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Research Article

In Vitro Design and Evaluation of Sustained Release Matrix Tablets Containing Prazosin

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ABSTRACT

The present investigation aimed to formulate and develop sustained-release tablets of Prazosin hydrochloride using the direct compression technique. Various polymers, including xanthan gum, HPMC K4M, and HPMC K100M, were employed to design nine formulations. Pre-compression and post-compression parameters were evaluated and found to be within pharmacopoeial limits. In vitro drug release studies were conducted for all formulations, among which formulation F-IX exhibited sustained drug release up to 24 hours. Further in vitro release studies of the optimized formulation were performed in phosphate buffer (pH 7.4) under varying conditions such as different concentrations of sodium lauryl sulfate (SLS), agitation speeds, and dissolution media. Optimal release conditions were observed with 1.5% SLS concentration, an agitation speed of 100 rpm, and a dissolution medium volume of 500 mL. Accelerated stability studies indicated that formulation F-IX remained stable for one month. Release kinetics analysis revealed that the optimized formulation followed the Korsmeyer–Peppas model, indicating a non-Fickian diffusion mechanism. Swelling studies further supported the sustained-release behavior of formulation F-IX.

KEYWORDS

Prazosin hydrochloride, Sustained release, Matrix tablet, In vitro release, Stability studies, Percentage of swelling.

Introduction

Oral ingestion is the traditionally preferred route of drug administration, providing a convenient method of effectively achieving both local and systemic effects [1]. In conventional oral drug delivery systems, there is very little control over release of the drug [2]. The effective concentration at the target site can be achieved by intermittent administration of grossly excessive doses [3]. Which in most situations, often results in constantly changing, unpredictable and often sub-or-supra therapeutic plasma concentrations leading to marked side effects [4]. Some limitations associated with such a conventional dosage form like, poor patient compliance, increased chances of missing the dose of a drug with short half-life for which frequent administration is necessary [5]. A typical peak plasma concentration time profile is obtained which makes reaching of steady state condition difficult [6]. The unavoidable fluctuation in the drug concentration may lead to under medication or over medication as the steady state concentration values fall or rise beyond the therapeutic range [7]. To overcome all this, it would be advantageous and more convenient to maintain the dosing frequency to once, or at most

twice-daily [8]. An appropriately designed sustained release dosage form can be a major advance in this direction compared to conventional immediate release dosage forms [9]. The development of improved method of drug delivery has received a lot of attention in the last two decades [10]. This technique for the drug administration is termed 'sustained release' or 'controlled release'. It is based on the concept of implanting into the body, a reservoir of a drug contained in a special biodegradable polymeric carrier material [11]. The overall objective is that, once the drug/carrier material has been injected, or otherwise implanted or taken orally into the body, the drug is released at some predetermined rate for some desired period of time [12]. In the last few years controlled release dosage forms have made significant progress in terms of clinical efficacy and patient compliance [13]. The objective of designing a controlled release system is to deliver drug at a rate necessary to achieve and maintain a constant drug blood level [14]. Moreover, these dosage forms have been specially designed to release the drug slowly over several hours, to protect the drug from the low pH of the stomach, and/or to protect the stomach from the irritating effects of the drug. Key advantages to the use of this technology are prolonged activity, fewer doses, fewer side effects and reduced toxicity. Moreover, much of medicine ingested or injected all at once in order to have a maintenance concentration can mean wasted material or toxic side effects. By decreasing the dose rate, it is possible to avoid these problems and to find a better efficacy results. A major task of the controlled release scientist is to determine the best speed of release to obtain optimal performance. Introduction of matrix tablet as sustained release dosage form has given a new breakthrough for novel drug delivery system in the field of pharmaceutical technology [15]. It excludes complex production procedures such as coating and pelletization during manufacturing and drug release rate from the dosage form is controlled mainly by the type and proportion of polymer used in the preparations [16]. The use of polymeric matrix devices to control the release of a variety of therapeutic agents has become increasingly important in the development of modified release dosage forms [17]. A matrix device is a drug delivery system in which the drug is dispersed either molecularly or in particulate form within a polymeric network [18]. The device may be a swellable hydrophilic monolithic system, an erosion-controlled monolithic system or a non-erodible system. In particular; the interest awakened by matrix type deliveries is completely justified in view of their biopharmaceutical and pharmacokinetics advantages over the conventional dosage forms [19]. Hypertension, also referred to as high blood pressure, is a medical condition in which the blood pressure is chronically elevated. Hypertension can be classified either as essential (primary) or secondary [20]. Essential hypertension indicates that no specific medical cause can be found to explain a patient's condition. Secondary hypertension indicates that the high blood pressure is a result of another condition, such as kidney disease or tumors. Medications that bind alpha adrenergic receptors and decrease the workload of the heart and lower blood pressure are known as alpha blockers [21]. They are commonly used to treat hypertension, peripheral vascular disease, and hyperplasia. Alpha1-adrenergic blockers are drugs that work by blocking the alpha1-receptors of vascular smooth muscle, thus preventing the uptake of catecholamines by the smooth muscle cells [22]. This causes vasodilation and allows blood to flow more easily [23]. These drugs, like alpha blockers are used for two main purposes to treat hypertension and to treat benign prostatic hyperplasia, a condition that affects men and is characterized by an enlarged prostate gland [24]. Commonly prescribed alpha blockers for hypertension and benign prostatic hyperplasia include doxazosin (Cardura), Prazosin (Minipress) and terazosin (Hytrin). Prazosin is also used in the treatment of congestive heart failure [25]. The main objective behind present study is to develop oral sustained release formulations based on hydrophilic monolithic matrices-hydrogels drug delivery system which provides therapy for the treatment of hypertension [26]. In the present studies, efforts were made to develop a sustained release formulation of Prazosin hydrochloride for treatment of hypertension. It has a half-life of 2-3 hours. Its daily oral dose is 20 mg/day in divided doses. Absorption of the Prazosin hydrochloride is in the GI tract and its bioavailability is 50-85%. Hence Prazosin hydrochloride is selected for matrix drug delivery system. Thus, Prazosin hydrochloride is suitable drug candidate for developing sustained release dosage form. Prazosin hydrochloride is available in the market as an extended release dosage form tablets in the form of osmotic pump system, which requires sophisticated facilities for the manufacture, complexity of the process, large quantity of excipients, and altogether making the formulation costly [27]. So, it was challenge to develop matrix tablets using simpler methods and cheaper excipients, which altogether reduces the cost of the tablets.

Materials and Methods

Materials

Prazosin hydrochloride, xanthan gum, ethyl cellulose, guar gum, hydroxy propyl methyl cellulose (HPMCK) 4M, HPMCK100, poly vinyl pyrrolidone, dibasic calcium phosphate, microcrystalline cellulose, magnesium stearate, aerosil are obtained as a gift samples from NATCO Pharma. Pvt .Ltd, Hyderabad.

Methodology

Analytical Methods

Prazosin HCl standard stock (100 µg/mL) in 0.1 N HCl

A standard stock solution of Prazosin hydrochloride was prepared by dissolving accurately weighed 10 mg of Prazosin hydrochloride in 0.1 N HCl solution in a 100 ml volumetric flask and the volume was made up to 100 ml with 0.1 N HCl solution to obtain a stock solution of 100 µg/ml [28].

Calibration curve of Prazosin hydrochloride in 0.1 N HCl

Accurately weighed quantity of Prazosin hydrochloride (10 mg) was dissolved in little quantity of 0.1 N HCl solution and volume was made up to 100 ml [29]. Appropriate aliquots were taken into different volumetric flasks and volume was made up to 10 ml with 0.1 N HCl solution so as to get drug concentrations of 5, 10, 15, 20, 25, and 30 µg/ml [30]. The absorbance of these drug solutions were estimated at λ_{max} 330.4 nm.

Prazosin HCl standard stock (100 µg/mL) in Phosphate Buffer Solution, (PBS) pH 7.4

A standard stock solution of Prazosin hydrochloride was prepared by dissolving accurately weighed 10 mg of Prazosin hydrochloride in phosphate buffer solution, pH 7.4 in 100 ml volumetric flask. The volume was made up to 100 ml with phosphate buffer solution, pH 7.4 to obtain a stock solution of 100 µg/ml [31].

Calibration curve of Prazosin hydrochloride in PBS pH 7.4

Accurately weighed quantity of Prazosin hydrochloride (10 mg) was dissolved in little quantity of phosphate buffer solution, pH 7.4 and volume was made up to 100 ml [28]. Appropriate aliquots were taken into different volumetric flasks and made up to 10 ml with phosphate buffer solution, pH 7.4, so as to get drug concentrations of 5 to 35 µg/ml [32]. The absorbance of these drug solutions were estimated at λ_{max} 340.4 nm.

Preformulation Studies

Organoleptic studies of pure drugs (color, odour and taste)

In this study pure drug (Prazosin hydrochloride) has been checked for its organoleptic properties such as taste, color, and odour [33].

Melting point determination

The melting point of pure drug (Prazosin hydrochloride) was determined by using open capillary method. The drug was filled into capillary tube whose one end was fused. The filled capillary tube was placed in electrical melting point apparatus. Temperature was raised slowly. The temperature at which the drug melted was recorded as the melting point. The procedure is repeated thrice [34].

Fourier Transform Infrared Spectroscopy (FTIR)

The pure Prazosin hydrochloride and polymers were subjected to IR studies alone and in combination. The ingredients which are to be use in the preparation of tablets are subjected to IR studies. Three mg quantities of pure drug/pure polymer/ and in combination of drug-polymer were mixed with potassium bromide. The mixtures were then placed in the sample holder of the instrument. These were analyzed by FTIR to study the interference of polymer with drug [35].

Manufacture of Prazosin hydrochloride tablets

The sustained release matrix tablets of Prazosin HCl were prepared using the ingredients shown in the Table 1. The direct compression technique was followed to manufacture the Prazosin hydrochloride tablets. Round shaped punches (6 mm) with concave faces were used for the compression on Rimek machine. The drug and the excipients were passed through the # 40-sieve except magnesium stearate which was passed through # 60-sieve. The weighed quantities of ingredients were mixed in polythene bag for 30 minutes to get uniform blend [27]. The blend was then lubricated by adding the required quantity of magnesium stearate. The powder blend was then finally compressed.

Pre-Compression Paarmeters

Angle of repose

The angle of repose of the tablet blends were determined by the funnel method (Reposogram). Accurately weighed drug or tablet blend was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of the powder blend [36]. The powder was allowed to flow through the funnel freely onto the surface. The diameter of the powder blend cone was measured and angle of repose was calculated using the following equation.

$\tan \theta = h/r$

where *h* and *r* are the height and radius of the powder blend cone, respectively.

Bulk density

Loose bulk density (LBD) and tapped bulk density (TBD) were determined. Prazosin hydrochloride was passed through 18-mesh sieve to break the clumps, if any. Accurately weighed 100 g of the drug mixture was placed in a 100 ml graduated measuring cylinder. Initial volume was observed. The cylinder was tapped initially 500 times from a distance of 14±2 mm. The tapped volume (V_a) was measured to the nearest graduated unit. The tapping was repeated additional 750 times. Again, the tap volume was measured to the

Table 1: Formulations of Prazosin hydrochloride tablets.

Ingredients (mg)	F-I	F-II	F-III	F-IV`	F-V	F-VI	F-VII	F-VIII	F-IX
Prazosin hydrochloride	5	5	5	5	5	5	5	5	5
Xanthan gum	30	40	50	40	50	15		-	-
Ethyl cellulose	-	-	-	10	10	-	-	-	-
Guar gum	-	-	-	-	-	35	-	-	-
HPMCK4M	-	-	-	-	-	-	40	-	-
HPMCK100M	-	-	-	-	-	-	-	40	35
Poly vinyl pyrrolidone (PVP)	-	-	-	-	-	2	2	-	-
Dibasic calcium phosphate	50	40	33	43	33	41	50	52	47
Microcrystalline cellulose	13	13	10	-	-	-	-	-	-
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Aerosil	-	-	-	-	-	-	1	1	1
Total weight (mg)	100	100	100	100	100	100	100	100	100

nearest graduated unit. The LBD and TBD were calculated in g per ml using following formula [37].

LBD = weight of the powder/volume of the packing before tapping
TBD = weight of the powder/tapped volume of the packing

Compressibility index

The compressibility of the powder was determined by the Carr's compressibility index.

Carr's index (%) = [(TBD – LBD) x 100]/TBD

Post-Compression Paarmeters

Evaluation of prepared Prazosin hydrochloride tablets

The tablets were evaluated for in process and finished product quality control tests i.e., appearance, dimensions (diameter and thickness), weight variation, hardness, friability, and drug content [37].

Appearance

The tablets were checked for the presence of cracks, depressions, pinholes [38].

Dimensions

Thickness and diameter of the tablets were measured using digital micrometer. These values were checked and used to adjust the initial stages of compression [39].

Uniformity of weight (weight variation test)

Twenty tablets were weighed individually. Average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percentage difference in the weight variation should be within the permissible limits (±7.5%). The percent deviation was calculated using the following formula [40].

$$\text{Percentage Deviation} = \frac{\text{Individual weight} - \text{average weight}}{\text{Average weight}} \times 100$$

Hardness test

The hardness was tested using Monsanto tester. "Hardness factor", the average of the six determinations, was determined and reported [41]. The force is measured in kilograms/cm^2.

Friability test

Permitted friability limit is 1.0 %. Roche friabilator was used to measure the friability of the tablets. Ten tablets were weighed collectively and placed in the chamber of the friabilator. In the friabilator, the tablets were exposed to rolling, resulting from free fall of tablets within the chamber of the friabilator. It was rotated at a rate of 25 rpm. After 100 rotations (4 minutes), the tablets were taken out from the friabilator and intact tablets were again weighed collectively. The percent friability was determined using the following formula [42].

$$\text{Friability} = \frac{(W_1 - W_2)}{W_1} \times 100$$

Where, W_1 = weight of the tablet before test, W_2 = weight of the tablets after test.

Content uniformity

Five tablets were selected randomly and average weight was calculated. Tablets were crushed in a mortar individually and accurately weighed amount of tablet triturate from each blend was taken. Then, samples were transferred to 50 ml volumetric flasks and 25 ml mixture of 0.1N CH_3COOH: methanol (30:70) was added. The flask was agitated for 30 min and filled with 25ml of the above mixture. The solution was filtered and the filtrate was used in the UV-spectrophotometric determination after appropriate dilution. The drug content in each tablet was estimated at λ_{max} 330.4 nm against blank [43].

In vitro drug release

In vitro drug release of the samples was carried out using USP-type II dissolution apparatus (paddle type). The dissolution medium, 500 ml of 0.1 N HCl solution containing 1% SLS was placed into the dissolution flask for 24 hours maintaining the temperature of 37±0.5 °C and rpm of 100. One Prazosin hydrochloride tablet was placed in each basket of dissolution apparatus. The apparatus was allowed to run for 24 hours. Samples measuring 5 ml were withdrawn after every 1, 2, 4, 8, 12, 16, 20, and 24 hours. During sampling samples were filtered through 10 µm filter. The fresh dissolution medium was replaced every time with the same quantity of the sample. Collected samples were suitably diluted with dissolution medium and analyzed at 330.4 nm using dissolution medium as blank. The cumulative percentage drug release was calculated [44].

Influence of different parameters on drug release

An attempt was made to know the drug release mechanism of tablets in different conditions. The effect of the concentration of SLS (0.5, 1, 1.5%), effect of agitation intensity (50, 75, and 100 rpm), effect of type of medium (0.1 N HCl and 7.4 pH phosphate buffer solution), and effect of the volume of the medium (500 and 900 ml) were also studied [44-47].

Swelling and water uptake study

Swelling behavior and water uptake studies of Prazosin hydrochloride tablets of optimized batch was studied in de-ionized water. A 20-mesh screen was placed at the bottom of dissolution flask. A Prazosin hydrochloride tablet was placed on the mesh to allow the hydration of tablet throughout its surface. A paddle was introduced and operated at 50 rpm. The tablet was removed along with the mesh at different time intervals. The weight and swelling of tablet were determined. Percent water uptake and percent axial swelling were determined using the following equations [27].

$$\text{Percent water uptake (weight gain)} = \frac{100\ (\text{wet weight - dry weight})}{\text{Dry weight}}$$

$$\text{Percent axial swelling} = \frac{100\ (\text{swollen thickness-original thickness})}{\text{Original thickness}}$$

Compatibility studies

FTIR compatibility studies were carried out to evaluate possible interactions between the drug and excipients. The pure drug, Prazosin hydrochloride, and the optimized formulation were analyzed using an FTIR spectrophotometer. Prior to analysis, samples were finely powdered and a background spectrum was recorded. The FTIR spectra of the samples were obtained over a wavenumber range of 4000–400 cm^{-1} under standard operating conditions [48].

Stability studies

The optimized tablets were packed in a black cover. It was then stored at 40 ± 2°C/75 ± 5% RH for 4 weeks. The tablets were evaluated for dissolution and compared with the tablets evaluated immediately after manufacturing (Zero month) [49].

Results and Discussion

Determination of λ_{max} for Prazosin HCl in 0.1 N HCl and PBS pH 7.4

From the standard stock solution (100µg/mL of 0.1 N HCl and PBS pH 7.4 individually), 1 ml was pipetted into 10 ml volumetric flask. The volume was made up to 10 ml with 0.1 N HCl and PBS pH 7.4 solution individually. The resulting solution containing 10 µg/ml was scanned between 200 and 400 nm, individually. $\lambda_{max,}$ 330.4 nm was considered as analytical wavelength for 0.1N HCL and 340.4 nm was considered as analytical wavelength for drug dissolved in PBS pH 7.4, as shown in Figure 1 and Table 2.

Table 2: Calibration plot data of Prazosin HCl in 0.1 N HCl and PBS (pH 7.4).

Concentration (µg/ml)	Absorbance at 330.4 nm (0.1 N HCl)	Absorbance at 340.4 nm [PBS (pH 7.4)]
0	0.000±0.000	0.000±0.000
5	0.139±0.003	0.088±0.001
10	0.281±0.002	0.161±0.002
15	0.411±0.005	0.235±0.002
20	0.564±0.003	0.308±0.001
25	0.706±0.001	0.387±0.002
30	0.845±0.004	0.460±0.001
35		0.540±0.002

(n=3) Avg ± S.D.

Standard calibration curve

Accurately weighed quantity of Prazosin hydrochloride (10 mg) was dissolved in little quantity of 0.1 N HCl and PBS pH 7.4 individually and volume was made up to 100 ml with respective liquid. Appropriate aliquots were taken into different volumetric flasks and volume was made up to 10 ml with 0.1 N HCl and PBS pH7.4 individually, so as to get drug concentrations of 5, 10, 15, 20, 25, and 30 µg/ml for 0.1 N HCl and 5, 10, 15, 20, 25, 30, 35 µg/ml for PBS pH7.4. The absorbance of these drug solutions was estimated at λ_{max} 330.4 nm and 340.4 nm. This procedure was performed in triplicate to validate the calibration curve. The data including standard deviation (SD) values are given in the Table 2. Calibration curve was constructed as shown in the Figure 2.

Standard calibration curve

Accurately weighed quantity of Prazosin hydrochloride (10 mg) was dissolved in little quantity of 0.1 N HCl and PBS pH 7.4 individually and volume was made up to 100 ml with respective

Spectrum Scanning

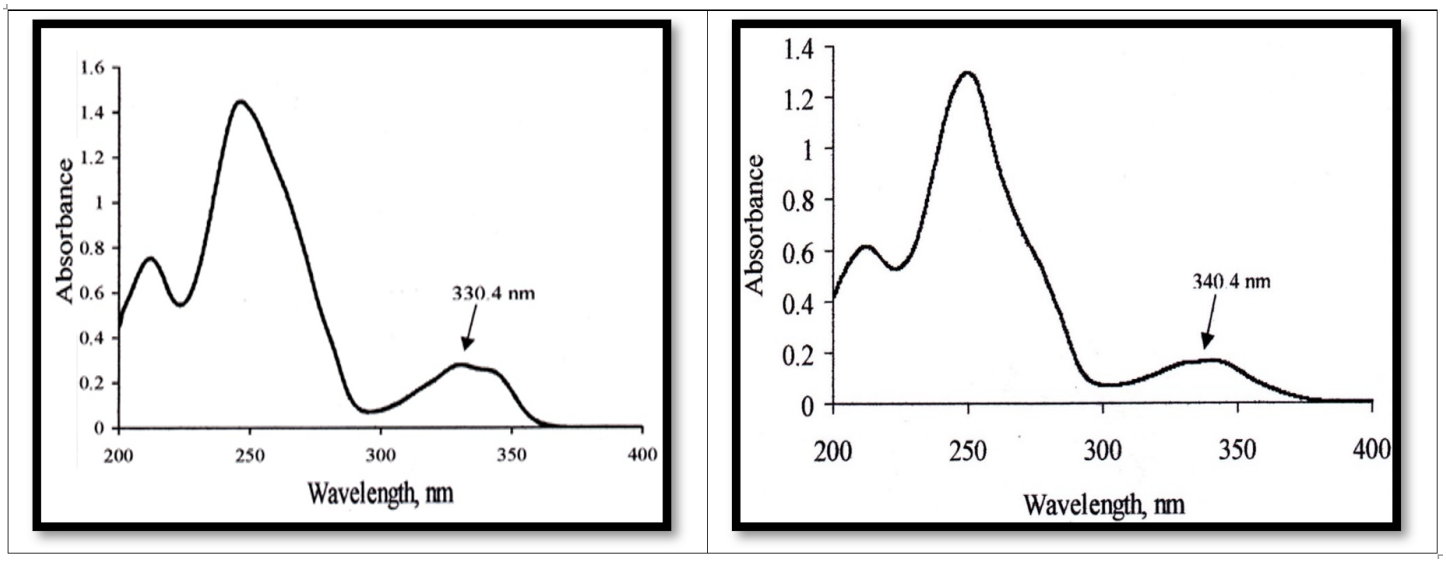

Figure 1: Spectrum scanning of Prazosin in 0.1 N HCl and PBS pH7.4 solution.

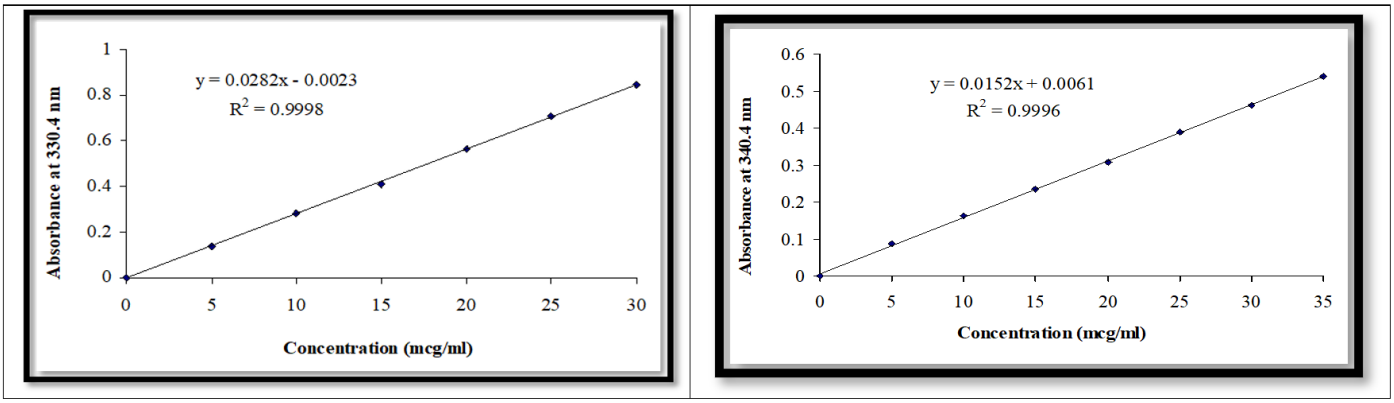

Figure 2: Calibration curve of Prazosin HCl in 0.1 N HCl solution and PBS pH 7.4.

liquid. Appropriate aliquots were taken into different volumetric flasks and volume was made up to 10 ml with 0.1 N HCl and PBS pH7.4 individually, so as to get drug concentrations of 5, 10, 15, 20, 25, and 30 µg/ml for 0.1 N HCl and 5, 10, 15, 20, 25, 30, 35 µg/ml for PBS pH7.4. The absorbance of these drug solutions was estimated at λ_{max} 330.4 nm and 340.4 nm. This procedure was performed in triplicate to validate the calibration curve. The data including standard deviation (SD) values are given in the Table 2. Calibration curve was constructed as shown in the Figure 2.

Organoleptic properties

Prazosin hydrochloride is a white color powder without any odor and taste.

Melting Point Determination

The melting point of pure drug (Prazosin hydrochloride) was determined by using open capillary method and was found to be 281±0.82 °C. This is matching with the literature value of 279 °C.

FTIR

The FT-IR spectroscopy studies were carried out for pure drug alone and also along with polymers. IR spectra of pure Prazosin, and in combination with xanthan gum, ethyl cellulose, guar gum, HPMC (K100 & K4M) as shown in Table 3. The pure sample of Prazosin shows the following characteristic peaks. These peaks were not affected and prominently observed in IR spectra of Prazosin hydrochloride along with polymers. This indicates that there is no interaction between Prazosin hydrochloride and physical mixture of polymers individually.

Pre-compression

The pre-compression parameters of formulations F-I to F-IX were evaluated to assess the flow and packing properties of the powder blends prior to compression. The results are summarized in Table 4 (Precompression methods). The loose bulk density of the formulations ranged from 0.305 to 0.431 g/cc. Formulations F-I to F-VII showed comparable bulk density values, indicating uniform particle packing, whereas F-VIII and F-IX exhibited lower bulk density, suggesting a relatively lighter and more porous powder blend. The tapped bulk density values varied between 0.390 and 0.572 g/cc. Higher tapped density observed in formulations F-I, F-VI, and F-VII indicates better particle rearrangement upon tapping, while lower values for F-VIII and F-IX suggest reduced compressibility. The angle of repose for all formulations was found to be in the range of 23.12° to 26.41°, indicating good to excellent flow properties. Formulations F-IV, F-V, and F-IX showed comparatively lower angles of repose, reflecting superior flow characteristics. The compressibility index (Carr's index) ranged from 20.48% to 25.66%. Formulations F-IV, F-V, and F-IX exhibited lower compressibility index values, indicating better flowability, whereas F-I showed a relatively higher value, suggesting moderate flow behavior. The Hausner ratio values were found between 1.26 and 1.35. Most formulations demonstrated Hausner ratios below 1.30, confirming acceptable flow properties, while F-I showed slightly higher value, indicating comparatively lower flow efficiency. Overall, the pre-compression evaluation revealed that all formulations possessed acceptable flow and compressibility characteristics suitable for tablet compression. Among them, formulations F-IV, F-V, and F-IX demonstrated superior flow properties, making them more favorable for further compression studies.

Table 3: Wave number of functional groups of Prazosin hydrochloride.

Functional group	Characteristics peaks of Prazosin hydrochloride (PH) in physical mixture (cm^{-1})				
	PH+ Xantham gum	PH+ Ethyl cellulose	PH+ guar gum	PH+ HPMC K100	PH+ HPMC K4M
N-H stretching	3308.77	3308.77	3303.95	3303.95	3303.95
C-H stretching	1642.00	1642.09	1637.27	1642.09	1642.09
C=O stretching	3124.12	3124.12	3128.94	3128.94	3124.12
C-O stretching	1111.76	1111.26	1111.26	1111.26	1116.58

Post-compression

The post-compression parameters of formulations F-I to F-IX were evaluated to determine the optimized tablet formulation. All formulations complied with pharmacopeial requirements for hardness, friability, weight variation, drug content, thickness, and diameter. The hardness of the tablets ranged from 5 to 7 kg/cm², indicating adequate mechanical strength for handling and packaging. The friability values of all formulations were found to be below 1%, complying with pharmacopeial limits and indicating good mechanical resistance from formulation FI-FIX. The uniformity of weight test revealed that all formulations complied with pharmacopeial specifications, with an average tablet weight of 100 ± 7.5 mg, indicating uniform die filling and consistent tablet production. The drug content of all formulations ranged from 96.16% to 100.55%, confirming uniform distribution of the drug within the tablets. The thickness and diameter of the tablets varied from 2.7 to 3.2 mm, and 6.0 to 6.1mm indicating uniform compression across batches as shown in Table 5.

In vitro dissolution studies

The *in vitro* drug release profiles of formulations F-I to F-IX were evaluated and compared with the marketed formulation (MF) using dissolution studies. The cumulative percentage drug release at different time intervals is presented in Table 6 (*In vitro* drug release studies). All formulations exhibited an initial lag phase followed by a gradual and controlled release of the drug. At 1 hour, the drug release ranged from 4.53% to 15.62%, indicating effective control of initial burst release. Formulation F-I showed comparatively higher initial release, whereas F-V and F-IX exhibited slower release behavior. At 4 hours, cumulative drug release varied significantly among formulations. F-I demonstrated rapid drug release (64.87%), while F-VI showed markedly lower release (10.29%), indicating strong retardation of drug diffusion. Formulations F-IV and F-VII showed moderate and controlled release patterns, releasing 41.89% and 31.92%, respectively. By 8 hours, F-I achieved almost complete drug release (97.62%), suggesting an immediate-release tendency. In contrast, formulations F-IX exhibited sustained release characteristics, with cumulative release values of 99.60 % up to 24 hrs. The marketed formulation showed 99.37 % drug release at this time point closely matching the marketed formulation confirming complete and sustained drug release as shown in Table 6 and Figure 3A-C.

In vitro drug release of Prazosin hydrochloride from F-IX in different media

The *in vitro* drug release behavior of Prazosin hydrochloride from the optimized formulation F-IX was evaluated in 0.1 N HCl and phosphate buffer saline (PBS) pH 7.4 to study the effect of dissolution medium on drug release. The cumulative percentage drug release at various time intervals is shown in Table 7 (*In vitro* release in different media). At the end of 24 hours, F-IX showed 99.60% drug release in 0.1 N HCl and 98.97% in PBS pH 7.4, confirming complete and sustained drug release over 24 hours was archived with 0.1 N HCL as shown in Figure 3D, so further studies are carried out with 0.1N HCl solution.

In vitro release of Prazosin hydrochloride from F-IX

The *in vitro* drug release behavior of the optimized formulation F-IX was studied under different dissolution conditions, including varying surfactant concentration (SLS), rotation speed (RPM), dissolution medium volume, and stability storage conditions, in order to evaluate the robustness and reproducibility of the formulation. The cumulative percentage drug release (% CDR) data are presented in Table 9.

Table 4: Precompression methods.

Parameter	F-I	F-II	F-III	F-IV	F-V	F-VI	F-VII	F-VIII	F-IX
Loose bulk density (gm/cc)	0.425	0.426	0.404	0.431	0.426	0.430	0.427	0.305	0.343
Tapped bulk density (gm/cc)	0.572	0.553	0.513	0.542	0.538	0.558	0.562	0.390	0.432
Angle of repose (θ)	24.86	25.38	26.02	23.54	23.82	24.89	26.41	24.58	23.12
Compressibility index (%)	25.66	23.05	21.29	20.48	20.82	22.98	24.09	23.12	20.60
Hausner ratio	1.35	1.30	1.27	1.26	1.26	1.30	1.32	1.28	1.26

Table 5: Post-compression parameters.

F Code	Hardness (kg/cm²)	Friability (%)	Uniformity of weight (mg)	Drug content (%)	Thickness (mm)	Diameter (mm)
FI	5 ± 0.2	0.050	100±7.5	100.55	2.7±0.1	6.0±0.01
F-II	5 ± 0.3	0.241	100±7.5	99.0	3.0±0.1	6.0±0.01
F-III	6 ± 0.2	0.335	100±7.5	96.63	3.2±0.1	6.1±0.04
F-IV	6 ± 0.3	0.117	100±7.5	99.72	3.1±0.1	6.1±0.01
F-V	6 ± 0.1	0.120	100±7.5	96.16	3.2±0.1	6.1±0.01
F-VI	5 ± 0.2	0.020	100±7.5	97.34	2.9±0.1	6.0±0.01
F-VII	6 ± 0.2	0.061	100±7.5	97.82	2.7±0.0	6.0±0.01
F-VIII	7 ± 0.1	0.286	100±7.5	99.48	2.7±0.1	6.0±0.01
F-IX	5 ± 0.2	0.482	100±7.5	97.58	2.9±0.0	6.0±0.01

(n=3) Avg ± S.D.

Table 6: *In vitro* drug release studies (FI-FIX).

Time (hrs)	F-I	F-II	F-III	F-IV	F-V	F-VI	F-VII	F-VIII	F-IX	MF
0	0.0±0.0	0.0±0.0	0.0±0.0	0.0±0.0	0.0±0.0	0.0±0.0	0.0±0.0	0.0±0.0	0.0±0.0	0.0±0.0
1	15.62±1.1	8.47±0.2	8.06±0.6	9.35±1.6	4.53±0.4	7.03±1.0	8.69±1.1	6.89±0.5	6.77±0.6	8.06±1.3
2	36.49±0.7	12.34±0.5	17.28±1.3	16.53±0.6	9.79±1.0	8.44±0.3	13.70±2.0	10.06±0.8	12.33±0.7	16.88±1.7
4	64.87±2.0	24.35±1.3	30.06±1.6	41.89±1.1	28.07±0.9	10.29±0.3	31.92±0.7	19.39±1.3	23.12±1.3	31.19±0.3
8	97.62±1.4	47.87±0.7	52.95±1.9	66.32±1.1	44.17±1.9	17.61±0.8	59.72±0.9	45.08±1.5	46.95±2.1	43.49±2.2
12	--	67.08±0.5	70.78±1.3	86.57±1.2	70.53±0.5	28.86±1.0	81.78±0.3	60.58±2.0	63.17±2.6	62.61±1.3
16	--	84.05±1.2	84.35±3.0	95.38±1.2	97.10±0.8	45.64±1.3	98.17±1.6	75.33±1.7	79.23±1.1	78.12±1.1
20	--	99.31±0.5	95.62±0.9	--	--	53.62±0.8	--	95.06±0.5	89.35±0.2	88.07±1.6
24	--	--	--	--	--	71.98±1.8	--	98.84±0.8	99.60±0.4	99.37±0.3

(n=3) Avg ± S.D.

Table 7. *In vitro* release of Prazosin hydrochloride from F-IX in different medium

Time (hours)	Cumulative percent drug release	
	0.1 N HCl	**PBS pH 7.4 solution**
0	0.0±0.0	0.0±0.0
1	6.77±0.6	6.07±0.0
2	12.23±0.7	11.92±0.5
4	23.12±1.3	22.75±0.5
8	46.95±2.1	46.99±0.5
12	63.17±2.6	62.98±0.5
16	79.23±1.1	78.24±1.4
20	89.35±0.2	89.32±1.5
24	99.60±0.4	98.97±0.4

(n=3) Avg ± S.D.

Effect of SLS Concentration

The effect of surfactant concentration on drug release was studied using 0.5%, 1.0%, and 1.5% SLS. At 1 hour, drug release increased with increasing SLS concentration, showing 6.08%, 13.28%, and 12.62% release for 0.5%, 1.0%, and 1.5% SLS, respectively. A similar trend was observed throughout the dissolution period. At 12 hours, cumulative drug release was 65.97% (0.5% SLS), 82.62% (1.0% SLS), and 79.32% (1.5% SLS) as shown in Figure 3E. Complete drug release was achieved by 24 hours in both 1.0% and 1.5% SLS, indicating that higher surfactant concentration enhances drug solubility and dissolution rate. However, the release profiles remained controlled, confirming the stability of the matrix system.

Effect of agitation speed (RPM)

The influence of agitation speed was evaluated at 50, 75, and 100 rpm. At 1 hour, drug release increased with RPM, showing 4.65%, 5.92%, and 6.77% release at 50, 75, and 100 rpm, respectively. This trend continued throughout the study, with 79.23% drug release at 16 hours and 99.60% at 24 hours observed at 100 rpm, as shown in Figure 3F.

Effect of dissolution medium volume

The effect of dissolution medium volume was studied using 900 ml and 500 ml. Drug release was consistently higher in 900 ml medium due to better sink conditions. At 8 hours, drug release was 60.70% in 900 ml compared to 49.28% in 500 ml. By 24 hours, nearly complete drug release was observed in both volumes (99.37% in 900 ml and 99.23% in 500 ml), as shown in Figure 3G. confirming that the formulation ensures complete drug release even under reduced dissolution volume.

Stability studies

Stability studies were conducted by comparing the dissolution profile of F-IX at zero day and after one month of storage. The results showed no significant difference in cumulative drug release at any time point. At 12 hours, the drug release was 63.17% (zero day) and 63.17% (one month), while at 24 hours, it was 99.60% and 99.51%, respectively. These findings indicate that F-IX remained stable during storage, with no change in drug release behavior, confirming the physical and chemical stability of the formulation, as shown in Table 8, and Figure 3H. Thus, F-IX can be considered a robust and reliable sustained-release formulation of Prazosin hydrochloride.

FTIR studies

FTIR analysis revealed that the characteristic peaks of the pure drug were retained in formulation, as shown in the Figure 4 and Table 8, demonstrating compatibility between the drug and the polymer used in the preparation.

Table 8: FTIR spectral studies.

Functional groups	Range (cm^{-1})	Prazosin hydrochloride (cm^{-1})	Formulation FIX (cm^{-1})
N-H stretching Amine/amide	3300-3320	3307.32	3303.95
C=O stretching Amide/Quinazoline	1600-1700	1640.64	1642.09
C-H stretching Aromatic	Above 3000	3126.04	3124.12
C-O stretching methoxy group	1000-1300	1287.25	1287.25

Similarity factor

In similarity index it was found that after a period of one month of storage there were no changes in the physical as well as drug release profiles of the tablets. The f_1 and f_2 values of the formulation F-IX were given in the Table 10.

Table 9. *In vitro* release of Prazosin hydrochloride from F-IX

Time (hours)	% CDR in SLS			% CDR at RPM*			% CDR at volume		% CDR for stability studies*	
	0.5 %	1.0 %	1.5 %	50 rpm	75 rpm	100 rpm	900 ml	500 ml	zero day	one month
0	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0
1	6.08	13.28	12.62	4.65±0.3	5.92±0.5	6.77±0.6	13.28	7.38	6.77±0.6	6.47±0.3
2	9.42	21.93	19.96	7.47±0.5	9.31±0.5	12.23±0.7	21.93	11.52	12.23±0.7	11.86±0.5
4	13.38	30.52	37.04	19.88±0.5	22.64±0.8	23.12±1.3	30.52	24.32	23.12±1.3	23.05±1.3
8	33.70	60.70	58.81	43.56±0.8	47.25±0.8	46.95±2.1	60.70	49.28	46.95±2.1	47.07±0.5
12	65.97	82.62	79.32	60.20±0.5	63.36±1.3	63.17±2.6	82.62	65.76	63.17+2.6	63.17±1.0
16	94.45	90.70	91.32	72.87±0.5	75.30±0.8	79.23±1.1	90.70	78.43	79.23±1.1	79.11±1.0
20	98.68	97.98	97.01	80.57±1.8	84.79±1.0	89.35±0.2	97.98	89.21	89.35±0.2	89.23±0.0
24		99.37	99.03	93.07±0.7	96.06±0.8	99.60±0.4	99.37	99.23	99.60±0.4	99.51±0.1

*n=3 Avg ± S.D., % CDR = Percentage cumulative drug release

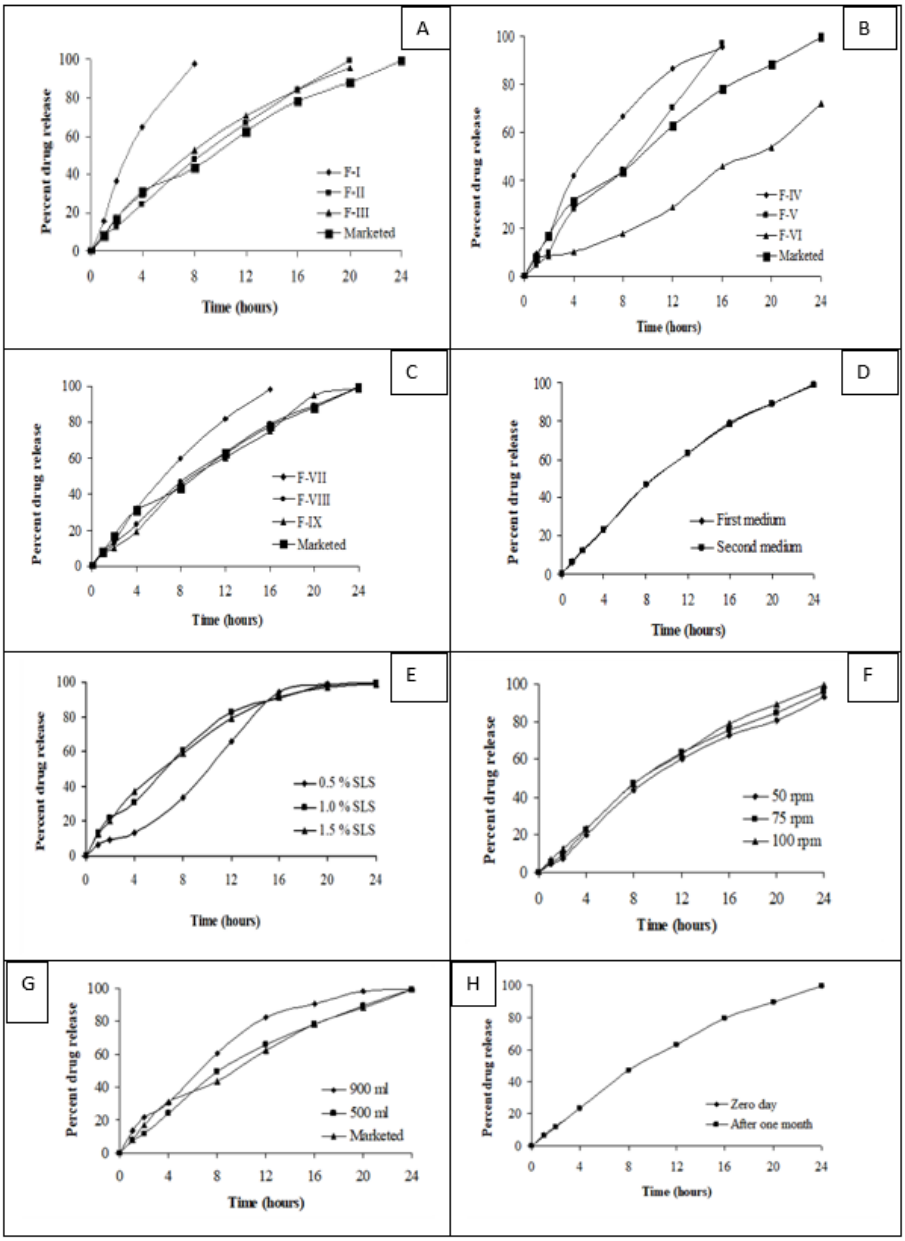

Figure 3: *In vitro* dissolution graphs.

Table 10: Similarity factor of F-IX tablets after one month.

Formulations	f_2 value-Similarity factor	Acceptable range	f_1 value-Dissimilarity factor	Acceptable range
Trail IX	99.62	50-100	0.28	0-15

Release Kinetics

The optimized F-IX batch was analyzed using multiple kinetic models. Graphical representations were constructed, and linear regression was applied to calculate the coefficients of regression (R^2), as presented in the accompanying Table 11, and Figures 5. Among the various kinetics models Korsmeyer-Peppas showed R^2 = 0.9961 and slope (*n*) value of 0.867. This *n* value is more than 0.45 and less than 0.89 as shown in Table 12, hence, it appears to indicate non-Fickian diffusion mechanism. The relative complexity of this formulation and its components may indicate that the drug release is controlled by diffusion process. Hence, non-Fickian diffusion may be the mechanism for the drug release from tablets of F-IX.

Swelling behavior and water uptake study

These studies are done for tablets of the formulation F-IX, which showed swelling property as well as water absorbing property. The results of percentage axial swelling and weight gain are given in Table 13. Graphical representations of these observations are as shown in Figure 6. From Figure 6 indicates that HPMC K100 has undergone swelling with the simultaneous release of the drug. HPMC K100 swells immediately with complete swelling in 12 hours. About 63.17% drug was released at the end of 12 hours and erosion process might have attributed gradual decrease in percent swelling after 12 hours. This may be because the mobility of polymer chains strongly depends on the water content of the system. At high water content, polymer chain relaxation takes place with volume expansion giving high swelling of the system. From the Figures 6, it can be seen that the swelling of tablet was much faster than the drug release from the tablet (swelling was 100% in 4 hours and 32% drug released). Also, this higher water content could predict the higher penetration of the gastric fluid in to the tablet leading to faster swelling of the tablet. So, the drug release was found to be high initially and then gradually decreased.

Table 11: Release kinetic studies of F-IX.

Time (hours)	Cumulative percent drug released	Log Percent drug released	Percent drug remains unreleased	Log percent drug remains unreleased
0	0.00	0.00	100	2
1	6.77	0.831	93.230	1.97
2	12.23	1.088	87.766	1.94
4	23.12	1.364	76.880	1.89
8	46.95	1.672	53.048	1.72
12	63.17	1.800	36.832	1.57
16	79.23	1.899	20.773	1.32
20	89.35	1.951	10.648	1.03
24	99.60	1.998	0.399	-0.40

Table 13: Swelling and water uptake studies of F-IX tablets.

Time (hours)	Percent water uptake	Percent swelling
0	0	0
1	318.37	33.33
2	351.02	66.67
4	502.04	100.00
8	568.37	133.33
12	716.33	166.67
16	864.29	133.33
20	1089.80	66.67
24	838.78	33.33

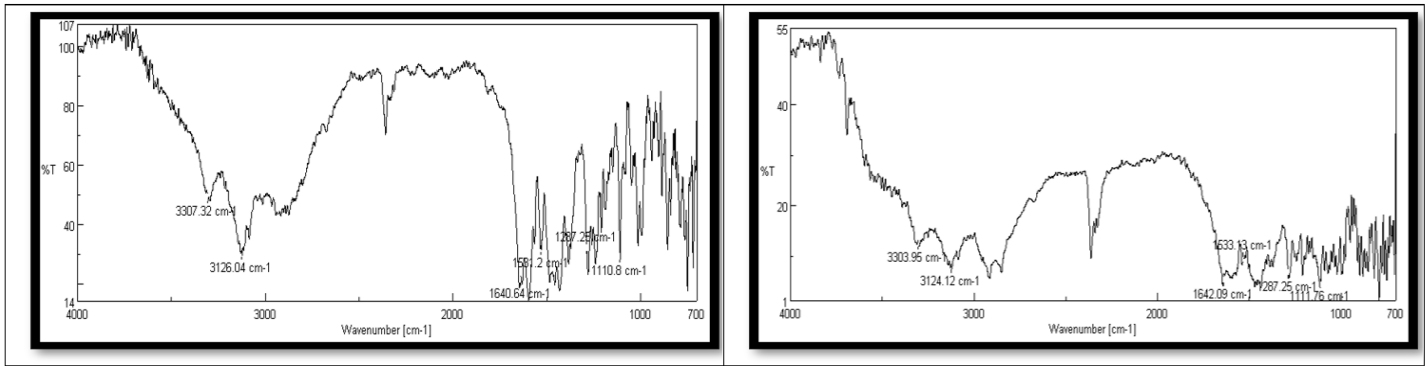

Figure 4: FTIR studies of pure drug (Prazosin hydrochloride) and F-IX.

Table 12: Release Kinetics of F-IX.

Release Kinetic Models / Regression analysis	Zero-order	First-order	Higuchi-plot	Korsemeyer-Peppas
Coefficient of determination (R^2)	0.9782	0.788	0.9717	**0.9961**
Linear regression equation	Y= -4.1376x+7.558	Y = - 0.077x+2.1962	Y = 22.21x-12.707	**Y= 0.867x+0.8413**

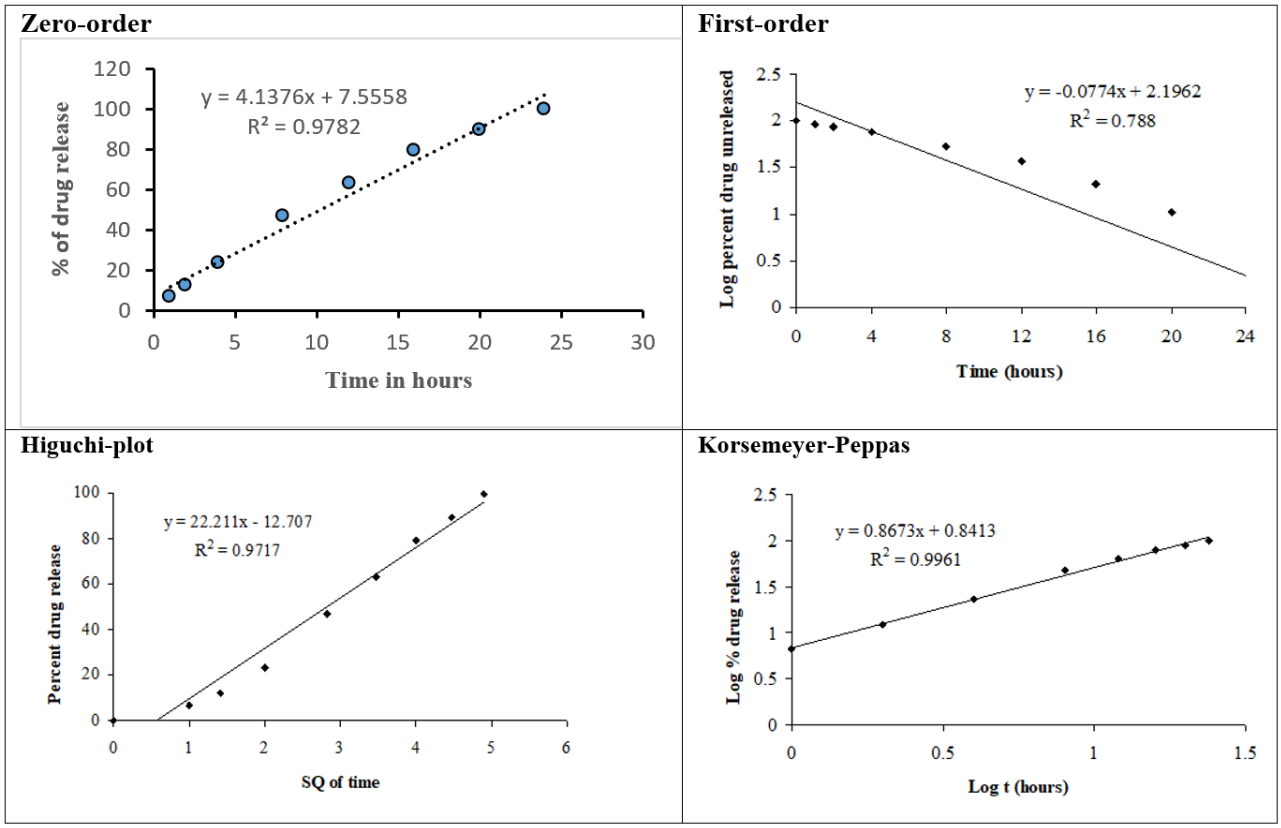

Figure 5: Release kinetics graph.

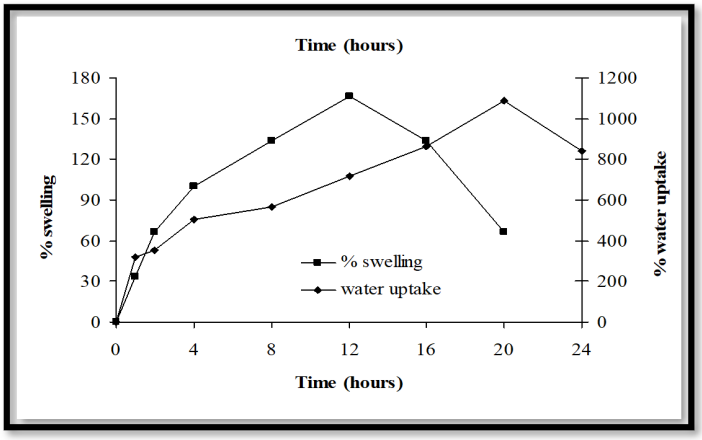

Figure 6: Graph of swelling and water uptake studies.

Summary

Suitable analytical method based on UV-visible spectrophotometer was developed for Prazosin hydrochloride. λ_{max} of 340.4 nm and 330.4 nm was identified in 0.1 N HCl and phosphate buffer pH 7.4 solution, respectively. All the excipients used did not interfere with the Prazosin hydrochloride. Procedure to manufacture matrix tablets by direct compression was established. Matrix tablets of Prazosin hydrochloride were successfully prepared using direct compression method. Tablets of F-IX passed all official and unofficial quality control tests. Based on the results, F-IX was identified as better formulation amongst all formulations for matrix tablets. The content uniformity of Prazosin hydrochloride in the tablets was ranged from 96.16 to 100.55 %. An *in vitro* release profile of optimized formulations of Prazosin hydrochloride matrix tablets (F-IX) was found to be similar to that of commercial marketed product. The average f_1 and f_2 values were found to be 99.62 and 0.28 for matrix tablets respectively. Prazosin hydrochloride release from the matrix tablets was independent of pH of the dissolution medium, assuring the release to be fairly independent on pH of the GIT. So, 0.1 N HCl is selected as dissolution medium. Prazosin hydrochloride release from the matrix tablet was inversely proportional to the agitation intensity of the dissolution medium. Drug release from the developed formulation follows Korsemeyer-Peppas model, it means the release is governed by a combination of drug diffusion and polymer. Hence Prazosin hydrochloride release from the tablets followed non-Fickian diffusion rate controlled. The manufacturing procedure was standardized and found to be reproducible. After one month of accelerated stability studies, developed formulations were found to be stable. The formulation shows the good swelling behavior and water uptake properties. The size and cost of the Prazosin hydrochloride sustained release tablets was decreased when compared to marketed products.

Conclusion

The conclusions arrived from this study indicated that the sustained

release formulations of Prazosin hydrochloride developed in this investigation was found to be equivalent to commercial marketed product, based on *in vitro* release studies. Thus, the objectives envisaged in this study are achieved. Further studies are needed to investigate these formulations for its performance *in vivo* and its bioequivalence with the available commercial products. Matrix tablets of Prazosin hydrochloride (F-IX) were successfully prepared using HPMC K100 by direct compression method. Drug release from the developed formulation follows Korsemeyer-Peppas plot. The size and cost of the tablets were decreased when compared to marketed products.

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Conflict of Interest

The author has no conflict of interest to publish this article in this journal.

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