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SHORT COMMUNICATION article

Formulation and evaluation of Alfuzosin hydrochloride extended-release tablets

Zakir Hussain [1], **P Ushasree** [2], **Suthakaran Raj** [3 *]
Abhiram Anand Vyavahare [4], and **Charan** [1]

[1] Department of Pharmaceutics, Vijaya College of Pharmacy, Hyderabad, India
[2] Department of Pharmacology, Vijaya College of Pharmacy, Hyderabad, India
[3] Department of Pharmaceutical Chemistry, Vijaya College of Pharmacy, Hyderabad, India
[4] Aurobindo Pharma Ltd, Bachupally, Hyderabad, India
[*] Author to whom correspondence should be addressed

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Abstract: The current research aimed to increase patient adherence, bioavailability, and medication release by developing and evaluating Alfuzosin HCI extended-release tablets. Ethyl Cellulose, Carbopol 940, and HPMC K4 were among the polymers used in the direct compression technique to develop a range of compositions. All pre-compression metrics, including bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio, were found to be within acceptable ranges in the manufactured tablets, indicating that the flow properties were satisfactory. The tablets that were crushed were tested for additional characteristics after compression, such as hardness, thickness, weight fluctuation, friability, drug content, and *in vitro* drug release. Again, they were determined to be satisfactory. F6, which contains Carbopol 940, showed the best results among all the formulations. It had an extended-release profile, releasing 99.83% of the medication over 12 hrs. The evaluation criteria revealed that formulation F6 was the most promising candidate for the treatment of benign prostatic hyperplasia with its extended-release dosage form.

Introduction

As a strategy to encourage innovation and progress, the pharmaceutical industry is putting more effort into developing extended-release medicine formulations. Reduced dosage frequency, extended drug effectiveness, and reduced occurrence of undesirable effects are only a few of the many safety and efficacy advantages of prolonged release dosage forms compared to immediate release pharmaceuticals. The extended-release versions of medications have been in use since the 1960s [1]. Several factors affecting extended-release drug delivery system, such as physicochemical properties of drug; due to limited gastrointestinal transit time of the intact medication and restricted solubility at the site of consumption, pharmaceuticals with low aqueous solubility often experience difficulties with oral bioavailability, making it difficult for the drug to remain in its formulation. Partition coefficient: A drug's bioavailability is greatly affected by its partition coefficient because biological membranes are naturally lipophilic. Aspirin is less soluble in the stomach but more soluble in the intestines. For novel oral drug delivery systems, it is ideal to have a medication that dissolves well in water and does not depend on pH. These formulations allow the medicine to be active for a longer period following oral administration. An extended-release medication enhances a medicine's therapeutic effect and safety while simultaneously boosting patient comfort and compliance by incorporating the dose into a unit dosage form and releasing the drug gradually over 24 hrs.

This formulation helps mitigate side effects at low and high doses [2]. *In-vivo* drug stability: With the majority of extended-release (ER) drug delivery systems aiming to release the medicine throughout the GI tract, it's crucial that the drug stays stable in that environment. Thus, unstable medicines, like nitroglycerine, cannot be designed as oral ER drug delivery systems because of bioavailability problems. Binding to proteins; when medications bind to proteins, it changes the distribution equilibrium of those pharmaceuticals. Because of their role as distributional buffers, plasma [3]. Biological properties of drug; the first criterion for an oral ER drug delivery system to be effective is absorption, which must occur at a higher rate than the drug's release from the dosage form. For medications with sluggish or unpredictable absorption rates, oral ER medicine delivery systems are not optimal. Low absorption levels can be caused by a number of factors, including insufficient water solubility, an inadequate partition coefficient, acid hydrolysis, or absorption-site metabolism [4]. Proteins lengthen the elimination half-life of medications, which can make it difficult to formulate them into controlled-release dosage forms. The only part of the drug that can diffuse into tissues from blood arteries is the unbound, free portion. Plasma concentration response relationship: The pharmacological response of a medication is largely affected by its plasma concentration and not by its size or dosage. Some drugs exhibit pharmacological actions that are independent of plasma concentrations, which is a problem for oral ER. Drug delivery methods; a predefined amount of time is allotted for the active ingredient to be released gradually in extended-release tablets [5-8]. Instead of being absorbed quickly upon administration, the active ingredient in these tablets is released into the body gradually, ensuring a sustained therapeutic influence, in contrast to formulations that provide an immediate release [9]. Ion exchange resins-controlled release; Ion exchange resins are water-insoluble due to the presence of ionizable functional groups in cross-linked polymers [5]. Controlled release systems and flavour masking are two of the most prevalent pharmacological applications of these resins. Ion exchange resins are perfect disintegrants for tablet formulations due to their swelling properties. Resin causes ionizable medications to form irreversible complexes after extended exposure. Medications linked to the resin can be released when the ion-exchange groups engage with certain ions. Regulatory aspects in the production of extended-release tablets; to ensure the quality, efficacy, and safety of extended-release tablets, their production is subject to stringent regulatory regulations. Good manufacturing practice, stability testing, bioequivalence testing, and accurate labelling are all part of these guidelines. To ensure that the excipients used in an extended-release formulation are compliant with FDA regulations, it is essential to look up the specific excipients in the inactive ingredient database [10].

Materials and methods

Analytical method development: Determination of wavelength: l0.0 mg of pure drug was dissolved in l0.0 ml of methanol (primary stock solution - 1000 pg/ml). From this solution 1.0 ml was taken out into 10.0 ml flask and made it up to 10.0 ml with the media (secondary stock solution - 100 pg/ml). From the secondary stock solution, again 1.0 ml was taken into another volumetric flask and made up to 10.0 ml with media (working solution - l0.0 pg/ml). The working solution was taken for determining the wavelength [11].

Determination of calibration curve: l0.0 mg of pure drug was dissolved in l0.0 ml of methanol (primary stock solution - 1000 pg/ml). From this primary stock solution 1.0 ml was pipette out into a 10.0 ml volumetric flask, and made it up to l0.0 ml with the media (secondary stock solution - l00 pg/ml). From the secondary stock solution required concentrations were prepared, and those concentrations absorbance were found out at the required wavelength [12].

Preformulation parameters: The quality of the tablet, once to related by rule, is generally dictated by the quality of the physicochemical properties of blends. There are many formulations and process variables involved in mixing, and all these can affect the characteristics of blends produced. The various characteristics of blends were tested as per the Pharmacopoeia.

Angle of repose: The frictional force in a loose powder can be measured by the angle of repose. It is defined as the maximum angle possible between the surface of the pile of the powder and the horizontal plane. More powder is added to the pile; it slides down the sides of the pile until the mutual friction of the particles producing a surface angle is in equilibrium with the gravitational force. The fixed funnel method was employed to measure the angle of repose. A funnel was secured with its tip at a given height above a sheet of graph paper that was placed on a flat horizontal surface. The blend was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius of the base of the conical pile was measured. The angle of repose was calculated using the formula [13].

Bulk density: Density is defined as weight per unit volume. Bulk density is defined as the mass of the powder divided by the bulk volume and is expressed as g/cm^3. The bulk density of a powder primarily depends on particle size distribution, particle shape and the tendency of particles to adhere together. Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend. It is also important in size-blending equipment. 10 gm powder blend was sieved and introduced into a dry 20.0 ml cylinder, without compacting. The powder was carefully levelled without compacting, and the unsettled apparent volume was read.

Tapped density: After carrying out the procedure as given in the measurement of bulk density, the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides 100 drops per minute and this was repeated until difference between succeeding measurements is <2.0%.

Measures of powder compressibility: The compressibility index (Carr's index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material, the more flowable it is. As such, it is measures of the relative importance of interparticle interactions. In a free- flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value. For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities [14].

Formulation development of tablet: All the formulations were prepared by direct compression. The compositions of different formulations are given in **Table 1**. The tablets were prepared as per the procedure given below and the aim is to prolong the release of Alfuzosin HCI. Total weight of the tablet was considered as l00 mg. Alfuzosin HCI and all other ingredients were individually passed through sieve no 60. All the ingredients were mixed thoroughly by triturating up to 15 min. The powder mixture was lubricated with talc.

Table 1: Formulation of Alfuzosin hydrochloride extended-release tablet

Ingredients (mg)	**Formulation**								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Alfuzosin HCI	10	10	10	10	10	10	10	10	10
Ethyl cellulose	5	10	15						
Carbopol 940				5	10	15			
HPMC K4	-	-	-	-	-	-	5	10	15
PVP K 30	4	4	4	4	4	4	4	4	4
Talc	2	2	2	2	2	2	2	2	2
Magnesium	2	2	2	2	2	2	2	2	2

Evaluation of post compression parameters for prepared tablet: The designed formulation tablets were studied for their physicochemical properties (weight variation, hardness, thickness, friability, drug content).

Weight variation test: To study the weight variation, twenty tablets were taken, and their weight was determined individually and collectively on a digital weighing balance. The average weight or' one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table, and none deviate by more than twice the percentage (**Table 2**).

Hardness: Is defined as the force applied across the diameter of the tablet to break the tablet. The resistance of the tablet to chipping, abrasion, or breakage under conditions of storage, transformation, and handling before usage depends on its hardness. For each formulation, the hardness of three tablets was determined timing Monsanto hardness tester and the average is calculated and presented with deviation.

Thickness: Tablet thickness is an important characteristic in reproducing appearance. Tablet thickness is an important characteristic in reproducing appearance. Average thickness for core and coated tablets is calculated and presented with deviation.

Friability: It is a measure of the mechanical strength of tablets. Roche Friabilator was used to determine the friability by following the procedure. Pre-weighed tablets were placed in the Friabilator. The tablets were rotated at 25 rpm for 4 min (100 rotations). At the end of test, the tablets were reweighed, and the loss in weight of the tablet is the measure of liability.

Determination of drug content: Tablets were tested for their drug content. Ten tablets were finely powdered quantities, of the powder equivalent to one tablet weight of drug were accurately weighed, transferred to a 100 ml volumetric flask containing 50.0 ml of water, and allowed to stand to ensure complete solubility of the drug. The mixture was made up to volume with media, the solution was suitably diluted, and the absorption was determined by UV-Visible Spectrofluorometer.

In-vitro drug: Release studies dissolution parameters: Apparatus dissolution medium; tablet was placed in the vessel and apparatus was operated for 2 hrs. and then the media 0.1 N HC1 were removed, and pH 6.8. At definite time intervals withdrawn, 5.0 ml of the sample was withdrawn, filtered, and again 5 in 1 media was replaced. Suitable dilutions were done with media and analysed by spectrophotometrically at the required wavelength using UV-Spectrophotometer.

Application of release rate kinetics to dissolution data: Furious models were tested for explaining the kinetics of drug release. To analyse the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first-order, Higuchi, and Korsmeyer-Peppas release models.

Korsmeyer and Peppas release model: The mechanism of drug release was evaluated by plotting the log percentage of drug released versus log time according to the Korsmeyer-Peppas equation. Hixson-Crowcll model describes the release of drugs from an insoluble matrix through mainly erosion

Table 2: Percentage of deviation (individual weight - average weight/average weight) x 100

Average weight of tablet (mg) (I.P)	Average weight of tablet (mg) (U.S.P)	**Maximum** percentage **difference allowed**
Less than SO	Less than 130	10
80-250	130-324	7.5
More than	More than 324	5

Results and discussion

The standard calibration curve of the drug in 0.1 N HCl is depicted. The data had a very high correlation co-efficient and the equation of the regression line is depicted in **Figure 1**. Preparation of a standard curve in a 6.8 pH buffer. The calibration curve was determined by plotting concentration (µg/ml) versus absorbance (nm) at 247 nm. The results were obtained as follows, as shown below. Thus, the present study aimed to develop extended-release tablets of Alfuzosin HCI using various ingredients, similar to the previous study [5]. Thus, all the formulations (F1 to F9) were evaluated for physicochemical properties and *in-vitro* drug release studies. With regard to analytical method, **Table 3**, graphs of Alfuzosin HCI were taken in 0.1 N HCl and in pH 6.8, phosphate buffer at 245 nm and 247 nm, respectively. Observations for graph of Alfuzosin HCI in 0.IN HCI (245 nm). The results of the quality control of the tablet are given in **Table 4**.

Table 3: Observations for the graph of Alfuzosin HCl in pH 6.8 phosphate buffer (247 nm)

Concentration mg/ml	Absorbance (nm)
0.0	0.0
10	0.171
20	0.328
30	0.483
40	0.644
50	0.795

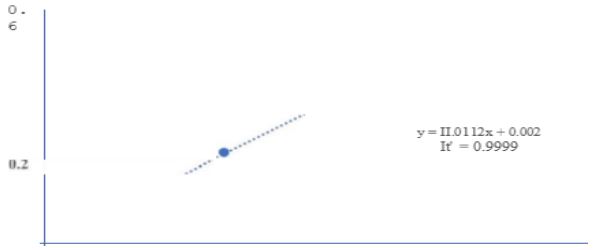

Figure 1: Standard graph of Alfuzosin hydrochloride in 0.1N HCl

Precompression parameters were evaluated for Alfuzosin HCI as shown in the Materials and Methods section, and the results are given in **Table 4**. The powders were evaluated for various flow properties. The powders of all showed good flow properties, which are evident from the results presented in this study. The angle of repose values ranged from 26.27±0.13 to 28.33±0.31. The results were found to be below 30; hence, they have good flow ability. The Carr's index value ranged from 13.85±0.60 to 15.31±0.60, and Hausner's ratio value ranged from 052±0.36 to 1.93±0.51; hence, they have good flow and free flowability. All the formulations in this study revealed good flow properties, which suggested that the blend is suitable for direct compression.

Post compression parameters were evaluated for Alfuzosin HCI, as shown above. The results are given in **Table 5.** The formulated controlled release tablets were then evaluated for various physical characteristics like thickness, weight variation, hardness, friability, and drug content uniformity. The thickness of tablets in all formulations ranged from 1.95 to 2.22. The weight variation of tablets in all formulations ranged from 95.22 to 102.56. The hardness and friability of all the formulations F1-F9 were found to be 1.55 to 2.16 and 0.22 to 0.51, respectively. The drug content of all the formulations ranged from 59.66 to 99.71.

Table 4: Quality control parameters for tablets

Formulation code	Angle of repose degree±SD	Bulk density (gm/ml±SD)	Tapped density (gm/ml±SD)	Carr's index (%±SD)	Hausner's ratio (%±SD)
F1	26.27±0.13	0.64±0.01	0.73±0.03	14.48±0.21	1.03±0.34
F2	28.33±0.31	0.63±0.01	0.75±0.04	14.57±0.54	1.10±0.40
F3	27.24±0.17	0.66±0.03	0.73±0.03	14.60±0.24	1.93±0.51
F4	27.48±0.71	0.64±0.01	0.73±0.03	14.34±0.02	0.88±0.37
F5	26.64±0.43	0.63±0.01	0.74±0.03	14.46±0.40	0.62±0.02
F6	27.05±1.06	0.65±0.02	0.74±0.01	15.31±0.05	0.96±0.58
F7	27.31±0.17	0.66±0.t)2	0.74±0.02	15.14±0.60	1.06±0.41
FS	26.40±0.40	0.66±0.03	0.71±0.01	13.85±0.60	0.52±0.36
F9	28.38±0.21	0.64±0.01	0.72±0.01	14.28±0.30	0.64 ±0.02

Table 5: *In-vitro* quality control parameters for tablets

Formulation codes	Weight variation (g)	Hardness (hg/cm)	Friability (% loss)	Thickness (mm)	Drug content (%)
F1	95.34	1.89	0.26	2.17	96.35
F2	99.76	1.90	0.33	2.12	59.66
F3	99.62	1.93	0.42	2.15	95.12
F4	101.42	1.97	0.51	2.08	97.83
F5	97.88	2.16	0.36	2.22	99.44
F6	100.13	1.77	0.22	2.05	99.39
F7	95.22	1.55	0.46	1.95	97.5S
FS	99.7	1.93	0.37	2.05	98.63
F9	102.56	1 85	0 49	1 96	99.71

An *in vitro* drug release study was carried out for formulations F1 to F9 containing different ratios. Among 9 formulations, F6 was selected as the best formulation based on *in vitro* drug release. The cumulative percentage drug release of F11 was 99.83% after 12 hrs.

Table 6: Dissolution data of Alfuzosin hydrochloride tablets

Time (hr.)	Cumulative percent drug dissolved								
	FI	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0.5	18.88	14.09	19.18	13.62	11.47	19.94	13.74	15.77	17.59
1.0	22.25	19.44	23.3S	17.27	19.59	25.66	18.33	21.06	25.45
2.0	26.69	25.22	29.65	32.38	29.25	31.55	27.57	29.94	36.17
3.0	31.08	35.69	39.39	37.53	39.14	35.38	32.48	38.12	41.28
4.0	39.42	41.28	48.94	43.18	46.66	43.28	38.53	43.66	47.16
5.0	42.96	45.57	55.69	48.66	52.12	49.66	46.28	49.54	52.32
6.0	56.53	49.92	63.91	55.11	59.38	52.92	53.33	55.99	58.84
7.0	59.38	63.46	72.69	59.05	68.58	61.73	57.18	58.44	62.01
8.0	63.15	74.99	79.55	63.49	75.93	68.56	62.88	68.13	66.72
9.0	74.26	79.24	84.22	69.97	79.17	72.98	66.22	74.26	73.95
10	81.95	83.88	88.53	75.13	84.53	88.16	74.96	79.98	77.54
11	85.03	91.24	93.27	79.73	92.44	96.55	89.01	83.08	89.63
12	89.11	94.14	97.13	86.16	95.29	99.83	95.25	89.41	92.84

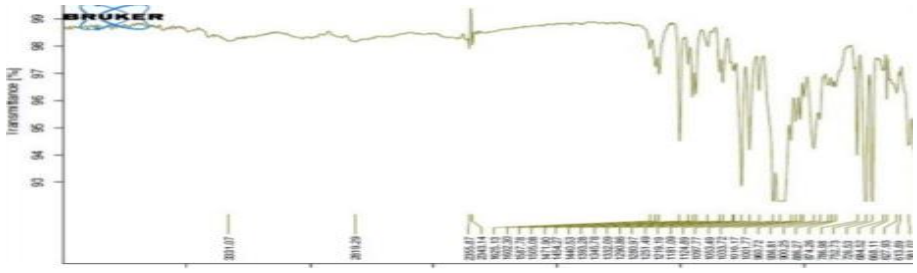

Figure 2: FT-IR Spectrum of pure drug

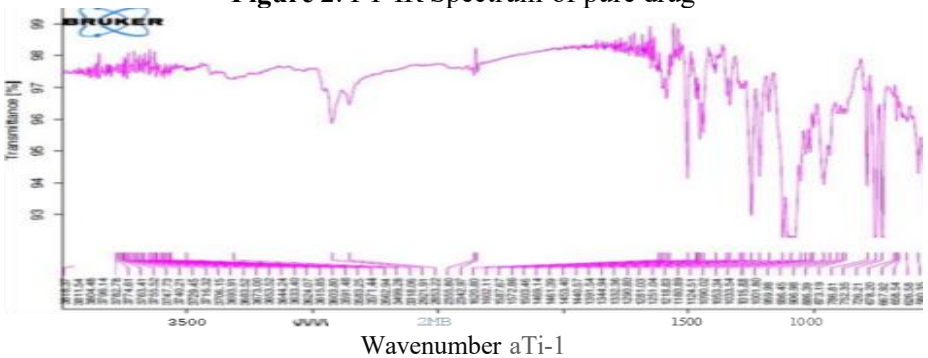

Figure 3: FT-IR Spectrum of optimized formulation

Conclusion: This study focused on the formulation and evaluation of Alfuzosin HCl extended-release tablets to achieve a prolonged therapeutic effect and improved patient compliance. The formulated batches were evaluated for pre-compression and post-compression parameters; all were found to be within acceptable limits, indicating good properties of the powder blend and satisfactory mechanical characteristics of the finished tablets. The *in vitro* drug release data demonstrated that the optimized formulation is capable of sustaining the release of Alfuzosin HCl over an extended period, complying with the desired release profile. Therefore, it can be concluded that the developed extended-release formulation of Alfuzosin HCl is a stable and effective dosage form capable of providing controlled drug delivery, reducing dosing frequency, and improving patient adherence in the management of benign prostatic hyperplasia.

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Author's contribution: ZH & AA conceived and designed the study. ZH & C collected data. ZH, PU, SR & C contributed to data analysis and interpretation of data. ZH & SR drafted the manuscript. All authors read and approved the final manuscript.
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