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# ALFUZOSIN HCL FLOATING TABLET – FORMULATION AND EVALUATION

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## ABSTRACT

The present work was to prepare and optimize floating tablet of Alfuzosin Hcl. Alfuzosin HCl is an alfa-1 adrenergic receptor blocker used for the treatment of benign prostatic hyperpleasia & hypertension which were design to increase the gastric residence time and thus prolonging the drug release. Alfuzosin HCL has the short biological half -life (3-5hrs) with dose range from 2.5mg thrice a day to maximum of 10mg once a day which results into inconveniency to the patients. By preparing the floating tablets of Alfuzosin HCl that delivers the drug for longer time, reduced dosage frequency & better patient compliance. The tablets were prepared by direct compression method by using different synthetic and natural polymers. All the batches were evaluated for pre compression & post compression parameters and results were observed within the limits. All the batches exhibited appropriate floating lag time with in prescribed limits. Formulation F13 was selected as an optimized formulation as it shown maximum % drug release at sustain rate at the end of 12 hours. Dissolution data were fitted to various kinetic drug release models.

**KEYWORDS:** Alfuzosin HCl, Alpha adrenergic receptor blocker, biological half life, Floating tablets, direct compression, synthetic and natural polymers, floating lag time, optimized formulation.

## INTRODUCTION

Oral route is the most preferable route for the delivery of various drugs due to the ease of administration, patient compliance and flexibility in the formulations. Oral administration of drugs progressed from immediate release to site- specific delivery. It is evident from the recent scientific and patented literature that an increased interest in novel dosage forms that are retained in the stomach for prolong and predictable period of time exist in academic and industrial research groups. Various attempts have been made to develop Gastro retentive delivery systems over the past three decades, the pursuit and exploration of devices designed to be retained in the upper part of the Gastro Intestinal Tract (GIT) has advanced consistently in terms of technology and diversity, encompassing a variety of systems and devices such as floating systems, rate systems, expanding systems, swelling systems, bioadhesive systems and low-density systems. This technology benefits drugs which have a narrow therapeutic window of absorption in the stomach and upper GI tract. Gastro retentive systems can remain in the gastric region for several hours and hence significantly prolong the gastric residence time of drugs. Prolonged gastric retention improves bioavailability, reduces drug loss, and improves solubility for drugs that are less soluble in a high pH environment. It has applications also for local drug delivery to the stomach and proximal small intestine. Gastro retention helps to provide better availability of new products with new therapeutic possibilities and substantial benefits for patients.[1,2] Therefore, control of placement of a Drug Delivery Systems (DDS) in a specific region of the GIT offers advantages for a variety of important drugs characterized by a narrow absorption window in the GIT or drugs with a stability problem.[3] These considerations have led to development of a unique oral controlled release dosage form with gastro retentive properties. One of the most feasible approaches for achieving a prolonged and predictable drug delivery in the GIT is to control the Gastric Residence Time (GRT), i.e. Gastro Retentive Dosage Form (GRDF).

Floating systems or hydro dynamically balanced systems, are low-density systems that have sufficiently buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time and a better control of the fluctuations in plasma drug concentrations. Many buoyant systems have been developed based on granules, powders, capsules, tablets, laminated films and hallow micro spheres.[4] Floating drug delivery systems are designed to prolong the study of drug in dosage form in the gastro intestinal tract and aid in enhancing the absorption. Such systems are best suited for drug having a better solubility in acidic environment and also having specific site

of absorption in upper part of the small intestine. To remain in the stomach for a prolonged period of time the dosage form must have a bulk density of less than 1. It should stay in the stomach, maintain its structural integrity, and release drug constantly from the dosage form.[5] Hence in the present wok is to develop the sustained release floating tablets of Alfuzosin Hydrochloride using different polymers in order to enhance the absorption followed by improving bioavailability.

## MATERIALS AND METHODS

### Materials

Alfuzosin HCl was obtained by Surya labs as a gift sample. HPLC K4M, Xanthum gum, Guar gum, Ethyl Cellulose, Microcrystalline cellulose, Sodium bicarbonate, citric acid, talc and magnesium stearate were obtained from Scientific syndicate, Hyderabad.

### Methodology

### Preparation OF Alfuzosin HCl Floating Tablets

All the ingredients were accurately weighed and pass through sieve No. 60.The drug was blended thoroughly with other ingredients except magnesium stearate in a mortar for 15 minutes. After this magnesium stearate was mixed for additionally 3 to 4min. The blended powder was compressed to tablets on a punching machine using flat surfaced, round shaped punches of 12mm diameter. The compressions of all the formulations were given in the table no. 1.

**Table 1: Composition of Alfuzosin HCl floating tablets.**

| Ingredients (mg) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 | F11 | F12 | F13 | F14 | F15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Alfuzosin Hcl | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| HPMC K4M | 60 | 80 | 100 | - | - | - | - | - | - | - | - | | 50 | 50 | 50 |
| Guar gum | - | - | - | 60 | 80 | 100 | - | - | - | - | - | | 50 | - | - |
| Xanthum gum | - | - | - | - | - | - | 60 | 80 | 100 | - | - | | - | 50 | - |
| Ethyl Cellulose | - | - | - | - | - | - | - | - | - | 60 | 80 | 100 | - | - | 50 |
| Sod.bicarbonate | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 |
| Citric acid | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| Mag.stearate | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Talc | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| MCC | 340 | 320 | 300 | 340 | 320 | 300 | 340 | 320 | 300 | 340 | 320 | 300 | 300 | 300 | 300 |
| Total Weight | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 |

## EVALUATION PARAMETERS

### Precompression parameters

The blended powdered formulations were evaluated for their bulk density, tapped density, compressibility index, hausner ratio and angle of repose which indicates flow property of powder blend were calculated.

### Post compression parameters

### Weight variation

20 tablets were selected randomly and weighed accurately and average weight of tablet calculated. Not more than two of the individual weight deviates from the average weight by ± 10% and none should deviate by more than twice that percentage. The weight variation test would be a satisfactory method of determining the drug content uniformity.

The percent deviation was calculated using the following formula:

$$\%\ Deviation = \frac{Individual\ weight - Average\ weight}{Average\ weight} \times 100$$

### Tablet Thickness

The Thickness and diameter of the tablets was determined using a Digital Vernier caliper. Ten tablets from each formulation were taken and average values were calculated.

### Tablet Hardness

Tablet hardness is defined as the force required to break a tablet. Tablets require a certain amount of strength, or hardness and resistance to withstand the mechanical shocks during handling, manufacturing, packaging and shipping. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. Six tablets were taken from each formulation and hardness was determined using Monsanto hardness tester and the average was calculated and was expressed in Kg/cm2.

### Friability Test

The percent loss of drug due to small mechanical forces during handling and shipping can be measured by using Roche friabilator consisting of a plastic chamber which revolves at a speed of 25rpm for 4 minutes. In each revolution the tablets were dropped from a height of 6 inches. For this test 10 tablets were selected from each batch and weighed accurately (Wi) and allowed to rotate for 4 min for 100 revolutions. Finally these were removed from

chamber dedusted and weighed again (Wf). The % loss can be calculated using the following formula,

$$\% \, Loss = \frac{Wi - Wf}{Wi} \times 100$$

**Uniformity of drug content**

5 tablets were powdered in a glass mortar and 100 mg of powder was placed in a 100 ml conical flask. The drug was extracted with 0.1N HCl with vigorous shaking on a mechanical gyratory shaker (100 rpm) for 5 hour and filtered into 50 ml volumetric flask through cotton wool. 10ml of above filtrate was diluted to 100ml with 0.1 N HCl and absorbance was measured at 245 nm against blank using UV Visible spectrophotometer.

***In vitro* buoyancy studies**

The *in vitro* buoyancy was determined by floating lag time.[6,7] The tablets were placed in 250ml beaker containing 200ml of 0.1N HCl. The time taken for a tablet to float to the surface of 0.1N HCl was determined as Floating lag time and the period up to which the tablet remained floating is determined as Total floating time.

**Swelling Index**

The swelling property of tablets was measured in terms of % weight gain. One tablet from each formulation weighed (Wi) and kept in a petridish containing 0.1N HCl. At regular one hr time interval for about 6hrs tablet was withdrawn and excess liquid on the tablet surface was removed carefully using a tissue paper. Then the swollen tablet was weighed again (Wf). The swelling index calculated using the following formula[7,8]

$$\% \, Swelling \, Index = \frac{Wf - Wi}{Wi} \times 100$$

***In vitro* dissolution studies[9]**

The *In Vitro* drug release studies were performed using USP type II (Paddle) apparatus at a rotational speed of 100rpm. 900ml 0.1N HCl used as dissolution medium maintained at a temperature of $37^0$ C ± $0.5^0$ C. A sample of 10ml was withdrawn at a specified time interval for about 24hrs and the same was replaced with pre warmed fresh dissolution media. The collected samples were filtered through Whatman filter paper and diluted if required with 0.1N HCl. Absorbance of these samples were measure at 245nm using UV Visible spectrophotometer.

**Curve fitting analysis**

The mechanism of drug release from the floating tablets was studied by fitting the dissolution data of optimized formulation in following models.

1. Zero order – Cumulative % drug release Vs Time
2. First order – Log cumulative % drug release Vs Time
3. Higuchi model – Cumulative % drug release Vs Square root of time
4. Korsemeyer and peppas equation – Log cumulative % drug release Vs log time

The mechanism of drug release was decided based on the slope and $R^2$ values obtained from above models.[10]

## RESULTS AND DISCUSSION

### Standard Graph of Alfuzosin HCl

The standard graph of Alfuzosin was plotted as per the experimental method using 0.1N HCl which showed good linearity and obeys "Beer – Lamberts" law.

**Table No. 2: Standard graph of Alfuzocin HCl.**

| S.NO | Concentration (µg/ml) | Absorbance |
|---|---|---|
| 1 | 0 | 0.000 |
| 2 | 2 | 0.171 |
| 3 | 4 | 0.3746 |
| 4 | 6 | 0.5676 |
| 5 | 8 | 0.745 |
| 6 | 10 | 0.9286 |

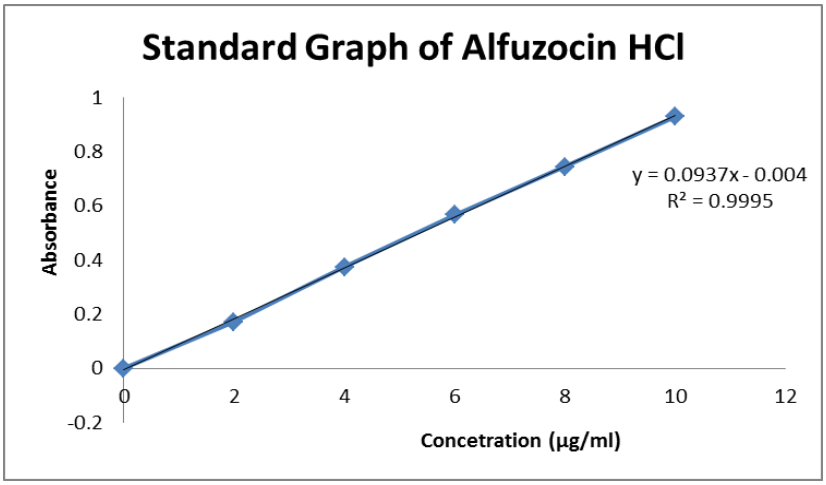



**Fig. No 1: Standard Graph of Alfuzocin HCl.**

**Precompression parameters**

The results of Precompression parameters were performed and presented in table no 3 indicating as per limit.

**Table No. 3: Precompression parameters of powder blend of Alfuzocin HCl.**

| Formulation code | Angle of repose (º) ± S.D | Bulk density ± S.D | Tapped density ± S.D | Carr′s index(%) ± S.D | Hausner′s ratio ± S.D |
|---|---|---|---|---|---|
| F1 | 25.49±0.72 | 0.214±0.01 | 0.251±0.01 | 14.74±0.42 | 1.17±0.01 |
| F2 | 26.24±0.71 | 0.308±0.01 | 0.364±0.02 | 15.38±0.67 | 1.18±0.04 |
| F3 | 29.05±0.73 | 0.276±0.04 | 0.322±0.02 | 14.28±0.56 | 1.16±0.02 |
| F4 | 29.25±0.211 | 0.324±0.02 | 0.376±0.05 | 13.82±0.28 | 1.16±0.11 |
| F5 | 32.27±0.21 | 0.320±0.06 | 0.397±0.04 | 19.39±0.68 | 1.24±0.03 |
| F6 | 33.65±0.22 | 0.521±0.04 | 0.629±0.04 | 17.17±0.44 | 1.20±0.03 |
| F7 | 33.21±0.81 | 0.518±0.04 | 0.627±0.02 | 17.38±0.71 | 1.21±0.02 |
| F8 | 25.56±0.17 | 0.422±0.02 | 0.506±0.01 | 16.60±0.37 | 1.19±0.10 |
| F9 | 28.758±0.33 | 0.481±0.01 | 0.572±0.03 | 15.90±0.59 | 1.18±0.02 |
| F10 | 27.33±0.32 | 0.475±0.03 | 0.566±0.04 | 16.07±0.43 | 1.19±0.02 |
| F11 | 25.38±0.12 | 0.524±0.05 | 0.599±0.01 | 12.52±0.14 | 1.14±0.04 |
| F12 | 26.43±0.16 | 0.412±0.01 | 0.483±0.01 | 14.69±0.28 | 1.17±0.01 |
| F13 | 24.77±0.28 | 0.488±0.05 | 0.537±0.02 | 9.12±0.55 | 1.10±0.04 |
| F14 | 26.42±0.67 | 0.439±0.02 | 0.521±0.03 | 15.73±0.34 | 1.18±0.02 |
| F15 | 31.68±0.19 | 0.361±0.13 | 0.514±0.23 | 29.77±0.24 | 1.42±0.08 |

**Post compression parameters**

**Table No. 4: Post compression parameters of Alfuzocin HCl tablets.**

| Formulation Code | Hardness ($kg/cm^2$) ± S.D | Thickness (mm) ± S.D | Weight (mg) ± S.D | Friability (%) ± S.D | Drug content (%) ± S.D |
|---|---|---|---|---|---|
| F1 | 5.50±0.44 | 5.08±0.17 | 519.8±1.48 | 0.36±0.01 | 98.25±1.37 |
| F2 | 5.70±0.31 | 5.11±0.25 | 500.4±0.54 | 0.39±0.01 | 95.28±0.80 |
| F3 | 5.58±0.40 | 5.10±0.80 | 506±0.41 | 0.43±0.03 | 99.12±2.47 |
| F4 | 7.25±0.57 | 5.38±0.66 | 520±1.14 | 0.44±0.02 | 100.24±1.25 |
| F5 | 6.0±0.30 | 5.33±0.25 | 511±0.83 | 0.48±0.03 | 99.53±1.87 |
| F6 | 7.5±0.57 | 5.24±0.71 | 499.9±0.67 | 0.34±0.01 | 98.8±1.99 |
| F7 | 6.41±0.60 | 5.32±0.89 | 515.0±0.43 | 0.37±0.02 | 95.35±1.14 |
| F8 | 6.50±0.44 | 5.38±0.73 | 520.5±0.80 | 0.37±0.01 | 96.34±2.18 |
| F9 | 6.05±0.31 | 5.20±0.68 | 512.2±0.83 | 0.42±0.01 | 97.29±0.98 |
| F10 | 6.08±0.37 | 5.48±0.88 | 502.1±0.93 | 0.48±0.03 | 97.35±0.43 |
| F11 | 6.41±0.70 | 5.21±0.36 | 518.2±0.97 | 0.15±0.01 | 98.88±0.88 |
| F12 | 7.33±0.50 | 5.26±0.46 | 505.2±0.83 | 0.27±0.02 | 96.7±1.22 |
| F13 | 7.58±0.57 | 5.48±0.38 | 502.2±0.92 | 0.29±0.02 | 99.8±2.09 |
| F14 | 6.75±0.77 | 5.25±0.37 | 499.0±1.22 | 0.33±0.03 | 99.54±2.15 |
| F15 | 6.27±0.25 | 5.34±0.28 | 497±0.73 | 0.39±0.07 | 97.25±0.59 |

***In vitro* buoyancy studies**

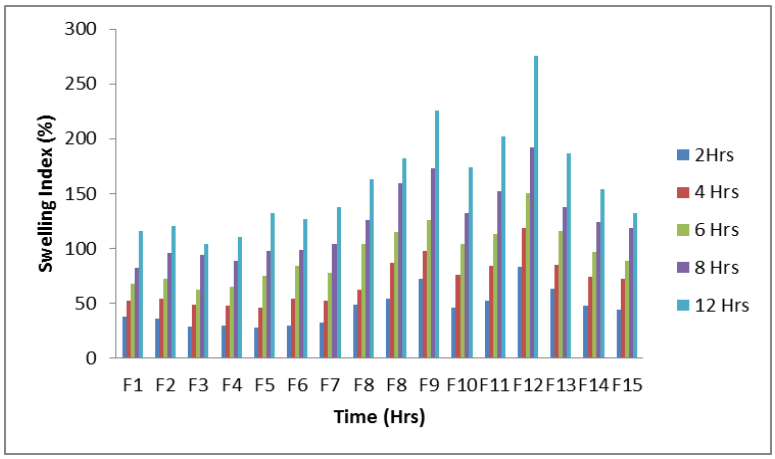
**Table No. 5: Buoyancy character of Alfuzosin HCl.**

| Formulation Code | Floating lag time (sec) | Total floating time (hrs) |
|---|---|---|
| F1 | 196 | >12 |
| F2 | 218 | >12 |
| F3 | 230 | >12 |
| F4 | 183 | >12 |
| F5 | 179 | >12 |
| F6 | 165 | >12 |
| F7 | 220 | >12 |
| F8 | 205 | >12 |
| F9 | 196 | >12 |
| F10 | 147 | >12 |
| F11 | 138 | >12 |
| F12 | 125 | >12 |
| F13 | 105 | >12 |
| F14 | 122 | >12 |
| F15 | 142 | >12 |

**Swelling Index**

**Table No. 6: % Swelling index of Alfuzocin HCl.**

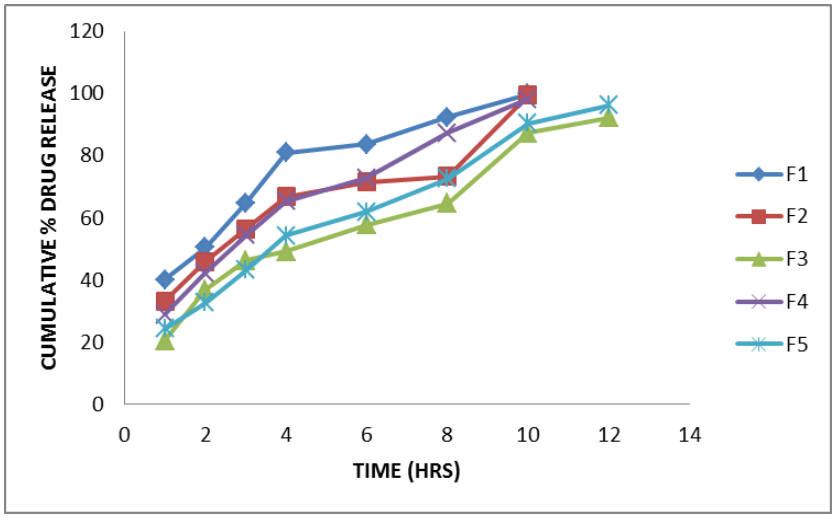
| Time (hr) | Swelling Index (%) | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F8 | F9 | F10 | F11 | F12 | F13 | F14 | F15 |
| 2 | 38 | 36 | 29 | 30 | 28 | 30 | 32 | 49 | 54 | 72 | 46 | 52 | 83 | 63 | 48 | 44 |
| 4 | 52 | 54 | 49 | 48 | 46 | 54 | 52 | 62 | 87 | 98 | 76 | 84 | 119 | 85 | 74 | 72 |
| 6 | 68 | 72 | 62 | 65 | 75 | 84 | 78 | 104 | 115 | 126 | 104 | 113 | 150 | 116 | 97 | 89 |
| 8 | 82 | 96 | 94 | 89 | 98 | 99 | 104 | 126 | 159 | 173 | 132 | 152 | 192 | 138 | 124 | 119 |
| 12 | 116 | 120 | 104 | 110 | 132 | 127 | 138 | 163 | 182 | 226 | 174 | 202 | 276 | 187 | 154 | 132 |

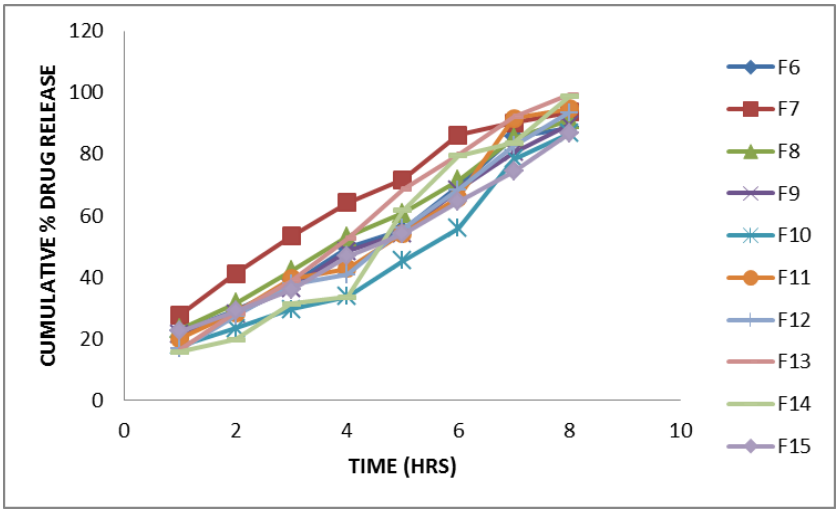



***In vitro* drug release studies**

**Table No. 7: Cumulative % drug release of Alfuzosin HCl floating tablets.**

| Time (hr) | Cumulative % drug release | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 | F11 | F12 | F13 | F14 | F15 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 40 ± 1.22 | 33.1± 0.78 | 20.5± 1.03 | 28.8± 0.78 | 24.3± 0.64 | 22.4± 0.61 | 27.7± 0.78 | 23.2± 0.64 | 21.3± 0.61 | 17.8± 1.66 | 20.1± 1.77 | 16.7± 1.34 | 16.4± 2.81 | 15.8 ± 1.67 | 22.4 ± 0.88 |
| 2 | 50.4± 0.37 | 45.8± 0.66 | 36.9± 0.87 | 42.3± 0.62 | 32.6± 0.52 | 29.1± 0.45 | 41.2± 0.62 | 31.5± 0.52 | 28.1± 0.45 | 23.4± 1.98 | 28.5± 0.75 | 27.4± 0.69 | 28.4± 0.29 | 19.8 ± 0.76 | 28.98 ± 0.72 |
| 3 | 64.8± 0.96 | 56.4± 0.53 | 46.2± 0.56 | 54.5± 0.52 | 43.1± 0.53 | 37.6± 0.52 | 53.4± 0.52 | 42.1± 0.53 | 36.5± 0.52 | 29.5± 0.13 | 39.5± 0.33 | 37.7± 0.56 | 38.8± 1.76 | 31.3 ± 0.19 | 35.84 ± 0.67 |
| 4 | 81± 0.74 | 66.8± 0.34 | 49.1± 0.45 | 65.4± 0.31 | 54.3± 0.34 | 49.5± 0.35 | 64.3± 0.31 | 53.2± 0.34 | 48.5± 0.35 | 33.8± 0.26 | 42.8± 2.95 | 40.8± 0.99 | 52.6± 0.51 | 33.6 ± 2.54 | 46.78 ± 0.46 |
| 6 | 83.7± 1.22 | 71.5± 0.18 | 57.6± 0.79 | 72.7± 0.19 | 61.8± 0.18 | 55.3± 0.19 | 71.6± 0.19 | 60.7± 0.18 | 54.3± 0.19 | 45.4± 0.76 | 54.3± 0.19 | 55.8± 0.59 | 68.6± 0.56 | 61.6 ± 0.45 | 53.98 ±0.78 |
| 8 | 92.3± 0.87 | 73.3± 0.77 | 64.6± 0.34 | 87.3± 0.87 | 72.5± 0.74 | 69.5± 0.64 | 86.2± 0.87 | 71.4± 0.74 | 68.4± 0.64 | 55.8± 2.45 | 65.9± 0.71 | 68.4± 1.57 | 79.9± 0.42 | 79.4 ± 0.73 | 64.67 ± 0.47 |
| 10 | 99.8± 0.54 | 99.4± 0.89 | 87.3± 0.45 | 98.1± 0.54 | 90.4± 0.44 | 85.6± 0.55 | 90.1± 0.54 | 85.3± 0.44 | 80.6± 0.55 | 78.3± 0.87 | 91.6± 0.82 | 82.8± 0.91 | 92.1± 0.56 | 83.6 ± 0.38 | 74.33 ± 0.67 |
| 12 | | | 92.1± 0.74 | | 96.1± 0.54 | 88.6± 0.81 | 93.6± 0.61 | 91.1± 0.54 | 89.5± 0.81 | 86.7± 0.65 | 94.7± 2.09 | 93.4± 0.41 | 99.2± 1.93 | 98.8 ± 0.61 | 86.78 ± 0.73 |




**Kinetic study**

**Table No. 8: Drug release Kinetics of optimized formulation of Alfuzosin HCl floating Tablets.**

| Formulations | Zero order $R^2$ | First order $R^2$ | Korsmeyer – peppas $R^2$ | Korsmeyer – peppas N | Higuchi $R^2$ |
|---|---|---|---|---|---|
| F13 | 0.965 | 0.842 | 0.992 | 0.735 | 0.995 |

## CONCLUSION

Alfuzocin HCl floating tablets were formulated in to different batches using various concentrations of synthetic and natural polymers by direct compression method. All the formulations were evaluated for pre and post compression parameters. All the formulations had shown all the parameters within the limit. It was observed that the increasing concentration of polymers had a retarding effect on the drug release from the polymer matrices. The HPMC K4M in combination with guar gum in F13 formulation having

prominent role in drug release and was selected as optimized formulation for further invivo evaluation.

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