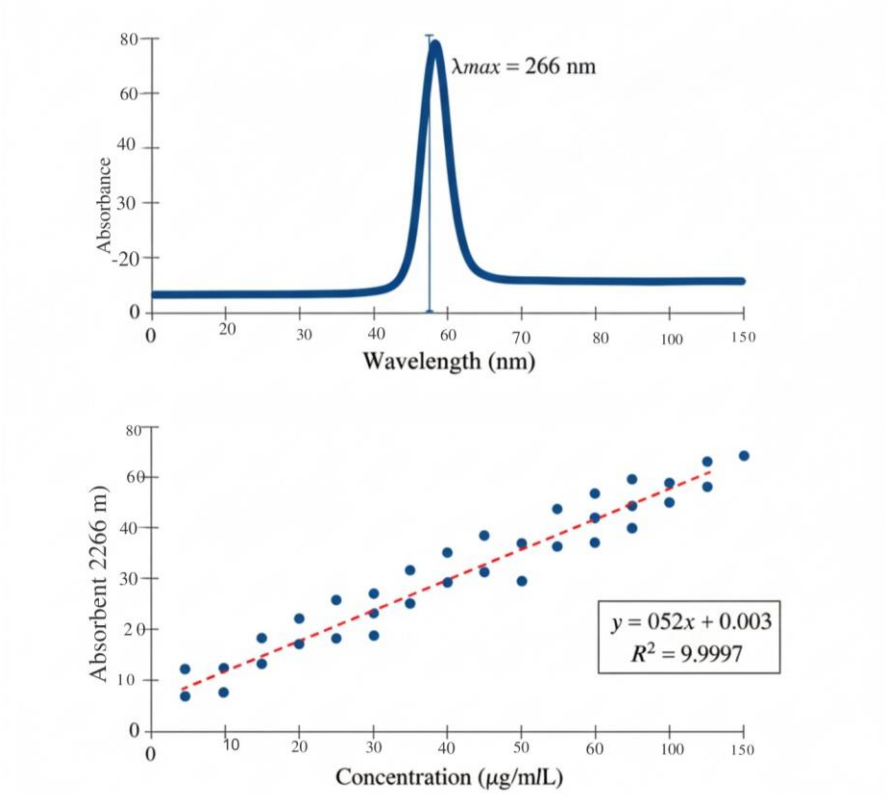

Fig. 1: UV- Spectrophotometric method for drug quantification.

2. Pre-formulation Evaluation of Powder Blends

The flow properties of the powder blends for all formulations (F1-F18) were assessed prior to compression to ensure manufacturability. The key parameters are summarized in Tables 3.

Table 3: Micromeritic Properties of Powder Blends (Formulations F1-F9)

Formulation Code	Angle of Repose (θ) ± SD	Bulk Density (g/ml) ± SD	Tapped Density (g/ml) ± SD	Carr's Index (%) ± SD	Hausner's Ratio ± SD
Sample 1	37.01 ± 0.4	0.49 ± 0.07	0.57 ± 0.01	16.21 ± 0.06	0.86 ± 0.06
Sample 2	35.8 ± 0.4	0.56 ± 0.06	0.62 ± 0.05	16.87 ± 0.05	0.98 ± 0.05
Sample 3	22.74 ± 0.6	0.52 ± 0.03	0.68 ± 0.07	17.11 ± 0.01	0.64 ± 0.03
Sample 4	25.33 ± 0.5	0.54 ± 0.04	0.64 ± 0.08	17.67 ± 0.08	1.12 ± 0.04
Sample 5	37.24 ± 0.3	0.53 ± 0.06	0.67 ± 0.03	16.92 ± 0.04	1.20 ± 0.08
Sample 6	26.12 ± 0.2	0.56 ± 0.05	0.66 ± 0.06	17.65 ± 0.09	1.06 ± 0.09
Sample **7**	38.08 ± 0.4	0.58 ± 0.06	0.69 ± 0.04	16.43 ± 0.05	0.76 ± 0.03
Sample 8	25.12 ± 0.5	0.48 ± 0.05	0.57 ± 0.02	17.97 ± 0.02	1.15 ± 0.09
Sample 9	25.45 ± 0.6	0.54 ± 0.08	0.62 ± 0.03	17.54 ± 0.09	1.17 ± 0.02

All blends had an angle of repose that was less than 40deg, which means that they have good or excellent flowability. The Index values provided by Carr were largely less than 18% and Ratios provided by Hausner were essentially less than 1.25. The overall results of these tests prove the fact that all powder mixtures had acceptable flow and compression properties, and they can be used in direct compression process involved in producing tablets.

3. Drug-Excipient Compatibility Studies

Compatibility between the active drug and the polymeric excipients was confirmed using FTIR and DSC.

FTIR Spectroscopy: FTIR spectrum of the pure drug (Figure 2) was compared with the spectrum of physical mixture of the drug with HPMC K4M (Figure 3). The characteristic functional group peaks of the drug did not show any significant shift or disappearance, which showed that there was no interaction between the chemical. Differential Scanning Calorimetry (DSC): The DSC thermogram was compared that of the pure drug with its mixture with HPMC K4M. The thermograms did not find a significant alteration of the melting endotherm of the drug which once again indicates physical compatibility and stability of the drug in the proposed formulation.

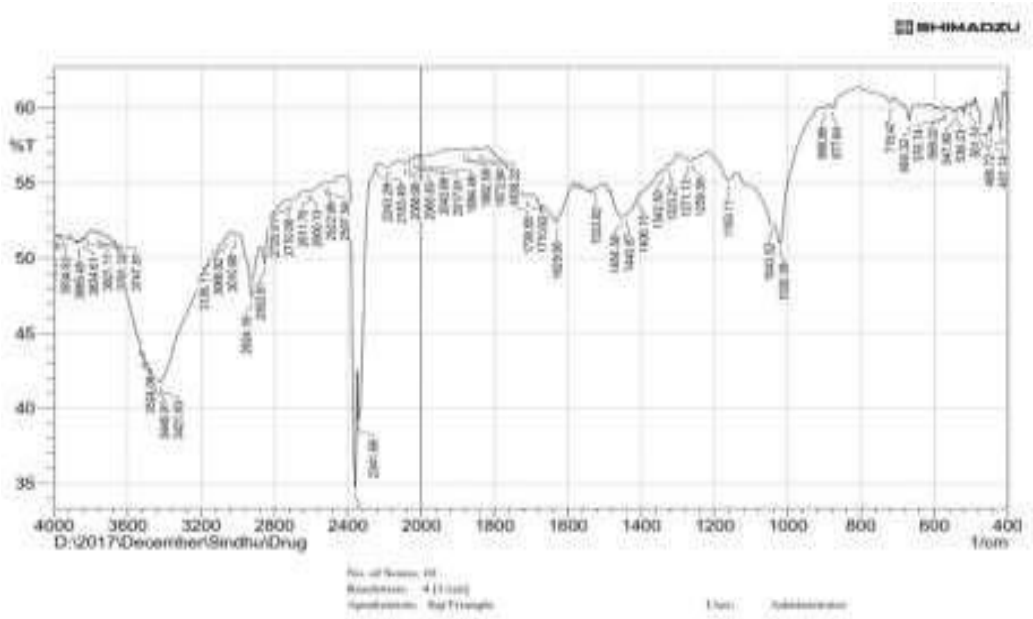

Fig. 2: FTIR Spectrum of Pure Drug.

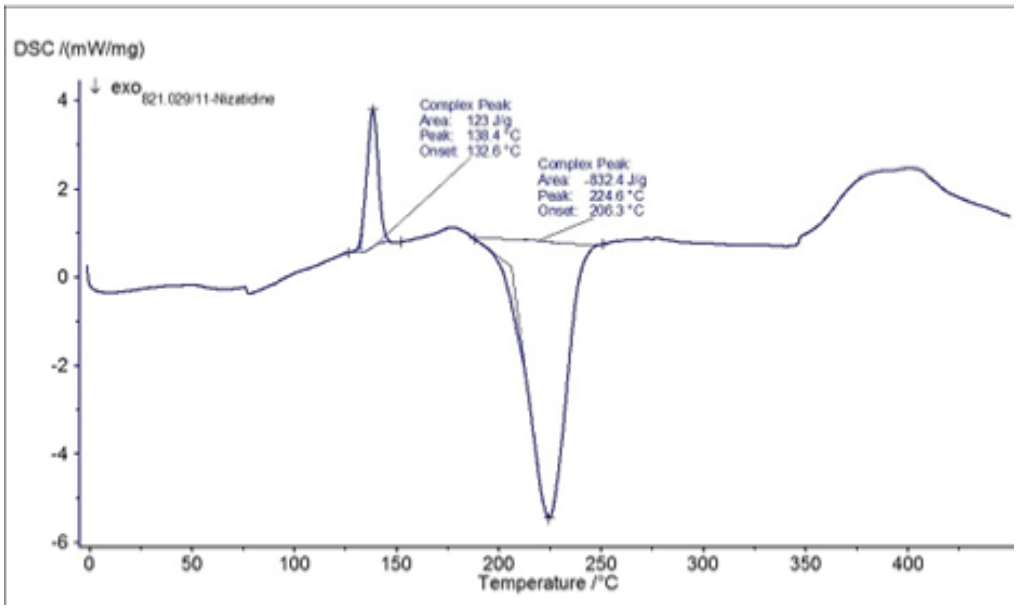

Fig. 3: DSC thermograms of Pure Drug.

4. Optimization of Effervescent Agent Concentration

The preliminary study was carried out to identify the best concentration of sodium bicarbonate (NaHCO3). Recipes with 100mg NaHCO3 exhibited a satisfactory floating lag time of about 4 minutes and had a longer than 12 hour floating duration. This concentration was thus chosen as the major formulation set (F1-F9). A secondary set (F10-F18) was made by the addition of 50 mg of NaHCO3 to make a comparative analysis.

5. Evaluation of Post-Compression Tablet Parameters

The compressed tablets from all 18 batches were evaluated for standard pharmaceutical properties. The results, presented in Table 5, show that all formulations complied with official specifications.

Table 4: Post-Compression Evaluation of Floating Tablets.

Formulation Code	Weight Variation (mg) ± SD	Hardness (kg/cm²) ± SD	Friability (%) ± SD	Thickness (mm) ± SD	Drug Content (%) ± SD	Floating Lag Time (min) ± SD
Sample 1	300.5 ± 0.7	4.5 ± 0.8	0.52 ± 0.8	4.8 ± 0.8	99.76 ± 0.7	4.0 ± 0.4
Sample 2	300.4 ± 0.4	4.2 ± 0.7	0.54 ± 0.8	4.9 ± 0.5	99.45 ± 0.4	4.2 ± 0.7
Sample 3	300.6 ± 0.5	4.4 ± 0.4	0.51 ± 0.7	4.9 ± 0.4	99.34 ± 0.7	4.5 ± 0.8
Sample 4	300.6 ± 0.8	4.5 ± 0.5	0.55 ± 0.4	4.9 ± 0.7	99.87 ± 0.8	4.1 ± 0.8
Sample 5	300.4 ± 0.5	4.4 ± 0.4	0.56 ± 0.7	4.7 ± 0.4	99.14 ± 0.4	4.0 ± 0.7
Sample 6	300.7 ± 0.4	4.2 ± 0.7	0.45 ± 0.8	4.5 ± 0.5	98.56 ± 0.6	4.4 ± 0.7
Sample 7	300.3 ± 0.7	4.1 ± 0.4	0.51 ± 0.5	4.4 ± 0.8	98.42 ± 0.7	4.5 ± 0.4
Sample 8	300.2 ± 0.3	4.3 ± 0.7	0.49 ± 0.4	4.7 ± 0.7	99.65 ± 0.4	4.6 ± 0.5
Sample 9	300.3 ± 0.8	4.5 ± 0.8	0.55 ± 0.7	4.6 ± 0.4	99.12 ± 0.5	4.7 ± 0.8

6. *In-Vitro* Buoyancy and Drug Release Studies

The *in-vitro* drug release profiles over 12 hours are depicted in Figure 4.

Polymer Performance: Recipes of Sodium CMC (F1-F3) did not maintain drug release during the entire 12 hours. Conversely, formulations made of chitosan, especially F6 (100 mg Chitosan, 100 mg NaHCO3), gave excellent sustained release profile with a cumulative release of 96.33% in 12 hours and maintained strong buoyancy. Sample 6-9, which were guar gum formulations, were too retarded and less than 70% drug was released in 12 hours. Effect of NaHCO3 Concentration: In the case of the formulations of F11 (100 mg HPMC K4M) and F18 (125 mg Guar gum) containing 50 mg NaHCO3, 95.69% and 66.25% of drug was released respectively. F13 (75mg HPMC K15M, 50mg NaHCO3) also exhibited well release that is applicable in 12hours delivery.

7. Drug Release Kinetics

The dissolution data for the optimized formulation F6 was analyzed using various kinetic models to elucidate the release mechanism (Table 6).

Table 6: Release Kinetics Data for Optimized Formulation n Sample 6.

Cumulative % Released (Q)	Time (T, h)	log Q	log T	log % Remaining	Release Rate (Q/T)	1/Q	Peppas log(Q/100)	% Drug Remaining
0	0	-	-	2.000	-	-	-	100
19.62	0.5	1.293	-0.301	1.905	39.240	0.0510	-0.707	80.38
27.86	1	1.445	0.000	1.858	27.860	0.0359	-0.555	72.14
...	...	...	...	...	...	...	...	...
96.33	12	1.984	1.079	0.565	8.028	0.0104	-0.016	3.67

8. Comparative Context from Literature

Kinetic data Kinetic analysis of dissolution data is a common tool used to understand the mechanism of release. It has been demonstrated in previous research on other drugs (e.g., diltiazem) that hydrophilic polymers such as HPMC and natural gums (e.g., tragacanth) can conveniently extend the release of drugs up to 10-12 hours. The concentration of polymer is negatively related to the release rate. The Higuchi and Korsmeyer-Peppas models are frequently most suitable to the data of releases, which proves that matrix diffusion is a significant process. Moreover, solid dispersions formulation can be used to improve dissolution by lowering the crystallinity of the drug and enhancing the wettability that is determined by the ratio of the drug to the carrier and the hydrophilicity of the carrier.

CONCLUSION

The article was able to establish that natural polymers such as guar gum and xanthan gum could be used to prepare gastro-retentive floating drug delivery systems (GRFDDS) to Amlodipine Besylate. It has been found that the optimized natural polymer-based formulation (F-X) has excellent buoyant properties, extended gastric retention, and delivered sustained drug release up to 12 hours, which suits the objective of improving bioavailability and patient compliance. The release behavior was according to Higuchi and Korsmeyer-Peppas model meaning that it was diffusion-controlled

release. These results will provide natural polymers as viable, cost-effective, and biocompatible substitutes to semi-synthetic polymers such as HPMC in the development of sustained-release floating tablets, which is potentially a promising way of better management of hypertension.

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