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Research Article

Design And Development of Sustain Release Matrix Tablet Containing Urapidil

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ABSTRACT

The study aimed to develop and evaluate sustained release (SR) matrix tablets of Urapidil to overcome its short half-life and frequent dosing, improving patient compliance in hypertension management. Tablets were prepared using varying concentrations of HPMC K15M, ethyl cellulose, and xanthan gum (F1–F6). Evaluation included pre-and post-compression parameters, swelling index, in-vitro release, release kinetics, and stability. The blends showed good flow properties, and tablets exhibited acceptable hardness (5.9–6.8 kg/cm²), friability (<1%), uniform weight, and drug content (99.18–99.72%). FTIR and DSC confirmed no drug–excipient interactions. The λmax of Urapidil was 269.5 nm with linear calibration (R^2 = 0.9982). Swelling studies showed polymer concentration influenced hydration, with F4 showing maximum swelling (198.2% at 12 h). In-vitro dissolution confirmed sustained release, with F4 releasing 80.26% drug at 12 h and following the Korsmeyer–Peppas model (R^2 = 0.9898). Stability studies showed no significant changes over 3 months.

INTRODUCTION

Sustained release (SR) dosage forms are designed to prolong the therapeutic activity of a drug by releasing it at a controlled, predetermined rate over an extended period. The primary objective of sustained release formulations is to maintain consistent plasma drug concentrations, thereby enhancing therapeutic efficacy and minimizing dosing frequency. In SR systems, the drug release rate is governed by the dosage form itself rather than the body's biological absorption processes. Among various drug delivery routes, the oral route remains the most preferred due to its convenience and patient compliance. However, conventional oral dosage forms often present limitations such as frequent dosing and fluctuating drug levels, which can be effectively addressed using sustained release systems.[1] Sustained release tablets are specifically designed to deliver an initial therapeutically effective dose of the drug,

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followed by a controlled release that maintains effective drug levels in the body over an extended period. These formulations offer several advantages, including prolonged therapeutic effect, reduced dosing frequency, and improved patient compliance. The controlled release of the drug from sustained release tablets is typically achieved using swelling polymers, waxes, or a combination of both, which regulate the drug release rate and ensure consistent delivery over time.[2] Controlled release drug delivery systems not only extend the duration of the drug's effects but also ensure uniform and predictable distribution of the drug throughout the body. It is important to note that while prolonged-release dosage forms maintain a steady drug concentration in the body for a longer duration, they may not necessarily provide regulated or controlled drug release. In contrast, controlled-release systems are specifically designed to release the drug at a predetermined rate, ensuring consistent therapeutic levels over an extended period.[3] Urapidil, an antihypertensive agent acting as a selective α_1-adrenoceptor antagonist and 5-HT_1A agonist, is an ideal candidate for a controlled release formulation. The drug has a short biological half-life of about 2.7–4 hours, requiring multiple daily doses to maintain therapeutic levels, which may reduce patient compliance. A controlled release system helps overcome these limitations by providing prolonged drug release, maintaining steady plasma concentrations, and minimizing fluctuations that may cause side effects or therapeutic gaps.

MATERIALS AND METHODOLOGY

Urapidil was a gift sample from Sirius Pharmaceuticals, Mumbai. HPMC and Ethyl cellulose obtained from Lobo chemie Pvt, Ltd, Mumbai. All others excipients and reagents used were of analytical grades, respectively.

Preformulation Studies

FTIR Study:[4]

FTIR analysis was carried out to determine any possible drug–excipient interactions. The FTIR studies were performed for the pure drug, individual polymers, and the optimized formulation. The samples were prepared using the potassium bromide pellet method and scanned in the wavelength range of 4000–400 cm^{-1} using an IR spectrophotometer.

Standard curve of Urapidil:[5]

A standard solution of Urapidil was prepared by accurately weighing 100 mg of the drug and transferring it to a 100 ml volumetric flask. About 50 ml of 0.1 N HCl was added and mixed until the drug completely dissolved. The volume was then made up to 100 ml with 0.1 N HCl to obtain a stock solution of 1000 µg/ml. From this stock solution, serial dilutions were prepared to obtain concentrations of 2, 4, 6, 8, and 10 µg/ml. The absorbance of these solutions was measured at a wavelength (λmax) of 269.5 nm.

Precompression Parameters

1. Angle of repose:[6]

The angle of repose (θ) is defined as the maximum angle formed between the surface of a powder pile and the horizontal plane. It was determined by the funnel method, in which the powder blend was allowed to flow freely through a funnel to form a conical heap. The height (h) and radius (r) of the pile were measured, and the angle of repose was calculated using the following equation.

$$\theta = \tan\text{-}1(h/r)$$

2. Bulk density & Tapped density:[7]

Bulk and tapped densities were determined using a 10 ml graduated cylinder. A measured quantity of the powder sample was poured into the cylinder, and the initial volume was recorded. The cylinder was then tapped mechanically 100 times, and the final tapped volume was noted. Bulk density and tapped density were calculated using the following formulas.

$$Bulk\ Density = \frac{Mass\ of\ powder}{Volume\ of\ powder\ (Bulk)}$$

$$Tapped\ Density = \frac{Mass\ of\ powder}{Volume\ of\ powder\ (Tapped)}$$

3. Compressibility index:[8]

CI of the powder was determined from the bulk and tapped density as follows,

$$Percentage\ Compressibility\ index = \frac{Tapped\ density - Bulk\ density}{Tapped\ density} \times 100$$

4. Hausner's ratio:

It was calculated as,

$$Hausne's\ ratio = \frac{Tapped\ Density}{Bulk\ Density}$$

Formulation Development of Urapidil Sustain Release Matrix Tablets:

Table 1: Formulation trails of Urapidil Sustain Release Matrix Tablets (F1-F6)

Sl.NO	Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)
1	Urapidil	90	90	90	90	90	90
2	HPMC K15 M	50	50	50	100	100	100
3	Ethyle Cellulose	50	75	100	50	75	100
5	Xanthan gum	-	-	-	20	20	20
6	Microcrystalline Cellulose	140	115	90	70	45	20
7	Polyvinyl Pyrrolidone K30	10	10	10	10	10	10
8	Magnesium striates	5	5	5	5	5	5
9	Talc	5	5	5	5	5	5
	Total weight in mg	350	350	350	350	350	350

Sustained release matrix tablets of Urapidil were formulated using the wet granulation method. The concentrations of all ingredients were optimized based on preliminary trial batches. Accurately weighed quantities of each component [Table 1] were taken, and the drug was thoroughly mixed with the polymers and other excipients, excluding talc and magnesium stearate, in ascending order of their weight. The mixture was blended for 20 minutes to ensure uniform drug distribution. Subsequently, magnesium stearate was added and mixed for not more than one minute to provide adequate lubrication. Approximately 350 mg of the final blend was accurately weighed and compressed into tablets using 12 mm flat-faced punches on a single-punch tablet compression machine.

Post-Compression Evaluation

1. Weight variation test:[9]

Twenty tablets were randomly selected and individually weighed to determine the average tablet weight. The differences between each tablet's weight and the mean weight were then compared.

2. Thickness:

The thickness of the tablets was measured using a vernier calliper. Tablet thickness was maintained within a ±5% variation from the standard value. The measured thickness values were expressed in millimetres.

3. Hardness test:[10]

A tablet was placed between the two anvils of a Monsanto-type hardness tester, and force was gradually applied until the tablet fractured. The applied force at the point of breakage was recorded as the crushing strength.

4. Content uniformity:[11]

The drug content of each tablet formulation was determined by placing the tablets in a beaker containing 100 ml of 0.1N HCl. After 24 hours, or once complete drug release was achieved, 1 ml of the solution was withdrawn, diluted to 10 ml with 0.1N HCl, and analyzed for absorbance at 269.5 nm using a UV spectrophotometer. The amount of drug released was calculated with reference to the standard calibration curve.

5. Friability:[12]

Twenty tablets were accurately weighed and placed in a Roche friabilator, where they were subjected to rolling and repeated impacts due to free falls within the chamber. After completing 100 revolutions, the tablets were reweighed, and friability was expressed as the percentage weight loss. A weight loss of 0.5% to 1% or less is generally considered acceptable.

6. Swelling Index:[13]

A 0.1 N HCl solution with a pH of 1.2 was used to determine the swelling index of the tablets at room temperature. The weight of the tablets after swelling was recorded at predetermined time intervals, and the swelling index was calculated using the following equation.

$$\text{Swelling Index} = \frac{Wt - W0}{W0}$$

Where, W0= initial weight of tablet, Wt = weight of the tablet in t (time)

7. *In-vitro* dissolution study:[14]

Urapidil sustained release matrix tablets were evaluated for in vitro drug release using a dissolution apparatus containing 900 ml of 0.1 N HCl as the medium for the first 2 hours, maintained at 37 °C and stirred at 50 rpm using a paddle. After 2 hours, the medium was replaced with 900 ml of freshly prepared pH 6.8 phosphate buffer for the remaining duration of the study. At predetermined time intervals of 0.5, 1, 2, 4, 6, 8, 10, and 12 hours, 10 ml of the dissolution medium was withdrawn and immediately replenished with an equal volume of fresh medium (either 0.1 N HCl or pH 6.8 phosphate buffer). The collected samples were analyzed spectrophotometrically at 269.5 nm using a UV spectrophotometer.

8. *In-vitro* drug release kinetics: [15,16,17]

Drug release kinetics were evaluated by fitting the data to various mathematical models, including Zero-order, First-order, Higuchi, and Korsmeyer-Peppas equations. The model with the highest correlation coefficient (R) and suitable release rate constant (k) was considered the best fit to describe the release mechanism of sustained release matrix tablets containing HPMC K15M, Ethylcellulose, and Xanthan gum.

9. Stability Studies:[18]

The optimized formulation was packed in aluminium pouches and subjected to accelerated stability studies at 40 ± 2 °C and 75% RH for three

months. Samples were withdrawn at predetermined time intervals and evaluated for drug content and *in vitro* drug release.

RESULTS AND DISCUSSION

FTIR studies:

FT-IR spectroscopy was employed to evaluate the compatibility between Urapidil and the polymers incorporated into the formulation. Comparative analysis of the FT-IR spectra for both the pure drug and the formulated tablets (as presented in Figures 1–4) demonstrated that the characteristic absorption peaks of Urapidil remained unchanged following formulation. This finding confirms the absence of significant chemical interactions between Urapidil and the selected polymers.

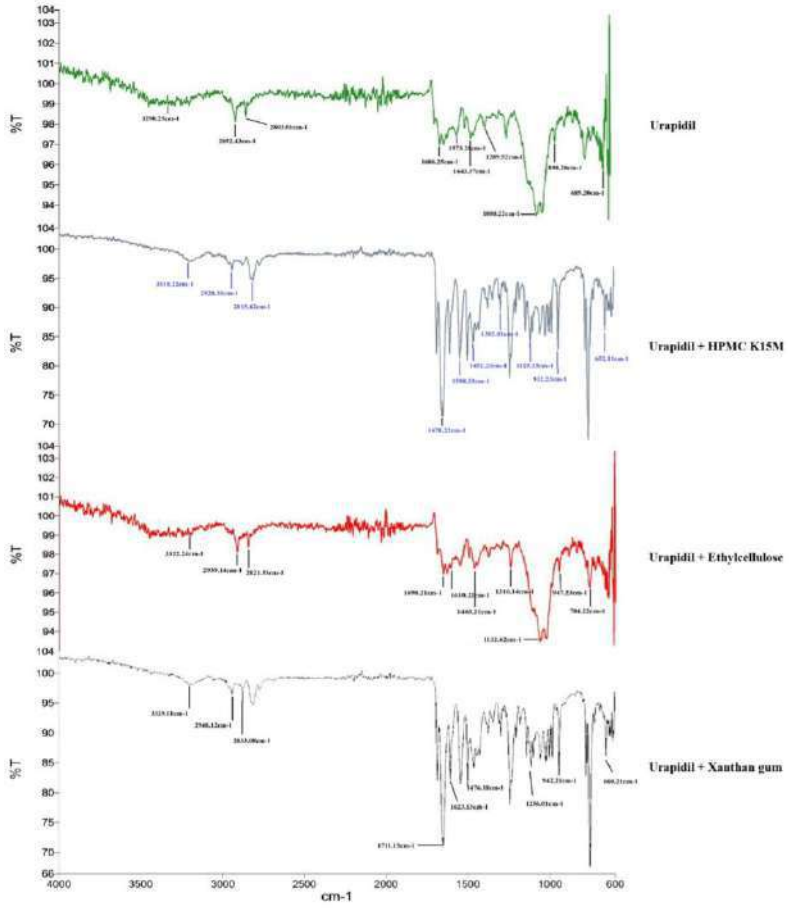

Figure 1: FTIR Spectra of Urapidil, HPMC K15M, Ethylcellulose and Xanthan gum.

Table 2: FTIR absorption spectra of different functional groups of drug and drug polymer mixture.

Sl. No	Functional group	Drug (cm^{-1})	Physical mixture (drug + polymer)		
			Drug + HPMC K15 M	Drug + Ethyle cellulose	Drug + Xanthan gum
1	Acid O-H stretching	3290.25	3310.32	3322.24	3329.11
2	C-H stretching	2892.43	2928.31	2939.14	2948.12
3	C=O stretching	2803.01	2815.42	2821.53	2833.08
4	C=C stretching	1686.25	1678.22	1690.21	1711.13
5	C-N stretching	1573.28	1598.33	1610.22	1623.16
6	C-O stretching	1443.37	1452.23	1465.21	1476.18

DSC studies:

The DSC analysis revealed that no interaction occurred between the drug and the polymers. The pure drug exhibited an endothermic peak at 169.01°C, and the physical mixtures with all polymers showed no significant deviation in the melting endotherms.

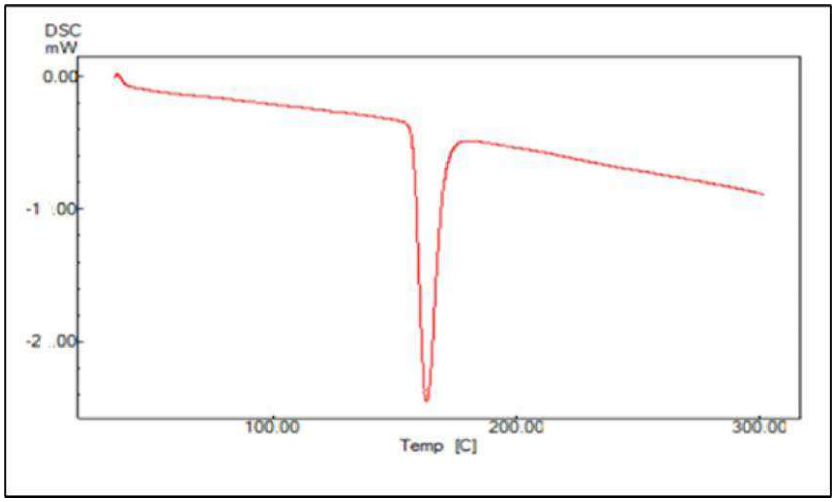

Figure 2: DSC of Urapidil

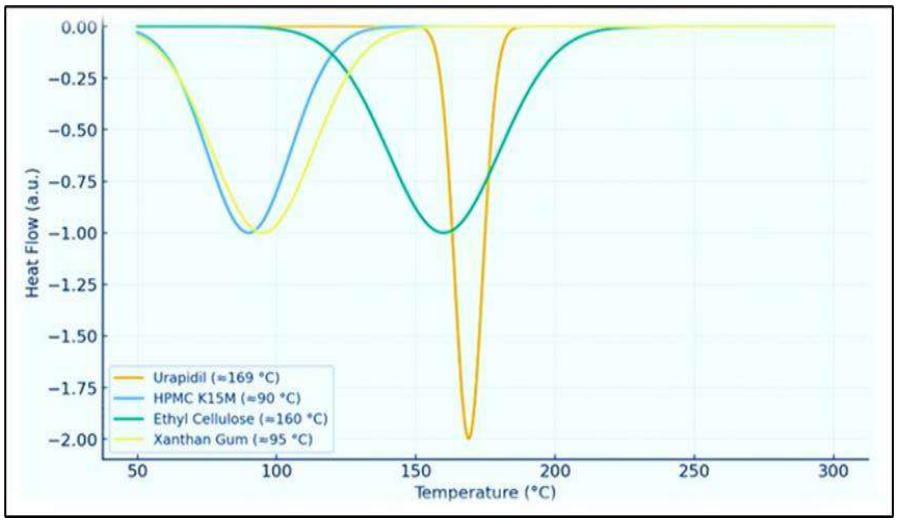

Figure 3: DSC of Urapidil, HPMC K15M, Ethylcellulose and Xanthan gum

Standard graph of Urapidil:

Standard calibration curve of Urapidil was drawn by plotting absorbance v/s concentrarion. The λmax of Urapidil in 0.1N HCl was found to be 269.5 nm. The absorbence values are tabulated in Table 3. It was found that the solution of Urapidil in 0.1N HCL shows linearity (R^2= 0.9982) in absorbance at concentration of 2-10(µg/ml) and obey Beer Lamberts Law.

Table 3: Standard plot of Urapidil

Concentration(µg/mL)	Absorbance
0	0
2	0.146±0.002
4	0.265±0.001
6	0.378±0.002
8	0.498±0.003
10	0.611±0.001

All values represented as mean ± standard deviation (n=3)

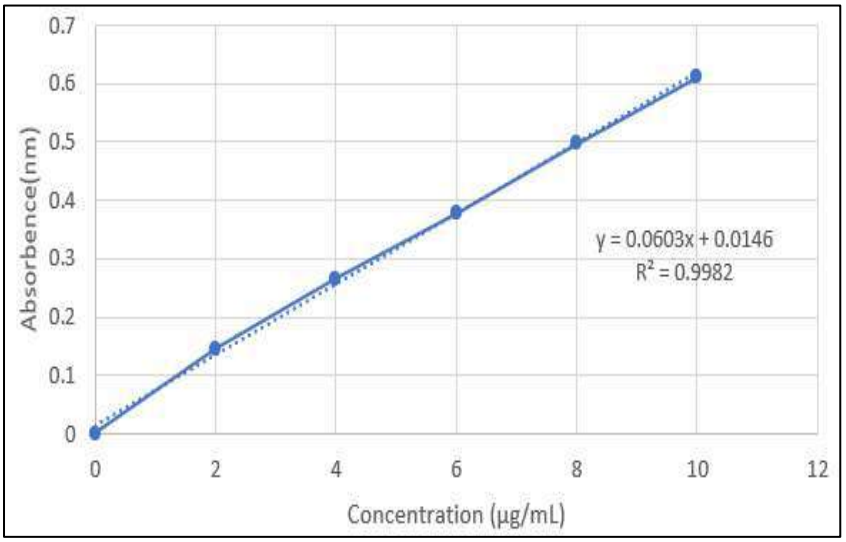

Figure 4: Standard Calibration curve of Urapidil

Precompression parameters of powder blends:

The prepared powder blend of all formulations was evaluated for pre-compression parameters such as angle of repose, bulk density, tapped density, compressibility index, and Hausner's ratio after the addition of glidants.The results have shown in table 4.

Table 4: Characteristics of final blend of Urapidil Sustain Release Matrix tablets.

Formulations code	Angle of repose (θ)	Bulk density (g/ml)	Tapped density (g/ml)	Compressibility index (%)	Hausner's ratio
F1	22.12^0±0.14	0.516 ± 0.16	0.481 ± 0.14	12.32 ± 0.21	1.08 ± 0.11
F2	24.16^0±0.11	0.481 ± 0.13	0.502 ± 0.03	16.14 ± 0.12	1.12 ± 0.10
F3	23.25^0±0.22	0.519 ± 0.05	0.499 ± 0.06	13.21 ± 0.33	1.15 ± 0.16
F4	25.70^0±0.16	0.483 ± 0.05	0.522 ± 0.14	14.32 ± 0.16	1.10 ± 0.10
F5	23.31^0±0.14	0.591 ± 0.14	0.478 ± 0.16	12.22 ± 0.18	1.11 ± 0.15
F6	26.21^0±0.12	0.531 ± 0.16	0.517 ± 0.03	17.53± 0.32	1.18 ± 0.18

All values represented as mean ± standard deviation (n=3)

During pre-compression studies, all formulations demonstrated flow properties that met IP standards, as evidenced by an angle of repose ranging from 22.120 ± 0.14 to 26.210 ± 0.12, confirming the satisfactory flowability of the powder blend. Bulk density values varied from 0.481 ± 0.13 to 0.591 ± 0.14 g/mL, while tapped density ranged from 0.478 ± 0.16 to 0.522 ± 0.14 g/mL. Additionally, the compressibility index was between 12.22 ± 0.18% and 17.53 ± 0.32%, and Hausner's ratio was observed from 1.08 ± 0.11 to 1.18 ± 0.18, all within acceptable limits.

Post - Compression Evaluation:

The prepared sustain released matrix tablets were evaluated for Average weight variation, Hardness, Friability, Drug content and Thickness, all the studies were performed. The results have shown in the table 5.

Table 5: Post compression of Urapidil Sustain release matrix

Formulations code	Average weight (mg)	Hardness (kg)	Friability (%)	Drug content (%)	Thickness (mm)
F1	350.1± 0.11	5.9± 0.12	0.62± 0.17	99.18± 0.13	3.25± 0.05

F2	349.2± 0.31	6.1± 0.15	0.69± 0.19	99.65± 0.19	3.30± 0.04
F3	350.4± 0.24	5.9± 0.19	0.65± 0.22	99.26± 0.17	3.35± 0.06
F4	350.3± 0.18	6.8± 0.14	0.59± 0.15	99.34± 0.25	3.42± 0.05
F5	350.9± 0.21	6.1± 0.20	0.72± 0.14	99.72± 0.11	3.56± 0.04
F6	350.5± 0.31	6.6± 0.19	0.58± 0.16	99.21± 0.18	3.60± 0.05

All values represented as mean ± standard deviation (n=3)

In the post-compression evaluation, all formulations complied with the specified limits of the Indian Pharmacopoeia (IP), with tablet weights ranging from 349.2 ± 0.13 to 350.9 ± 0.12 (within 5% variation), hardness between 5.9 ± 0.12 and 6.8 ± 0.14 (increasing with polymer concentration due to improved cohesiveness), friability from 0.58 ± 0.16 to 0.72 ± 0.14 (within limits), drug content from 99.18 ± 0.13% to 99.72 ± 0.11% (permissible range), and thickness from 3.25 ± 0.05 mm to 3.60 ± 0.05 mm (uniform across formulations).

Swelling Index:

The Percentage swelling index of all formulations results were given in table 6 and graphically shown in Figure 6.

Table 6: Swelling index (%) of Formulations

Time(hrs)	Formulations					
	F1	F2	F3	F4	F5	F6
0.5	18.2± 0.4	16.3± 0.5	12.4± 0.5	32.5± 0.2	28.20±0.3	24.30± 0.4
1	32.3± 0.3	29.8± 0.3	25.9± 0.3	50.3± 0.4	42.71± 0.5	38.20± 0.5
2	46.5± .0.2	41.6± 0.1	38.7± 0.4	78.9± 0.6	67.22± 0.7	55.26± 0.2
4	57.4± 0.5	53.2± 0.2	49.3± 0.7	99.8± 0.1	80.36±0.9	72.34± 0.6
6	72.8± 0.2	69.5± 0.4	65.8± 0.2	120.3± 0.3	97.20± 0.4	89.24± 0.3
8	89.5± 0.1	83.6± 0.2	79.7± 0.3	165.7± 0.2	115.10± 0.2	99.34± 0.2
10	98.2± 0.3	94.7± 0.6	90.8± 0.6	172.5± 0.5	134.22± 0.6	119.25± 0.7
12	110.5± 0.2	105.8± 0.3	102.8± 07	198.2± 0.7	172.32± 0.8	158.25±0.8

All values represented as mean ± standard deviation (n=3)

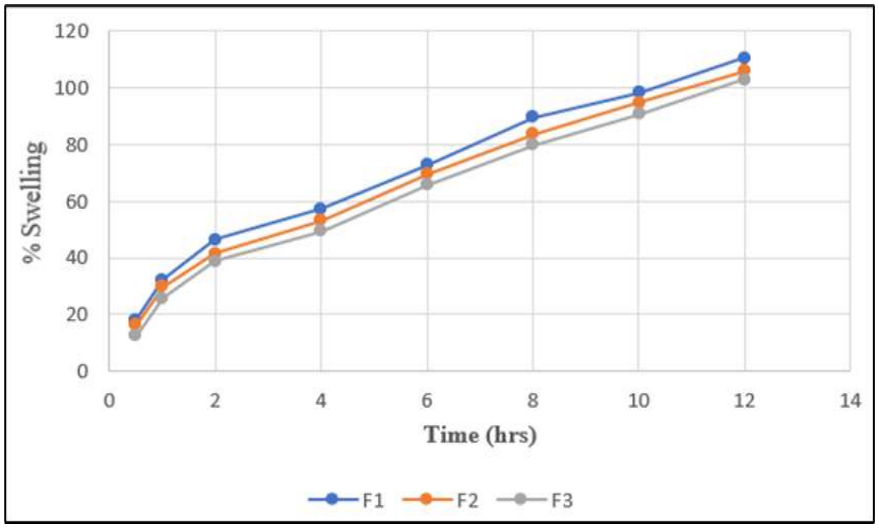

Figure 5: Swelling Index % of Formulations F1-F3

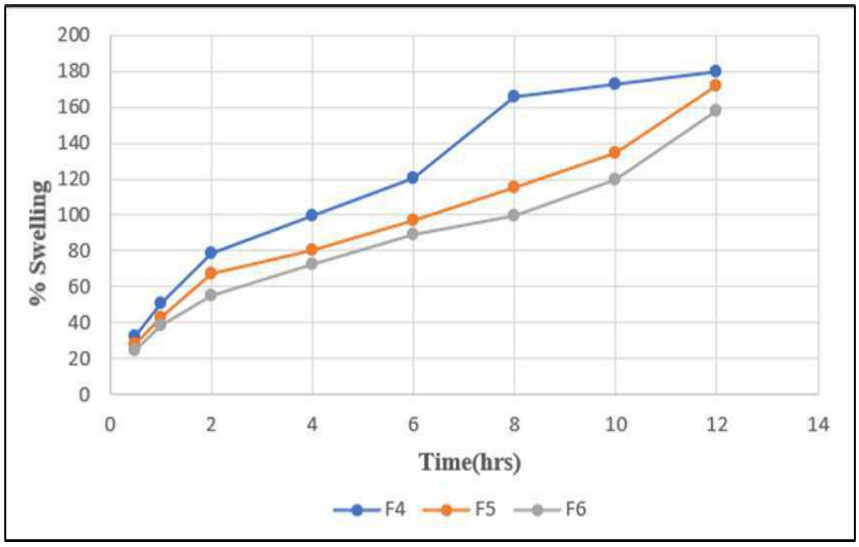

Figure 6: Swelling Index % of Formulations F4-F6

The swelling index of all formulations was evaluated in 0.1N HCl. The results are presented in the table, showing variation among the formulations. Tablets containing HPMC K15M (F4) exhibited the highest swelling at 12 hours, with a sharp rise up to 8 hours. This may be attributed to the higher concentration of HPMC K15M, which retains water and forms a thick swollen matrix.

In-vitro drug release studies

In-vitro drug release studies were performed using a USP type II dissolution apparatus operated at 50 rpm. The dissolution medium consisted of 900 mL of 0.1 N HCl (pH 1.2), maintained at 37.5 °C. Samples were withdrawn at predetermined time intervals, and the amount of drug released was analysed using a UV–Visible spectrophotometer at 269.5nm.

Table 7*: In-vitro* dissolution test of Urapidil sustain release matrix tablet.

Time (hrs)	Formulations					
	F1	F2	F3	F4	F5	F6
0.5	13.20± 0.3	11.32± 0.4	8.93± 0.5	6.53 ± 0.2	5.50± 0.3	4.23± 0.1
1.0	20.80± 0.5	18.42± 0.5	13.96± 0.7	16.14± 0.6	11.62± 0.7	9.21± 0.7
2.0	33.40± 0.1	29.55± 0.7	24.33± 0.4	27.59± 0.5	18.81± 0.2	12.01± 0.4
4.0	48.10± 0.2	38.66± 0.2	33.41± 0.2	39.70± 0.1	27.86± 0.4	21.10± 0.5
6.0	63.80± 0.3	52.37± 0.3	47.23± 0.6	48.64± 0.4	36.71± 0.6	32.15± 0.3
8.0	76.20± 0.8	65.28± 0.6	59.23± 0.1	61.08± 0.7	52.20± 0.5	41.30± 0.2
10.0	87.10± 0.2	79.38± 0.1	69.32± 0.3	71.54± 0.3	68.32± 0.7	53.20± 0.3
12.0	92.86±0.4	82.26± 0.8	78.31± 0.8	80.26± 0.3	73.36± 0.8	69.24± 0.8

All values represented as mean ± standard deviation (n=3)

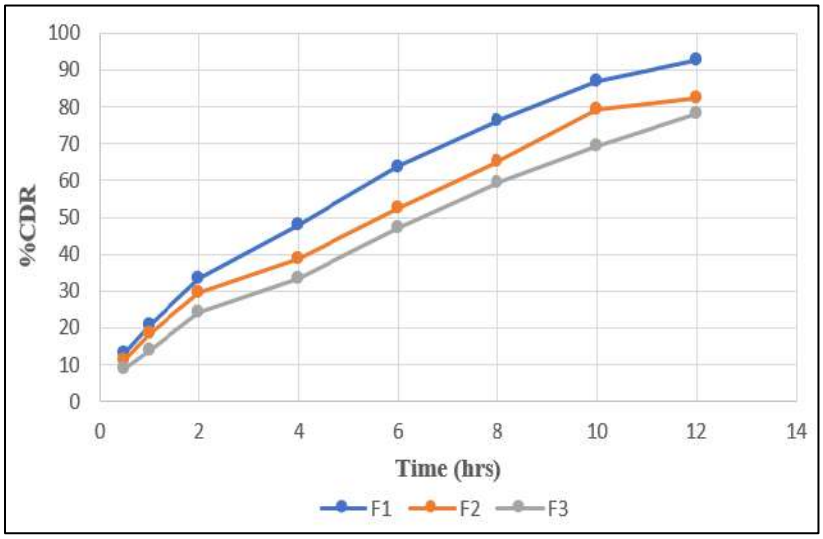

Figure 7: *In-vitro* dissolution profile of F1 to F3 Formulations

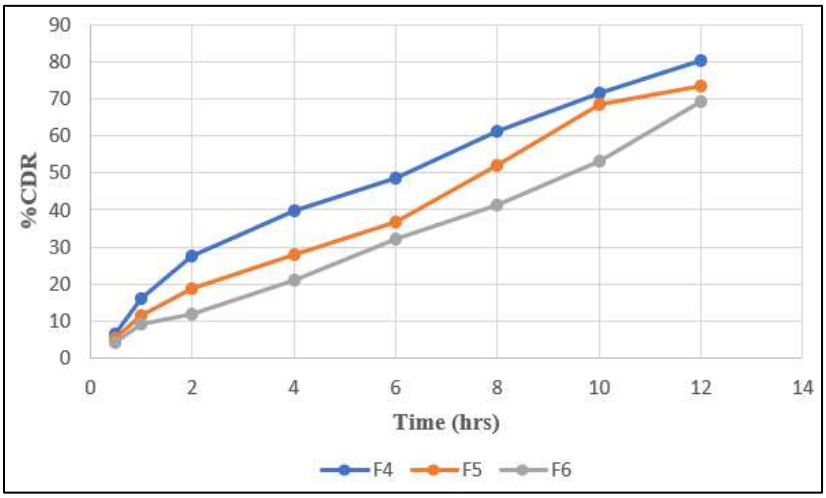

Figure 8: *In-vitro* dissolution profile of F4 to F6 Formulations

The *in-vitro* drug release study of formulations F1–F6 revealed sustained release over 12 hours, with variations influenced by polymer concentration and composition. Formulation F1 showed the fastest release (92.86% in 12 hours) due to lower polymer content, while F2 and F3 exhibited moderate release (82.26% and 78.31%), indicating improved retardation with increased polymer levels. F4 demonstrated controlled and uniform release (80.26%), balancing drug diffusion and polymer swelling. In contrast, F5 and F6 showed slower release (73.36% and 69.24%) due to thicker gel formation from higher HPMC K15M. Thus, F4 was optimized, confirming polymer concentration's key role in drug release control.The results are shown in table 7.

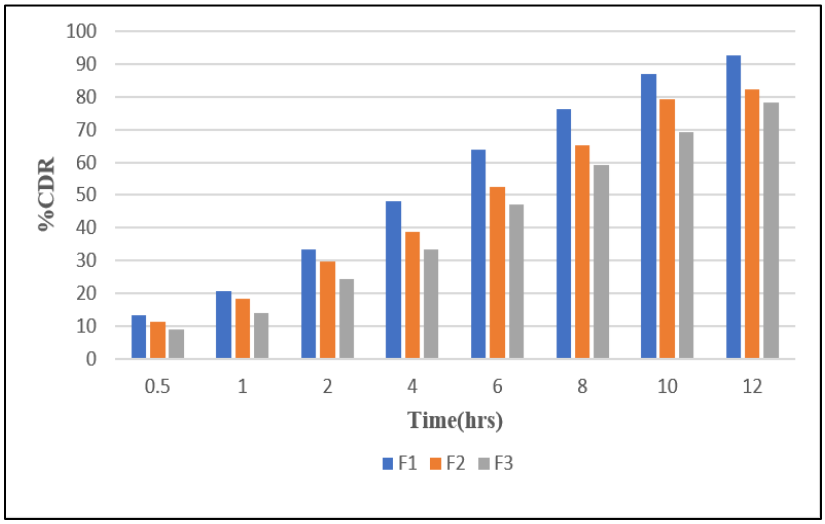

Figure 9: Graphical depiction of *In-vitro* drug release profile for F1-F3 formulations.

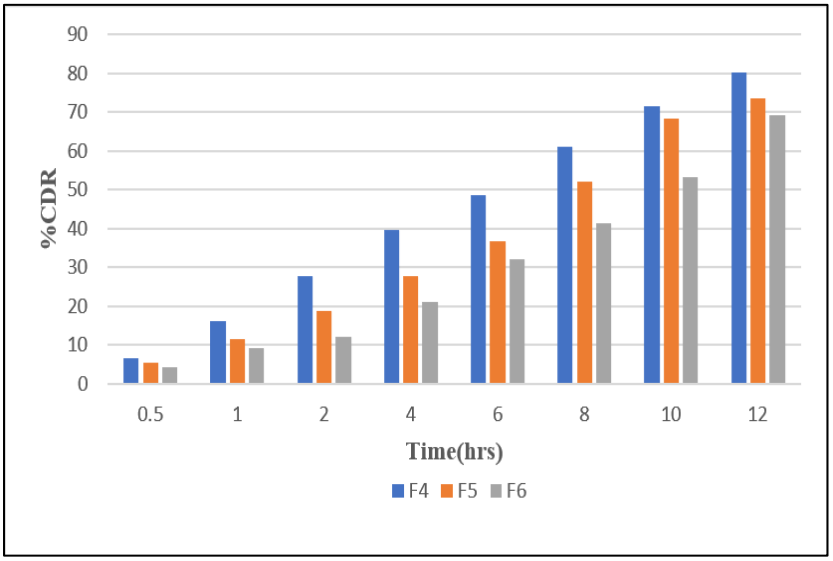

Figure 10: Graphical depiction of *In-vitro* drug release profile for F4-F6 formulations

Drug release kinetics

The in vitro release data of the sustained release matrix tablets were fitted to various mathematical models to analyze drug release kinetics. The most suitable model was identified based on the highest regression coefficient (R^2) value, with $R^2 = 1$ indicating linear, constant release over time. Formulation F4 showed the highest R^2 (0.989) in the Korsmeyer-Peppas model, indicating that drug release occurs through a polymeric network. This confirms that the optimized formulation follows Korsmeyer-Peppas kinetics, as shown in the corresponding release plots.

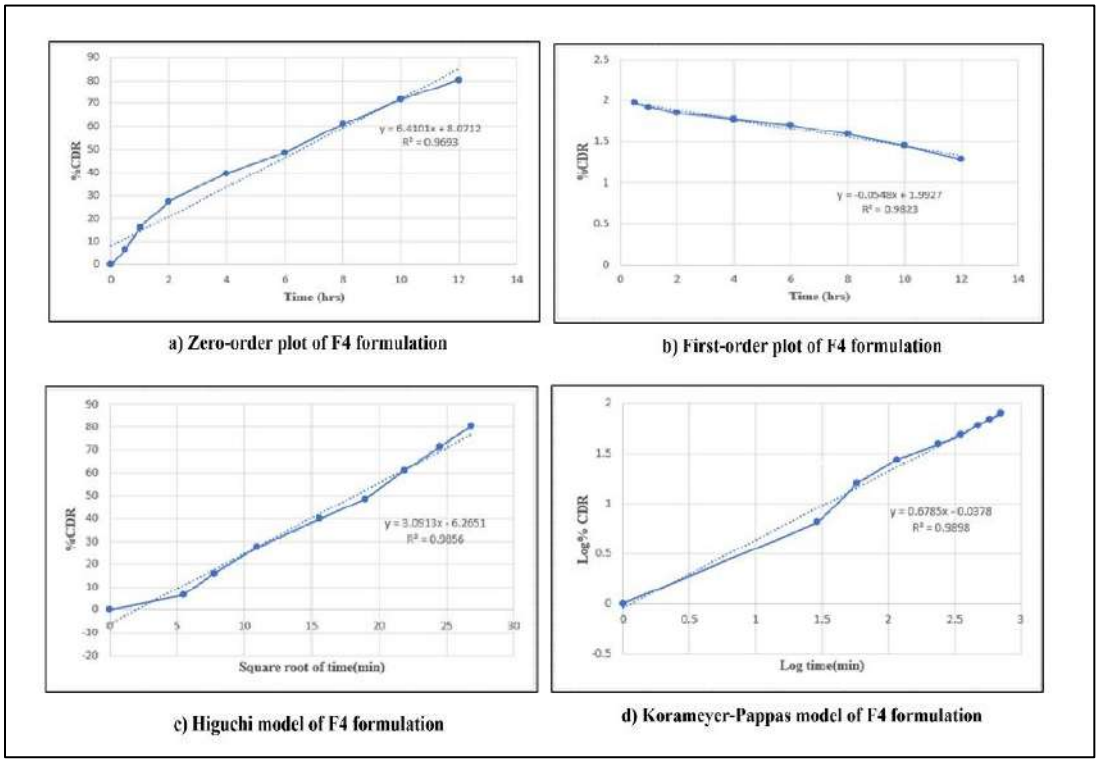

Figure 11: Graphical representation of in-vitro drug release kinetics of F4 formulation

Table 15: Drug release kinetics data for F4

Formulation	Correlation Coefficient (R^2)			
	Zero order	First order	Higuchi	Kores Meyer's -Peppas
F4	0.9693	0.9823	0.9856	0.9898

Stability Studies:

Accelerated stability studies were performed on the optimized formulation (F3) at 40 °C ± 2 °C and 75% ± 5% RH for three months, following ICH guidelines. Drug content and in vitro drug release were assessed at monthly intervals. The results (Table) showed no significant changes in either parameter throughout the study period, indicating that the optimized formulation remained stable under the tested conditions.

Table 16: Stability studies with optimized Formulation

Trial	Drug Content (%)	In-vitro Drug release (%)
0	99.21± 0.2	80.26± 0.3
1st Month	99.13± 0.3	80.18± 0.4
2nd Month	99.08± 0.4	80.14± 0.9
3rd Month	99.04± 0.2	80.09± 0.5

All values represented as mean ± standard deviation (n=3)

CONCLUSION

The study successfully developed sustained release matrix tablets of Urapidil using a combination of hydrophilic and hydrophobic polymers. FTIR and DSC analyses confirmed the absence of drug–excipient interactions, while all formulations exhibited satisfactory micromeritic and mechanical properties. The results showed polymer concentration-dependent swelling and drug release behavior, with HPMC K15M identified as the key sustaining polymer. Formulation F4 was optimized, showing controlled release (80.26% in 12 hours) following Korsmeyer–Peppas kinetics and stability under accelerated conditions. Thus, HPMC K15M-based

Urapidil tablets effectively prolonged drug release, reduced dosing frequency, enhanced patient compliance, and demonstrated potential for scale-up and clinical application.

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