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Original Article

Design and Optimization of *Ziziphus mauritiana* Fruit Polysaccharide-Based Beads for Controlled Release of Propranolol Hydrochloride Using Response Surface Methodology

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ABSTRACT

Background: Polysaccharides from nature have attracted significant interest as biocompatible and eco-friendly polymers used as carriers in drug delivery systems. ZMBP, which stands for *Ziziphus mauritiana* fruit pulp polysaccharide, is an example of such polymers; nevertheless, it is crucial to optimize its formulation for effective release of drugs. The objective of this research was to formulate and optimize propranolol hydrochloride loaded on ZMBP based polymeric beads. **Materials and Methods:** The ZMBP was isolated, characterized and used to formulate polymeric beads via ionotropic gelation process using different concentrations of ZMBP, sodium alginate and tragacanth. RSM design was used as the optimization method. The prepared beads were evaluated for their particle size, entrapment efficiency, swelling property, drug release and kinetics. **Results:** ZMBP had a yield of 10.7%, an amorphous structure. The optimized model was found to be statistically significant (p=0.0012) and ZMBP and sodium alginate were found to be the main factors that influenced the performance of formulations. The developed beads had sizes in the range of 0.78-0.91 mm, entrapping efficiency of 91.58-98.54%, pH dependent swelling, and biphasic release pattern with controlled release for up to 12 hr. **Conclusion:** Optimized ZMBP-based polymeric beads provide an effective, tunable, and sustainable platform for controlled drug delivery.

Keywords: Controlled release drug delivery, Polymeric beads, *Ziziphus mauritiana*, ZMBP Polysaccharide.

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INTRODUCTION

Oral administration of drug continues to be the most favored due to convenience, safety, and excellent patient compliance. Nevertheless, most drugs lack adequate solubility in aqueous solution, possess extensive first-pass effect and low bioavailability, making them less efficacious (Bhalani *et al.*, 2022). Propranolol hydrochloride is a well-known non-selective adrenergic receptor antagonist which is used extensively in the treatment of hypertension and cardiovascular diseases but is affected by extensive first-pass effect making the bioavailability of the drug low and hence requiring dosing frequently (Kalam *et al.*, 2020). Controlled-release drug delivery systems formulated using biopolymers have proven to be an effective approach to addressing such challenges by offering stability, controlled release and improved compliance. As compared to synthetic polymers, natural polymers are biodegradable, biocompatible, renewable, nontoxic and environmentally friendly (Chander *et al.*, 2022; Auriemma *et al.*, 2020).

Of all the biopolymers extracted from plants, *Ziziphus mauritiana* fruit pulp is one of the under-utilized sources of polysaccharides that can be used for preparation of polymeric beads. The said polysaccharides exhibit physicochemical properties favorable for the development of controlled drug delivery systems coupled with value addition in the utilization of agricultural products (Ji *et al.*, 2019). Propranolol hydrochloride inclusion into *Z. mauritiana* polysaccharide beads could offer long-term drug delivery, reduced variation in the concentration of drug in blood and better therapeutic effects in patients suffering from chronic cardiovascular diseases (Ray *et al.*, 2021). Therefore, this study

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was done to the problem of poor oral bioavailability and frequent administration of propranolol hydrochloride through the use of a controlled-release bead formulation prepared with *Ziziphus mauritiana* fruit pulp polysaccharide as an innovative natural biopolymer.

MATERIALS AND METHODS

Materials

Propranolol Hydrochloride was a kind gift from Sura Pharma Ltd., Sodium Alginate, Tragacanth were obtained from Loba Chemie Ltd., All solvent used were of AR grade and distilled water was used in the experiments.

Isolation of polysaccharide

Fruit pulp polysaccharide of *Ziziphus mauritiana* (ZMBP) was isolated using the protocol described by Pathak *et al*. with slight modifications. Fruit pulp was extracted using distilled water at 75ºC for 6 hr, cooled overnight to 4ºC, filtered, and centrifuged. The supernatant was evaporated, precipitated with 95% ethanol (ratio 1:5, v/v), and separated using centrifugation. Precipitate was dialyzed (molecular weight cut-off 12-14 kDa) for 12 hr and lyophilized to get pure ZMBP (Pathak *et al*., 2024).

Crystallographic analysis of ZMBP

The crystalline characteristics of the ZMBP polysaccharide powder were evaluated using powder X-ray Diffraction (PXRD). Diffraction patterns were recorded on a Smart Lab 9 kW, Rigaku, Japan equipped with a monochromatic CuKα radiation source (λ=1.314 Å), operated at 40 kV. Data acquisition was performed over a 2θ range of 5° to 80°, employing a scanning rate of 1°/min with a step size of 0.05°, to ensure precise resolution of diffraction peaks and assessment of crystallinity (Ogawa *et al*., 2022).

Experimental Design for preparation of polymeric beads

Polymeric beads containing propranolol hydrochloride were synthesized by using ionotropic gelation technique with ZMBP. Three-factor and three-level Response Surface Methodology (RSM) was applied for studying the influence of ZMBP (X_1: 1-3%), sodium alginate (X_2: 1-5%) and tragacanth (X_3: 1-3%) on drug release after 12 hr. Polymeric beads were prepared through extrusion technique into a calcium chloride crosslinking solution, then washed. Optimization of formulations was done using quadratic polynomials and ANOVA (Banerjee *et al*., 2016).

Preparation of polymeric beads

Polymeric beads containing propranolol hydrochloride were prepared via ionotropic gelation method using sodium alginate along with polysaccharide from *Ziziphus mauritiana* fruit (ZMBP) as the matrix forming polymer, while tragacanth as a co-polymer. Beads were formed by extrusion of the drug polymer suspension into 5% w/v calcium chloride solution, then cured, washed, and dried. Nine formulations (F1-F9) (Table 1) with different polymer ratios were prepared for studying the effect of polymers on beads and drug release profile (Kaushik *et al*., 2024).

Entrapment efficiency

For determination of drug entrapment, the amount of drug present in the clear supernatant after centrifugation was determined (w) by UV spectrophotometer at 254 nm. A standard calibration curve of drug was plotted for this purpose. The amount of drug in supernatant was then subtracted from the total amount of drug added during the preparation (W). Effectively, (W-w) will give the amount of drug entrapped in the polymeric beads (Gopaiah *et al*., 2022).

$$\% \text{ Drug Entrapment Efficiency} = \frac{W - w}{W} \times 100 \quad (1)$$

Drug loading capacity

Drug content in the preparation was determined by extracting Propranolol Hydrochloride from the polymeric beads with 0.1M hydrochloric acid. In this method beads (50 mg) were stirred in 50 mL hydrochloric acid until dissolved. It was filtered by Millipore filter paper and drug content was determined, after suitable dilution. At 254 nm, the drug loading was detected by UV spectroscopy (Bhalekar *et al*., 2013). The loading efficiency (L) of the polymeric beads was calculated according to following formula:

$$L\,(\%) = \frac{Qn}{Wn} \times 100 \quad (2)$$

Where, Q_n is the amount of drug present in polymeric beads and W_n is weight of polymeric beads.

Swelling and degradation studies

20 mg of beads were placed in several watch glasses containing 5 mL of 0.1N HCl in each. The experiment was scheduled at room temperature. Swelled beads were removed at a definite time interval i.e. 30 min, 60 min, 90 min, 120 min, 180 min and dried at room temperature for 24 hr. The change in weight was measured by using an electronic digital balance. The test was continued by putting the recovered beads in phosphate buffer pH 7.4. The fractional change in weight was measured at interval of 30 min till the beads disintegrated (Thummala *et al*., 2023).

Microscopic Studies

The particle size of beads was measured by microscopic analysis methods. The average particle sizes of different formulations were calculated and reported (Mariello *et al*., 2024).

In vitro dissolution studies

The *in vitro* drug release was carried out under physiological gastrointestinal conditions using the USP Type I Basket Apparatus with a stirring speed of 50 rpm and a temperature of 37±0.5ºC.

The polymeric beads corresponding to 50 mg propranolol hydrochloride were placed in the pH 1.2 buffer solution for 2 hr and then transferred to pH 6.8 phosphate buffer solution for 6 hr. Samples were taken at specific time intervals and subjected to UV-visible Spectrophotometric analysis at 290 nm (Li *et al.*, 2023).

Release kinetics studies

The release pattern of the drug *in vitro* was analyzed by applying the release kinetics of zero order, first order, Higuchi, and Korsmeyer-Peppas models to understand the mechanism of drug release. The best fit of the kinetic model was obtained on the basis of correlation coefficients (R^2). The Korsmeyer-Peppas model was used to calculate the value of n (release exponent) (Nwazojie *et al.*, 2023).

Statistical analysis

The values are expressed as the mean ± standard error of the mean. IC_{50} values were derived with the use of non-linear regression analysis of percentage inhibition versus logarithmic concentrations based on triplicate data (n=3).

RESULTS

Yield of polysaccharide

The aqueous extraction method employed for isolating the polysaccharide from ripe fruits of *Ziziphus mauritiana* yielded 10.7% (w/w) of ZMBP. This yield is significantly higher compared to previously reported values for other Ziziphus species (4.48%), indicating the efficiency of the extraction process and the rich polysaccharide content of the selected fruit source (Chen *et al.*, 2025).

Crystallographic analysis

From the X-ray Diffraction (XRD) pattern obtained for the isolated polysaccharide from *Ziziphus mauritiana* fruit pulp (ZMBP), a broad diffuse halo was observed at $2\theta \approx 18\text{-}22^{o}$ without any crystalline peak, which indicated the amorphous character of the polysaccharide (Figure 1). The lack of any regular molecular arrangement is attributed to the amorphous character of the natural polysaccharides, due to their highly branched nature and extensive hydrogen bonding. The amorphous character is a positive attribute when it comes to the use of such a polysaccharide as a pharmaceutical excipient (Ogawa *et al.*, 2022; Dey and Ghosh, 2022).

Experimental design for polymeric bead formulation

The optimization of *Ziziphus mauritiana* polysaccharide-based beads was systematically performed using Response Surface Methodology (RSM), and the effect of formulation variables on % drug release (Y) was best described by a second-order polynomial model:

$$Y=\beta0+\beta1X1+\beta2X2+\beta3X3+\beta12X1X2+\beta13X1X3+\beta23X2X3+\beta11X21+\beta22X22+\beta33X23$$

Based on regression analysis, the fitted equation for drug release was obtained as:

$$Y=53.50-2.75X1-2.25X2-0.50X3-0.25X1X2+0.25X2X3+0.125X21+0.625X22+0.125X32$$

The negative values for X_1 (ZMBP) and X_2 (sodium alginate) were due to the fact that increased concentrations of the polymers minimized drug release through the formation of a denser matrix. ANOVA analysis validated that the significance of the model was 0.0012, where the main variables included X_1 (p<0.0001) and X_2 (p<0.001), while X_3 (tragacanth) had no significant influence on the response (p>0.05). The predicted drug release (48-59%) coincided well with the experimental data, thus confirming the accuracy of the model (Liu *et al.*, 2016).

Evaluation of polymeric beads

Drug content and encapsulation

Propranolol hydrochloride was uniformly distributed among formulations (F1-F9), according to drug content analysis. Drug loading varied from 7.09±0.39% to 9.09±0.32%, and entrapment efficiency ranged from 91.58±0.38% to 98.54±0.21%, with F9 exhibiting the highest entrapment (Table 2). While lower polymer concentrations led to decreased drug retention, higher polymer content improved matrix formation, which decreased drug diffusion during gelation and improved entrapment (Dhone *et al.*, 2023).

Table 1: The composition of prepared polymeric beads.

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Propranolol HCl (mg)	100	100	100	100	100	100	100	100	100
Sodium Alginate (% w/v)	2	3	4				1	1.5	2
ZMBP Polysaccharide (% w/v)				2	3	4	1	1.5	2
Tragacanth (% w/v)	1	0.75	0.5	1	0.75	0.5	1	0.75	0.5
Calcium Chloride Solution (% w/v)	5	5	5	5	5	5	5	5	5
Distilled Water (mL)	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Table 2: Drug entrapment and loading capacity in polymeric beads.

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Entrapment efficiency (%)	91.58± 0.38*	94.77± 0.52	95.80 ± 0.44	94.12± 0.39	97.23± 0.32	96.99± 0.51	97.11± 0.46	97.88± 0.59	98.54± 0.21
Drug loading capacity (&)	7.11± 0.19*	7.44± 0.22	7.09± 0.39	7.76± 0.17	7.33± 0.07	7.75± 0.30	7.88± 0.56	8.34± 0.34	9.09± 0.32

*Values are expressed as Mean ± SD (n=3). Data were analyzed using one-way analysis of variance (ANOVA) followed by Tukey's multiple comparison test. Differences were considered statistically significant at $p<0.05$.

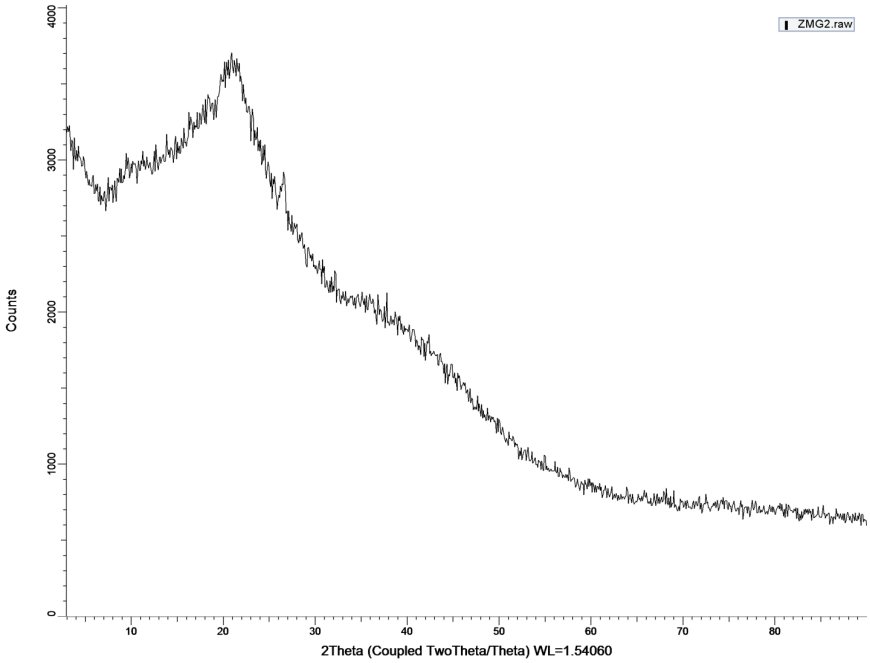


Figure 1: X-Ray diffraction spectra of ZMBP polysaccharide.

Swelling studies of the beads

The swelling behavior was depending on both pH and formulation. At pH 1.2, all formulations showed very little swelling; at pH 7.4, the swelling was noticeably higher (Table 3). Despite the hydrophilic nature of alginate, formulations F1-F3 showed the most swelling, while F7-F9 showed the least because of higher polymer concentration, which created a denser matrix that limited solvent penetration and decreased hydration (Eltaib, 2025).

Microscopic evaluations of the beads

Microscopic evaluation of formulations (F1-F9) showed oval to spherical beads with diameters of 0.78-0.91 mm. Polymer composition significantly influenced morphology: lower sodium alginate or ZMBP concentrations produced porous beads, whereas higher concentrations formed denser, compact structures (Figure 2). These morphological differences correlated with drug release, where porous beads promoted faster diffusion and compact beads ensured controlled release (Rehman *et al.*, 2024).

In vitro release studies of the polymeric beads

In vitro dissolution studies of propranolol hydrochloride loaded beads (F1-F9) indicated a two-step drug release pattern, consisting of a rapid burst (20-25%) in the first 2 hr of dissolution and subsequently slow release for 12 hr, indicating efficient matrix-controlled release system. The total amount of drug release gradually declined from ~95% (F1) to ~75% (F9) on increasing concentration of ZMPS and sodium alginate, suggesting enhanced matrix density and diffusion barrier (Figure 3). Reduced polymer amount resulted in quick drug diffusion whereas increased polymer amount facilitated the formation of a dense cross-linked network resulting in delayed release. This shows that polymer composition can be effectively utilized for controlling drug release from beads (Malviya *et al.*, 2019).

Release Kinetics

The kinetic study revealed that the release profile of the drugs from formulations F1-F9 was fitted best to the Korsmeyer-Peppas model (R^2=0.997-0.999) (Table 4), demonstrating anomalous (non-Fickian) transport due to a combination of diffusion and relaxation of the polymers. The high zero-order correlation (R^2=0.986-0.988) demonstrated that the drug release was

near-constant, while the good Higuchi model fit (R^2=0.971-0.976) verified diffusion through the hydrated polymer network as an important release mechanism. The low first-order correlation (R^2=0.89-0.98) revealed that the release was not highly concentration-dependent. The increased polymer concentration resulted in increased matrix density and diffusional resistance, thereby extending drug release (Dwivedi *et al.*, 2023).

DISCUSSION

The current work shows that the polysaccharide derived from *Ziziphus mauritiana* (ZMBP) fruit pulp has advantageous physicochemical and functional characteristics for use as a natural polymer in controlled oral medication administration. ZMBP is a promising, stable, and biodegradable excipient due to its amorphous form, remarkable thermal stability, and relatively high extraction yield of 10.7%. Similar findings have been documented for polysaccharides produced from plants, where an amorphous polymeric network promotes regulated drug diffusion and improves water uptake without sacrificing matrix integrity (Ogawa *et al.*, 2022). The increased extraction yield of ZMBP makes it more feasible for widespread medicinal uses when compared to other naturally occurring polysaccharides. ZMBP and sodium alginate concentrations were found to be the main variables influencing microsphere performance using response surface approach. Higher entrapment efficiency (>91%), less swelling, and slower drug diffusion were the outcomes of a denser ionically cross-linked matrix created by increasing polymer concentration. These results are consistent with other studies showing that in alginate-based delivery systems, polymer concentration and cross-linking density are important factors influencing encapsulation effectiveness and prolonged drug release (Auriemma *et al.*, 2020). Propranolol hydrochloride and other highly water-soluble medications can be incorporated into ZMBP thanks to its exceptional encapsulation efficiency.

The microspheres showed significant pH-responsive swelling, with more swelling at intestinal pH and little hydration under simulated stomach circumstances. Because it reduces early drug release in the stomach and encourages persistent release at the principal site of absorption, this characteristic is beneficial for oral controlled-release formulations. The improved formulation (F9) best fit the Korsmeyer-Peppas model and showed the slowest drug release (~60% over 12 hr), suggesting anomalous (non Fickian) transport including both diffusion and polymer relaxation. Natural polysaccharide-based matrices designed

Table 3: Swelling studies of polymeric beads at different pH.

	F1 (mg)	F2 (mg)	F3(mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)	F9 (mg)
Acidic pH (pH 1.2)									
0 min	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
60 min	23.66	24.18	24.55	24.12	24.43	24.02	22.19	21.07	20.77
120 min	27.14	24.77	25.56	25.11	25.34	24.79	23.89	23.21	21.22
Phosphate Buffer (pH 7.4)									
180 min	31.56	28.12	27.88	30.89	27.94	26.89	24.56	23.76	23.06
240 min	35.13	29.88	29.76	31.03	30.06	27.78	25.06	24.14	24.11
300 min	40.07	34.14	32.54	32.78	31.77	29.04	25.99	25.73	24.71
360 min	44.11	37.12	35.78	33.29	32.88	32.45	26.87	26.90	25.88
480 min	47.88	40.49	38.98	35.11	35.32	33.20	28.03	27.77	26.32

Table 4: *In vitro* release kinetics of the formulations F1-F9.

Formulation	Zero-order	First-order	Higuchi	Korsmeyer-Peppas	
	R^2	R^2	R^2	R^2	N
F1	0.9883	0.9843	0.9598	0.9712	0.632
F2	0.9915	0.9833	0.9493	0.9774	0.690
F3	0.9936	0.9899	0.9496	0.9893	0.817
F4	0.9917	0.9823	0.9559	0.9831	0.660
F5	0.9904	0.9837	0.9524	0.9698	0.665
F6	0.9960	0.9882	0.9417	0.9883	0.911
F7	0.9903	0.9652	0.9268	0.9761	0.730
F8	0.9943	0.9759	0.9344	0.9634	0.713
F9	0.9875	0.9656	0.9187	0.9546	0.694

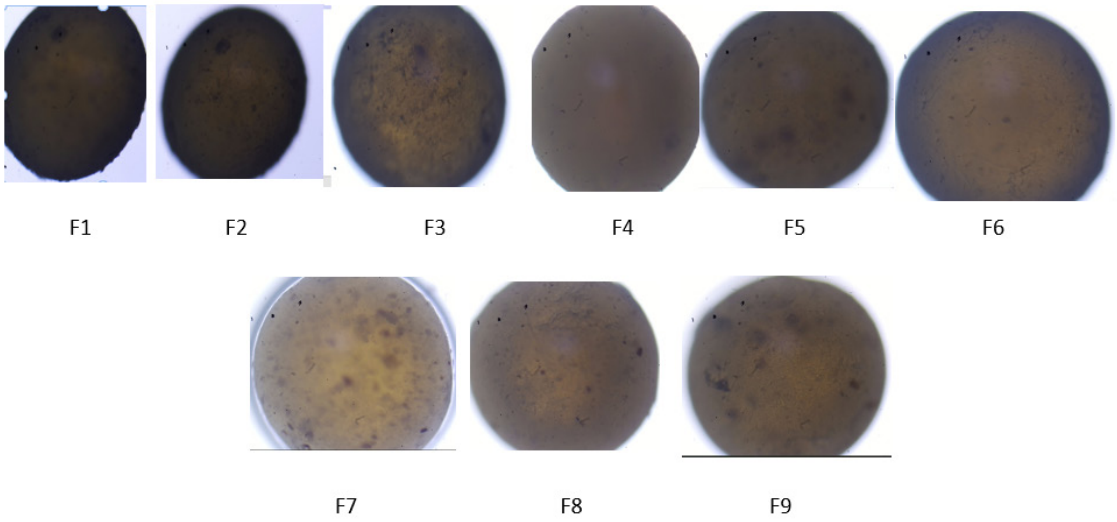


Figure 2: Microscopic features of the polymeric bead formulations (F1-F9).

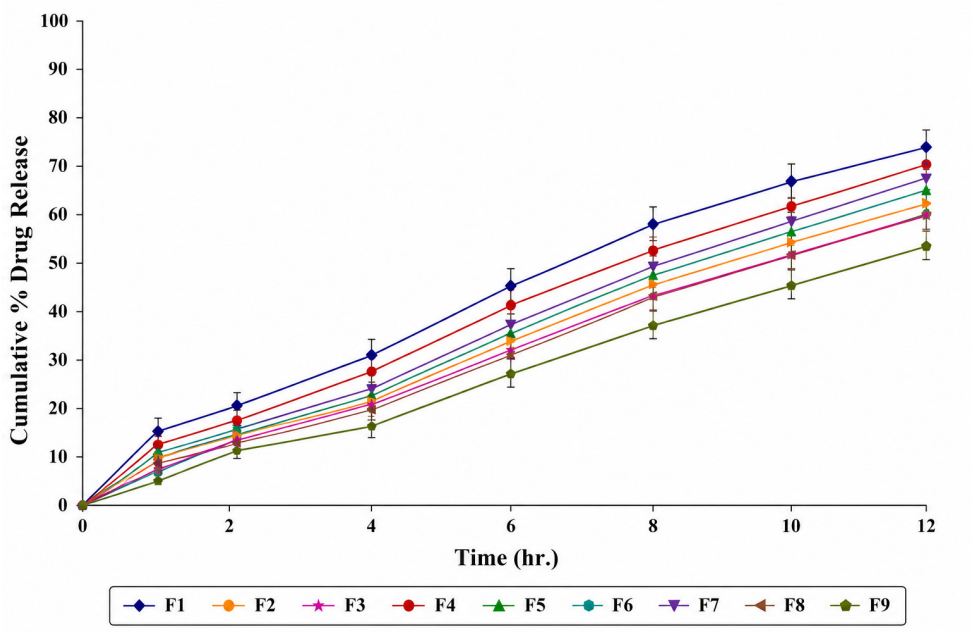


Figure 3: *In vitro* release profiles the polymeric bead formulations. Values are expressed as Mean ± SD (n=3). Drug release studies were performed in triplicate. Statistical analysis was carried out using one-way ANOVA followed by Tukey's *post hoc* test, with $p<0.05$ considered statistically significant.

for extended therapeutic action have been shown to exhibit comparable release characteristics (Pathak *et al.*, 2024). This main feature of the study is thorough characterisation of ZMBP and methodical formulation optimization utilizing response surface approach, which makes it possible to identify the crucial formulation variables affecting drug release. However, the study is limited to *in vitro* characterization, and the absence of *in vivo* pharmacokinetic evaluation, long-term stability studies, and scale-up assessment limits direct clinical translation. Future investigations should therefore focus on *in vivo* bioavailability, toxicity, stability, and industrial manufacturability to establish the therapeutic potential of ZMBP-based delivery systems (Rehman *et al.*, 2024).

Overall, the findings establish ZMBP as a sustainable, biodegradable, and effective natural excipient capable of producing pH-responsive, controlled-release oral formulations. Its high drug entrapment, excellent compatibility with sodium alginate, and sustained release characteristics highlight its potential for developing next-generation oral drug delivery systems, particularly for drugs requiring prolonged therapeutic plasma concentrations.

CONCLUSION

Polysaccharides from *Ziziphus mauritiana* fruit pulp (ZMBP) had great potential to be used as a sustainable natural excipient for controlled release drug delivery system. The high yield (10.7%

w/w), amorphousness, and thermal stability (244-301°C) justified its pharmaceutical applicability. High entrapment efficiency (91.58-98.54%) and drug load were observed for polymeric beads, but the concentration of the polymer significantly affected their swelling capacity and drug release behavior. The beads were pH-sensitive; less swelling was observed in acidic medium, whereas increased swelling was observed in intestine pH, which led to biphasic release pattern with drug release occurring for 12 hr. The drug release followed Korsmeyer-Peppas equation (R^2=0.997-0.999), suggesting anomalous transport by means of diffusion and relaxation of polymer.

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ABBREVIATIONS

AR: Analytical Reagent; **DSC:** Differential Scanning Calorimetry; **DTG:** Differential Thermogravimetric Analysis; **HCl:** Hydrochloric Acid; **PXRD:** Powder X-ray Diffraction; **R^2:** Coefficient of Determination; **RSM:** Response Surface Methodology; **SD:** Standard Deviation; **USP:** United States Pharmacopeia; **XRD:** X-ray Diffraction; **ZMBP:** *Ziziphus mauritiana* Fruit Pulp Polysaccharide.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS CONTRIBUTIONS

Concept- Saptarshi Samajdar; Design - **Baisnabdas Pathak**; Supervision - **Deepshikha Datta**, **Bimal Das**.; Resources - **Baisnabdas Pathak**; Materials - **Baisnabdas Pathak**, **Saptarshi Samajdar**; Data Collection and/or Processing - **Baisnabdas Pathak**, **Saptarshi Samajdar**; Analysis and/or Interpretation - **Baisnabdas Pathak**, **Saptarshi Samajdar**, **Deepshikha Datta**; Literature Search - **Baisnabdas Pathak**; Writing - **Saptarshi Samajdar**.

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