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RESEARCH ARTICLE

# Formulation and Evaluation of Fast Dissolving Tablet of Atenolol

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## ABSTRACT

The objective of this study was to formulate & evaluate Fast dissolving tablet of atenolol. Tablets of Atenolol were prepared by direct compression method using super disintegrants polymers like sodium starch glycolate, croscarmellose sodium, crospovidone in different ratios and their combinations. Fast dissolving tablets were evaluated by different methods for parameters such as thickness, Diameter, hardness, friability, weight variation, drug content, wetting time, *In-vitro* disintegration time, In-vitro dispersion time, In-vitro drug release, stability studies, drug-excipient compatibility studies like FTIR, DSC. The tablets were evaluated for *in vitro* release in pH 1.2 phosphate buffer for 30 mins in standard dissolution apparatus. Drug release was increased with increase in the concentration of Crospovidone and their combination with other super disintegrants. In order to determine the mode of release, the data was subjected to Zero order, First order, Higuchi and Peppas diffusion model. Short term stability studies on the promising formulations indicated that there are no significant changes in drug content, hardness, *in vitro* dissolution characteristics. IR spectroscopic studies indicated that there are no drug-excipient interactions. The prepared fast dissolving tablets of Atenolol could release the drug from tablet within the criteria of fast dissolving tablet.

## KEYWORDS

Fast Dissolving Tablet, superdisintegrants polymers, Atenolol, sodium starch Glycolate, croscarmellose sodium, crospovidone

## INTRODUCTION

Oral route is most preferred route by medical practitioners and manufacturer due to highest acceptability of patients. Oral routes of drug administration have worldwide acceptance up to 50-60% of total dosage forms. However, many patients groups, such as the elderly, children and patients who are mentally retarded, paediatric, geriatric, and bedridden, non-cooperative, nauseated or on reduced liquid intake/diets have difficulties swallowing these dosage forms. Patients with persistent nausea, who are travelling, or who have little or no access to water are also good candidates for FDDTs.[1]

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Fast dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva. The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form.[2] Atenolol, a beta-blocker used in the treatment of hypertension and angina pectoris. It is incompletely absorbed from the gastrointestinal tract and has an oral bioavailability of only 50%, while the remaining is excreted unchanged in faeces. Peak plasma concentration is reached in 2-4 hours. This is because of its poor absorption

in lower gastrointestinal tract. It undergoes hepatic first pass metabolism and its elimination half-life is 6 to 7 hours. Atenolol results in poor bioavailability when administered in the form of conventional tablets because of hepatic first pass metabolism and exhibit fluctuation in the plasma drug level resulting in reduction in drug concentration at receptor site. By this attempt was made to develop Fast dissolving tablets of atenolol since it was not available in such dosage form. In this present study, an attempt was made to develop fast dissolving tablets by direct compression method by using superdisintegrants such as Crospovidone croscaremellose, sodium starch glycolate.[3]

## MATERIAL AND METHODS

Atenolol was obtained as gift sample from Emcure Pharmaceuticals, Pune. Crospovidone and Croscaremellose from S.D. Fine chem. Ltd, Mumbai.Sodium Starch glycolate From Loba Chem, Mumbai. All other chemicals and solvents used were of analytical grade.

### Drug Excipient Compatibility Study by FTIR

Compatibility of the drug with the excipients is determined by subjecting the physical mixture of the drug and the excipient of the main formulation to infrared absorption spectral analysis (FTIR). Any changes in chemical composition of the drug after combining it with the excipients were investigated with I.R. spectral analysis. Weighed amount of drug (3mg) was mixed with 100mg of potassium bromide (dried at 40-50oC). The mixture was taken and compressed under 10-ton pressure in a hydraulic press to form a transparent pellet. The pellet was scanned by IR spectrophotometer.

### Drug Excipient Compatibility Study by DSC

DSC studies were carried out pure drug Atenolol and best formulations like, F3, F8 and F14 DSC scan of about 5 mg; accurately weighed Atenolol and optimized formulations were performed by using an automatic thermal analyzer system. (DSC60 Shimadzu Corporation, Japan) Sealed and perforated aluminium pans were used in the experiments for all the samples. Temperature calibrations were performed using indium as standard. An empty pan sealed in the same way as for the sample was used as a reference. The entire samples were run at a scanning rate of 10°C/min from 0-300°C.

### Formulation of Fast Dissolving Tablet

Tablets were prepared by Dry granulation method. Drug and excipients quantity of each ingredient was taken for each specified formulation were mentioned in Table 1. All ingredients were sifted through sieve no.60. Then these ingredients were subjected to grinding to a required degree of fineness (except magnesium stearate and talc). Finally magnesium stearate and talc was added to prepared blend. The mixed blend of drug and excipients was compressed using a single punch tablet punching machine at 30 PCI to produce convex faced tablets, weighing 100 mg each with a diameter of 2mm.A minimum of 20 tablets were prepared for each batch.

### Evaluation Parameters

#### *Pre Compression Evaluations*

#### *Angle of Repose*[4]

Angle of repose was determined using fixed funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and the angle of repose (ɵ) was calculated using the formula.

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

#### *Bulk Density*[5]

Bulk density was determined by pouring the blend into a graduated cylinder. The bulk volume (V) and weight of the powder (M) was determined. The bulk density was calculated by using the below mentioned formula,

$$\text{Bulk density} = \frac{\text{Mass of granules}}{\text{Volume of granules}}$$

#### *Tapped Density*[5]

The measuring cylinder containing a known mass of blend was tapped for a fixed time.

Table 1: Composition of fast dissolving tablets

| Ingredients | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 | F11 | F12 | F13 | F14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Atenolol | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| Cross Povidone | ___ | 5 | 10 | ___ | ___ | ___ | ___ | 5 | ___ | 5 | 5 | ___ | 5 | 5 |
| Croscaremellose | ___ | ___ | ___ | 5 | 10 | ___ | ___ | 5 | 5 | ___ | 5 | 5 | ___ | 5 |
| Sodium Starch Glycolate | ___ | ___ | ___ | ___ | ___ | 5 | 10 | ___ | 5 | 5 | ___ | 5 | 5 | 5 |
| Mannitol | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 45 |
| Micro crystalline cellulose | 20 | 15 | 10 | 15 | 10 | 15 | 10 | 10 | 10 | 10 | 08 | 08 | 08 | 10 |
| Sodium Saccharine | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Talc | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 2 |
| Magnesium Stearate | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 2 |
| Total (mg/tablet) | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |

The minimum volume (Vt) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density was calculated using the following formula,

$$\text{Tapped density} = \frac{\text{Weight of the blend}}{\text{Volume occupied in the cylinder (Vt)}}$$

***Compressibility Index[6]***

The simplest way for measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility index (I) which is calculated as follows,

$$I = \frac{Vo - Vt}{Vbx}$$

Here, Vo is bulk volume and Vt is tapped volume. The value below 15% indicates a powder with usually give rise to good flow characteristics, whereas above 25% indicate poor flowability.

***Hausner's Ratio[6]***

Hausner's ratio is an indirect index of ease of powder flow. It is calculated by the following formula,

$$\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Lower Hausner's ratio (<1.25) indicates better flow properties than higher ones (>1.25).

The physical properties of granules were shown in Table 2.

### *Post Compression Evaluations[7, 8]*

### *Weight Variation Test*

Twenty tablets were selected randomly and average weight was determined. Then individual tablets were weighed and was compared with average weight. The comparison variation within the I.P limits, it passes the weight variation test.

### *Tablet Hardness*

Tablet crushing strength (Fc) or hardness, the force required to break a tablet in a diametric compression, was measured using Monsanto tablet hardness tester.

### *Thickness & Diameter*

The thickness and diameter of individual tablets was measured using Vernier caliper, which permits accurate measurements and provides information of the variation between tablets.

### *Tablet Friability*

The friability of the tablets was measured in a Roche friabilator. Tablets of a known weight (W0) or a sample of 20 tablets were dedusted in a drum for a fixed time (100 revolutions) and weighed (W) again. Percentage friability was calculated from the loss in weight as given in equation as below. The weight loss should not be more than 1%. Determination was made in triplicate.

$$\% \text{ friability} = \frac{W0 - W}{W0}$$

### *In-Vitro Disintegration Time*

The test for disintegration was carried out in Electrolab USP disintegration test apparatus. It consists of 6 glass tubes which are 3 inches long, open at the top, and held against a 10 mesh screen, at the bottom end of the basket rack assembly. To test the disintegration time of tablets, one tablet was placed in each tube and the basket rack was positioned in a 1 litter beaker containing pH 1.2 buffer solution at 37°C ± 1°C such that the tablet remains 2.5 cm below the surface of the liquid. The time taken for the complete disintegration of the tablets was noted.

### *Wetting Time*

A piece of tissue paper (12 cm X 10.75) folded twice was placed in a Petri dish (internal diameter = 9 cm) containing 9 ml of water. A tablet was placed on the paper and the time taken for complete wetting was noted. Three tablets from each formulation were randomly selected and the average wetting time was noted.

### *In Vitro Dispersion Time*

In vitro dispersion time was measured by dropping a tablet into a petridish containing 10ml of phosphate buffer pH 1.2 solutions. Three tablets from each formulation were randomly selected and tested. In vitro dispersion time was found and expressed in seconds.

### *Drug Content Uniformity*

The tablets were tested for their drug content uniformity. At random 20 tablets were weighed and powdered. The powder equivalent to 100 mg was weighed accurately and dissolved in 100ml of 0.1 N HCl. Its concentration 1000 mcg/ml. The undissolved matter was removed by filtration through Whatmann No.41 filter paper. 10ml from the stock solution taken and diluted to 100ml buffer, it makes 100µg/ml. Then the dilute the solution to obtain 10µg solution. The absorbance of the diluted solutions was measured at 224.2 nm. The concentration of the drug was computed from the standard curve.

### *Dissolution Studies[9]*

*In Vitro* dissolution studies for all the prepared tablets was carried out using USP paddle method at 50 rpm in 900 ml 1.2 pH buffer as dissolution media, maintained at 37 ± 0.5°. 5 ml of sample was withdrawn from the dissolution medium at 5 min interval for 30mins filtered through

Whattmann filter paper and assayed spectrophotometrically at 224.2 nm. An equal volume of prewarmed (37ºC) fresh medium was replaced into the dissolution medium after each sampling, to maintain the constant volume throughout the test. Then the cumulative percentage of drug release was calculated and represent graphically.

**Kinetic Release Study[10]**

The release data were fitted to various mathematical models as under to know which model is best fitting the obtained release profile.

1) Zero order release kinetics

2) First order release kinetics

3) Higuchi model

4) Korsmeyer-Peppas model.

**Stability Studies[11,12]**

The selected formulations were packed in bottles, which are tightly plugged with cotton and capped. They were then stored at 400C / 75% RH for 45 day and evaluated for their hardness, friability, disintegration time and In vitro drug release.

## RESULTS AND DISCUSSION

**Drug Excipient Compatibility Study by FTIR**

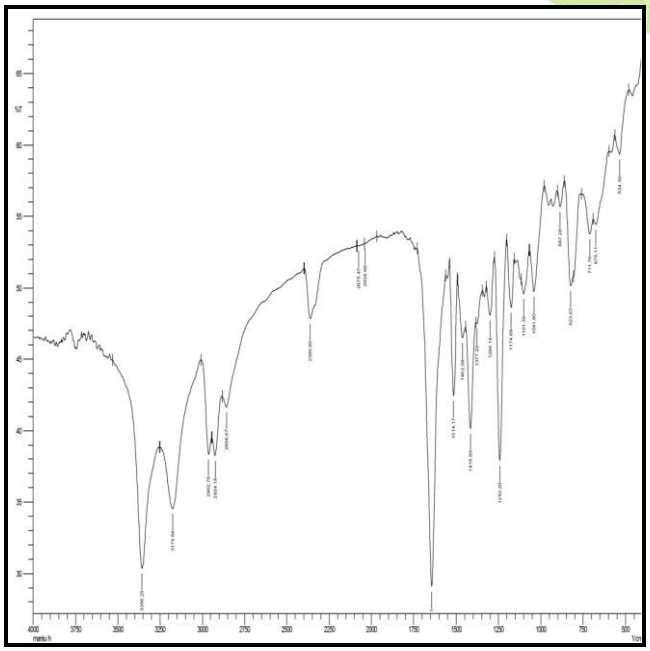

Figure 1: FT-IR of Atenolol

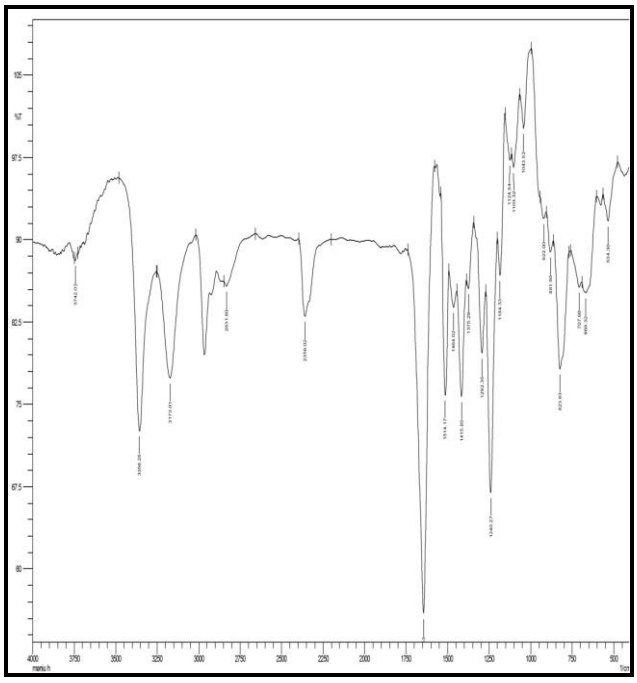

Figure 2: FT-IR of Atenolol + crospovidone(F3)

Compatibility studies were performed using FTIR spectrophotometer. The FTIR spectrum of pure drug and physical mixture of drug and excipients were studied. The characteristic absorption peaks of Atenolol were obtained at 3336.2 cm-1 (NH Amine), 2962.7 cm-1(CH Alanes), 1645 cm-1(Aromatic Ring C=O), 1242 cm-1(C-O Stretch) and In the present study, it has been observed that there is no chemical interaction between atenolol and the excipients used. From the IR spectrum no 1 & 2.

**Drug Excipient Compatibility Study by DSC**

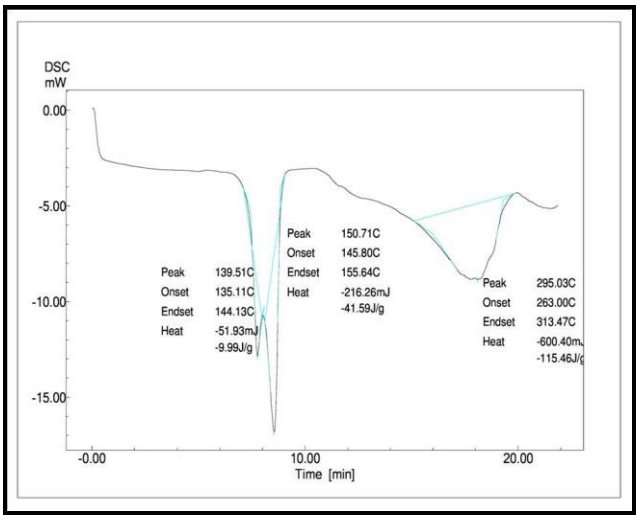


Figure 3: DSC of Atenolol (pure drug)

 

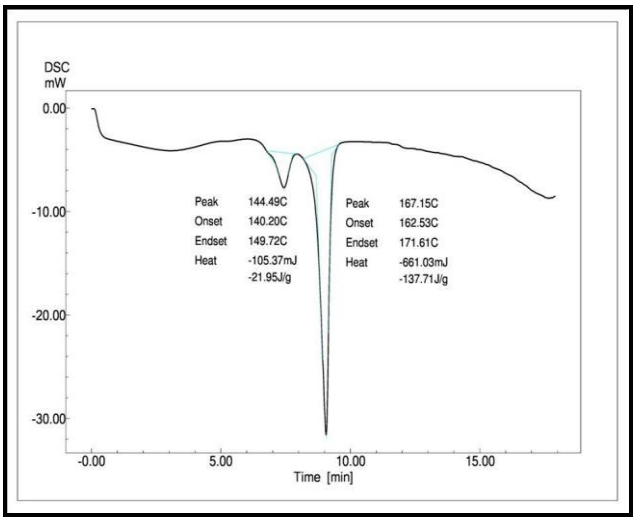


Figure 4: DSC of F3 Formulation

DSC studies were carried out pure drug Atenolol and best formulations like F3. The entire samples were run at a scanning rate of 10°C/min from 0-300°C. The thermogram of pure drug Atenolol shows endothermic peak corresponding to the temperature 150°C to 155°C.This temperature is an agreement with reported literature value of the Atenolol drug which is in the range of 152-155°C.

The DSC thermograms of formulation F3 also exhibit the characteristic endothermic peak corresponding to the temperature 167°C to 171°C for the polymers and Atenolol drug respectively almost in the same range of temperature (Shown in Fig.3). The slight variation in the nature of peaks may be due to the combination of two or more polymers and excipients used.

## Evaluation Paramaters

### *Precompression Evaluations*

The prepared tablets were subjected for precompression properties. The results of Bulk density and tapped density are in the range of 0.3372 to 0.3680gm/cc and 0.3915 to 0.460gm/cc respectively. By using these two density data, Hausner's ratio and compressibility index was calculated. The compressibility correlation data indicated a fairly good flowability of the powder blend. The good flowability of the powder blend was also evidenced with angle of repose (range of 24 – 32º), which is below 40º indicating good flowability. Micromeretic results of the all batches were shown in Table 2.

Table 2: Evaluation of Pre-Compression Parameters

| Formulation Code | Bulk Density (g/cc) | Tapped Density (g/cc) | Angle of Repose (degree) | Carr's Index (%) | Hausner's Ratio |
|---|---|---|---|---|---|
| **F1** | 0.3372 ± 0.5 | 0.4122 ± 1.0 | 25.45 ± 0.24 | 1.22 ± 0.20 | 18.19 ± 0.50 |
| **F2** | 0.3600 ± 0.23 | 0.4235 ± 0.50 | 24.44 ± 1.20 | 1.17 ± 0.08 | 14.99 ± 0.4 |
| **F3** | 0.3427 ± 0.22 | 0.3968 ± 0.25 | 26.56 ± 1.50 | 1.15 ± 0.25 | 13.63 ± 0.5 |
| **F4** | 0.3390 ± 0.04 | 0.4144 ± 0.27 | 24.94 ± 0.43 | 1.22 ± 1.00 | 18.19 ± 0.8 |
| **F5** | 0.3372 ± 0.06 | 0.4364 ± 1.50 | 23.05 ± 0.10 | 1.29 ± 1.50 | 22.73 ± 0.7 |
| **F6** | 0.3680 ± 0.38 | 0.4600 ± 0.46 | 25.45 ± 0.18 | 1.25 ± 0.04 | 20.0 ± 0.10 |
| **F7** | 0.3381 ± 0.50 | 0.3915 ± 0.23 | 24.94 ± 0.08 | 1.06 ± 0.25 | 13.63 ± 0.5 |
| **F8** | 0.3660 ± 0.05 | 0.4305 ± 0.06 | 22.20 ± 0.50 | 1.17 ± 0.50 | 14.98 ± 0.5 |
| **F9** | 0.3418 ± 0.40 | 0.3957 ± 0.22 | 22.20 ± 0.25 | 1.15 ± 0.50 | 13.62 ± 0.45 |

| | | | | | |
|---|---|---|---|---|---|
| **F10** | 0.3400 ± 0.24 | 0.4155 ± 1.20 | 24.44 ± 0.50 | 1.22 ± 0.25 | 18.17 ± 0.50 |
| **F11** | 0.3381 ± 0.08 | 0.4133 ± 1.00 | 23.49 ± 1.20 | 1.22 ± 1.30 | 18.19 ± 0.8 |
| **F12** | 0.3680 ± 0.15 | 0.4600 ± 1.43 | 24.94 ± 0.34 | 1.25 ± 0.45 | 20 ± 0.40 |
| **F13** | 0.3372 ± 0.08 | 0.4364 ± 0.24 | 22.61 ± 1.20 | 1.29 ± 0.24 | 22.73 ± 0.45 |
| **F14** | 0.3381 ± 0.26 | 0.4133 ± 0.28 | 23.96 ± 0.50 | 1.22 ± 0.07 | 18.19 ± 0.15 |

Table 3: Evaluation of Physical Parameters of Fast dissolving tablet of Atenolol

| **Formulation Code** | **Thickness (mm)** | **Diameter (mm)** | **Hardness (kg/cm$^2$)** | **Friability (%)** | **Weight variation test (%)** |
|---|---|---|---|---|---|
| **F1** | 1.93 ± 0.45 | 2.150 ± 0.30 | 4.2 ± 0.0 | 0.27 ± 0.7 | 101 ± 1.5 |
| **F2** | 1.90 ± 0.10 | 2.153 ± 0.14 | 2.4 ± 0.50 | 0.33 ± 0.20 | 100 ± 0.6 |
| **F3** | 1.42 ± 0.25 | 2.145 ± 0.50 | 2.3 ± 0.03 | 0.17 ± 1.30 | 101 ± 1.5 |
| **F4** | 1.97 ± 0.50 | 2.151 ± 0.03 | 3.3 ± 0.03 | 0.19 ± 0.01 | 100 ± 0.6 |
| **F5** | 1.47 ± 0.8 | 2.147 ± 0.30 | 3.4 ± 0.0 | 0.24 ± 0.10 | 100 ± 0.6 |
| **F6** | 1.42 ± 0.30 | 2.146 ± 0.50 | 3.2 ± 0.0 | 0.21 ± 0.4 | 100 ± 0.6 |
| **F7** | 1.92 ± 1.20 | 2..151 ± 0.90 | 4.6 ±0.0 | 0.24 ± 0.06 | 101 ± 1.7 |
| **F8** | 1.48 ± 0.8 | 2.145 ± 1.27 | 3.3 ± 0.10 | 0.30 ± 0.45 | 101 ± 0.8 |
| **F9** | 1.91 ± 0.09 | 2.151 ± 0.80 | 3.8 ± 0.10 | 0.24 ± 0.5 | 101 ± 1.4 |
| **F10** | 1.91 ± 0.15 | 2.150 ± 1.00 | 3.3 ± 0.03 | 0.38 ± 1.2 | 100 ± 1.0 |
| **F11** | 1.47 ± 0.5 | 2.149 ± 1.10 | 3.4 ± 0.10 | 0.23 ± 0.4 | 101 ± 1.5 |
| **F12** | 1.93 ± 0.02 | 2.153 ± 0.70 | 3.5 ±0.03 | 0.30 ± 0.7 | 100 ± 1.6 |
| **F13** | 1.93 ± 0.3 | 2.153 ± 0.3 | 3.5 ± 0.13 | 0.21 ± 0.9 | 100 ± 0.2 |
| **F14** | 1.90 ± 0.40 | 2.150 ± 0.0 | 3.3 ± 0.10 | 0.27 ± 0.3 | 101 ± 0.0 |

**Post Compression Evaluations**

The prepared tablets were subjected for post compression properties, the thickness of tablet is in range 1.42 to 1.93 mm and diameter is 2.145 to 2.155 mm. The hardness of the tablets between 2.3 and 4.65, friability of the all batch tablets were found below 1% indicating good mechanical resistance of tablets and weight variation also passes the test according to IP Limits.

The drug content was found in the range of 99.74 – 100.70%.

The disintegration time were found to be in range of 12 ± 0.50 to 92 ± 0.66 sec, wetting time 9 ± 0.34 to 57 ± 0.17 sec, and dispersion time 10 ± 0.16 sec.

The results of these parameters were found to be within the prescribe limits and satisfy the criteria of Fast dissolving tablets.

Table 4: Evaluation of Physical Parameters of Fast dissolving tablet of Atenolol

| Formulation Code | Disintegration time (Sec) | Wetting time (Sec) | Dispersion time(Sec) | Drug Content (%) |
|---|---|---|---|---|
| **F1** | 218 ± 0.0 | 148 ± 1.17 | 164 ± 1.17 | 97.4 ± 0.4 |
| **F2** | 24 ± 0.50 | 17 ± 0.5 | 17 ± 0.50 | 99.2 ± 0.5 |
| **F3** | 12 ± 0.34 | 9 ± 0.34 | 10 ± 0.16 | 100.3 ± 1.2 |
| **F4** | 91 ± 0.16 | 71 ± 0.33 | 67 ± 1.50 | 99.6 ± 0.3 |
| **F5** | 73 ± 0.33 | 60 ± 0.50 | 58 ± 0.33 | 98.5 ± 0.23 |
| **F6** | 80 ± 0.17 | 60 ± 0.84 | 71 ± 0.34 | 98.1 ± 0.33 |
| **F7** | 68 ± 0.50 | 61 ± 0.50 | 56 ± 0.00 | 99.8 ± 0.09 |
| **F8** | 36 ± 0.34 | 19 ± 0.17 | 23 ± 0.34 | 99.2 ± 0.23 |
| **F9** | 58 ± 0.33 | 25 ± 0.0 | 42 ± 0.90 | 98.7 ± 0.50 |
| **F10** | 61 ± 0.16 | 42 ± 0.67 | 46 ± 1.00 | 98.3 ± 0.4 |
| **F11** | 72 ± 0.17 | 53 ± 0.00 | 61 ± 0.83 | 99.4 ± 0.62 |
| **F12** | 92 ± 0.66 | 57 ± 0.17 | 71 ± 0.0 | 99.8 ± 0.7 |
| **F13** | 43 ± 0.50 | 27 ± 0.17 | 38 ± 1.67 | 100.7 ± 0.14 |
| **F14** | 35 ± 0.30 | 21 ± 0.10 | 27 ± 0.17 | 99.8 ± 0.5 |

***In Vitro Drug Release Study***

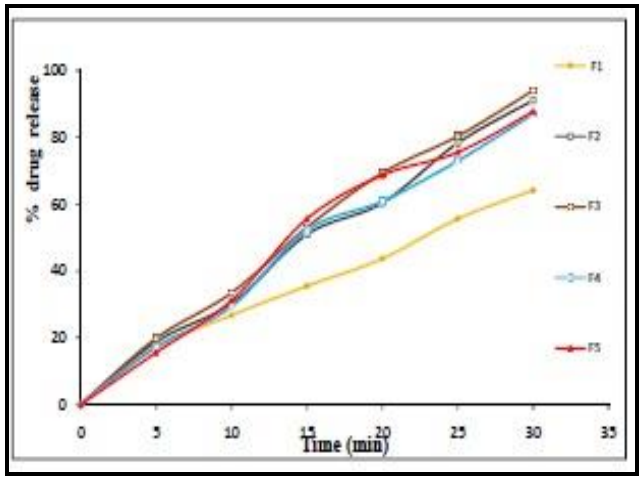


Figure 5: *In Vitro* Dissolution Profile of F-1 to F-5 Formulations

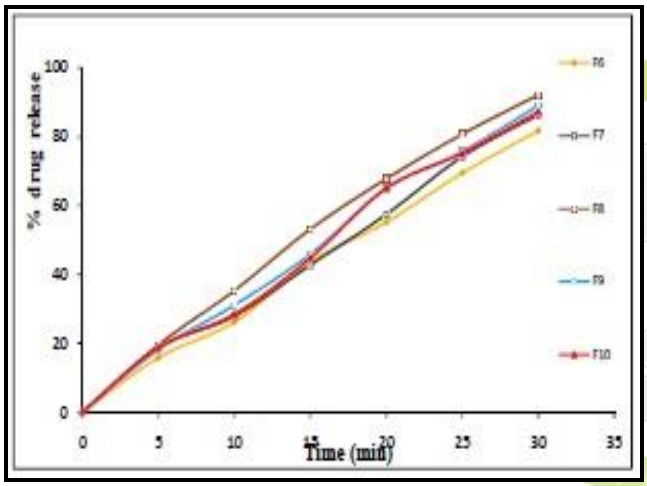


Figure 6: *In Vitro* Dissolution Profile of F-6 to F-10 Formulations

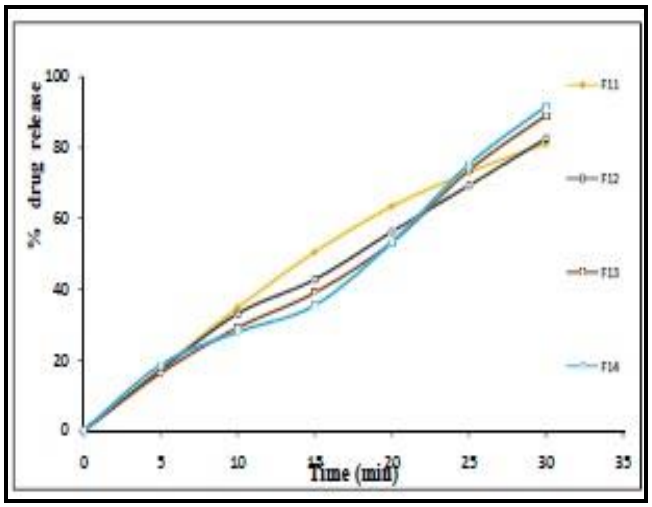


Figure 7: *In Vitro* Dissolution Profile of F-11 to F-14 Formulations

The simultaneous in-vitro drug release study showed that the tablets were releasing the drug within 30 mins, Among those 14 formulations F3 shows highest drug release 94.02% and F1 shows slow drug release because it not contains superdisintegrants drug release was depend on its rapid swelling capacity & capillary action.

**Kinetic Release Study**

Table 5: Kinetic Release Data Profiles of Fast dissolving tablet of Atenolol

| Form Code | Zero order | First order | Higuchi | Korsemeyer-Peppas |
|---|---|---|---|---|
| F1 | 0.9893 | 0.9899 | 0.9550 | 0.9935 |
| F2 | 0.9956 | 0.9502 | 0.9244 | 0.9909 |
| F3 | 0.9939 | 0.9635 | 0.9383 | 0.9953 |
| F4 | 0.9890 | 0.9720 | 0.9331 | 0.9876 |
| F5 | 0.9792 | 0.9837 | 0.9330 | 0.9826 |
| F6 | 0.9980 | 0.9706 | 0.9192 | 0.9932 |
| F7 | 0.9963 | 0.9529 | 0.9137 | 0.9833 |
| F8 | 0.9930 | 0.9746 | 0.9461 | 0.9984 |
| F9 | 0.9960 | 0.9711 | 0.9302 | 0.9957 |
| F10 | 0.9929 | 0.9683 | 0.9212 | 0.9840 |
| F11 | 0.9825 | 0.9972 | 0.9575 | 0.9926 |
| F12 | 0.9958 | 0.9699 | 0.9388 | 0.9969 |
| F13 | 0.9921 | 0.9237 | 0.8941 | 0.9853 |
| F14 | 0.9794 | 0.8890 | 0.8655 | 0.9506 |

The drug release profiles fitted for kinetic models, n value shows in range of 0.9794 to 0.9980 and the n value shows with in 1 that indicating the drug release followed zero order kinetics.

**Stability Data**

Table 6: Stability data of FDT of Atenolol

| Formulation Code | Sampling Interval (Days) | 40 ± 2°C / 75 ± 5% RH | | | |
|---|---|---|---|---|---|
| | | Physical Appearance | Friability | Hardness | Drug Content |
| F3 | 0 | No Change | 0.175 | 2.13 | 100.30 |
| | 15 | No Change | 0.175 | 2.13 | 100.30 |
| | 30 | No Change | 0.175 | 2.13 | 100.30 |
| | 45 | No Change | 0.175 | 2.13 | 100.30 |
| F8 | 0 | No Change | 0.306 | 3.3 | 99.20 |
| | 15 | No Change | 0.306 | 3.3 | 99.20 |
| | 30 | No Change | 0.306 | 3.3 | 99.20 |
| | 45 | No Change | 0.306 | 3.3 | 99.20 |

Stability studies of the formulations were carried out as per the ICH guidelines. The optimization formulation F3 & F8 was subjected to stability studies at 40º C and 75% RH for a period of 45 days.

The physical stability was assessed by the appearance and the chemical stability by change in the drug content, appearance, friability, hardness. It shows no chemical change in any characters.

## CONCLUSION

It can be concluded from this study that, the prepared tablets gave promising results with respect to faster release of atenolol from the dosage form. Further work can be extended as *in-vivo* study can be carried out in animals for better prediction of *in- vivo* behaviour of the system. Bioavailability studies can be conducted to assess the relative usefulness of these formulations in targeting the drugs to human.

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