Available online on 15.07.2014 at http://jddtonline.info
Journal of Drug Delivery and Therapeutics
Open access to Pharmaceutical and Medical research


RESEARCH ARTICLE

# FORMULATION AND EVALUATION OF PIROXICAM FAST DISSOLVING TABLETS USING DIFFERENT NATURAL SUPERDISINTEGRANTS

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**ABSTRACT**

The demand for fast dissolving tablets has been growing during the last decade, especially for geriatric and pediatric patients who have swallowing rapidly. Piroxicam is a potent anti-inflammatory drug used in treatment of osteoarthritis, rheumatoid arthritis, ankylosing Spondylitis and acute gout disease. In the present work, 9 formulations of fast dissolving Tablets of Piroxicam (F1 to F9) were prepared using three different Superdisintegrants namely isapghula, fenugreek and guar gum with three concentrations (4%, 5% and 6%) and a control F10 (without superdisintegrant) by direct compression method. The final blend of the drug and excipients were evaluated for powder flow properties, bulk density, tapped density, compressibility index and hausner's ratio. All the formulations were evaluated for thickness, weight variation, disintegration time, hardness, friability. Formulation F7 showed the lowest disintegration time. In-vitro dissolution studies revealed that formulation F4 showed 99.18 % percent drug release at the end of 60 minutes.

**Keywords:** Anti-inflammatory, Direct compression, fast dissolving, Piroxicam, Superdisintegrant

## INTRODUCTION

Piroxicam is a potent anti-inflammatory drug. It is used in treatment of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and acute gout disease[1].It has prolonged half life of about 45hrs[2].It is poorly water soluble drug and when administered orally it may cause bioavailability problems due to its poor solubility and dissolution rates in biological fluids[3]. Hence the present work was aimed at increasing the rate of dissolution of Piroxicam thus providing faster rate of absorption by adding potential superdisintegrants like isapghula, Crobitter taste of Piroxicam, and aspartame was used as sweetening agent. Nine formulations of fast dissolving tablets of Piroxicam using three superdisintegrants namely isaphgula (4%, 5% and 6%), fenugreek (4%, 5% and 6%) and guar gum (4%, 5% and 6%) and a control formulation (without superdisintegrant) were prepared by direct compression method isaphgula and fenugreek in different concentrations[4] .

## MATERIALS AND METHODS

Piroxicam was procured from XL Pharmaceuticals Ltd, Rajasthan, India. Microcrystalline

Cellulose, and Aspartame, Mannitol, Magnesium stearate, were procured from CDH, New-Delhi India.

### Preparations of Piroxicam fast dissolving tablets

Piroxicam fast dissolving tablets were prepared by direct compression method according to the formula given in Table no-1. A total of nine formulations (F1toF9) of Piroxicam fast dissolving tablets were prepared using three superdisintegrants namely isapghula, fenugreek and guar gum with three different concentrations (4%, 5% and 6%). A control tablet was also prepared without any superdisintegrant (F10).

All the ingredients were passed through mesh no. 60 separately and collected. The drug, mannitol and microcrystalline cellulose were mixed uniformly with gentle trituration using mortar and pestle to get a uniform mixture. Required quantity of superdisintegrant and aspartame were taken for each specified formulation and mixed with the above mixture. Finally magnesium stearate were added and mixed well. The mixed blend of drug and excipients were compressed using 7 mm punch on 10 stations "B" Tooling Rotatory Tablet Punching Machine to produce convex faced tablets, weighing 200 mg each (Table-1). Before tablet preparation, the mixture blend of all the formulations were subjected to compatibility studies (IR) and Precompression parameters like Angle of repose, bulk density, tapped density, compressibility index and hausner's ratio.

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 ISSN: 2250-1177 CODEN (USA): JDDTAO

**Table 1: Formulation of Piroxicam Fast dispersible Tablets .**

| S.No | Compositon(mg) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Piroxicam | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 2 | Isapghula | 8 | 10 | 12 | - | - | - | - | - | - | - |
| 3 | Fenugreek | - | - | - | 8 | 10 | 12 | - | - | - | - |
| 4 | Guar gum | - | - | - | - | - | - | 8 | 10 | 12 | - |
| 5 | Microcrystalline cellulose | 104 | 102 | 100 | 104 | 102 | 100 | 104 | 102 | 100 | 112 |
| 6 | Mannitol | 58 | 58 | 58 | 58 | 58 | 58 | 58 | 58 | 58 | 58 |
| 7 | Aspartame | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| 8 | Magnesium stearate | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | Total Weight(mg) | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

*FA1, FA2, FA3- Isapghula (4%, 5% and 6%).*
*FA4, FA5, FA6- fenugreek (4%, 5% and 6%).*
*FA7, FA8, FA9- Guar Gum (4%, 5% and 6%).*
*F10-Control (without Superdisintegrants).*

**Evaluation of powder blend**

**Angle of repose:**

The angle of repose of powder blend was determined by the funnel method. The accurately

Weighed powder blend were taken in funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the heap of the powder blend. The powder blend was allowed to flow through the funnel freely onto the surface [5] .The diameter of the powder cone was measured and angle of repose was calculated using the following equation

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

Where 'h' and 'r' are the height and radius of the cone

**Bulk Density:**

Bulk density Pb is defined as the mass of the powder divided by the bulk volume and is expressed as g/cm3. Weighed quantity of powder blend from each formulation was taken in a measuring cylinder and the initial volume of the powder blend (Vb) in the measuring cylinder was noted [6]. This was calculated by using the formula

$$Pb = M / Vb$$

Where, Pb - Bulk density, M - Weight of the sample in g, Vb- volume of the blend in cm3

**Tapped Density:**

It is the ratio of total mass of the powder to the tapped volume of powder. The volume was measured by tapping the powder blend for 50 times. Then the tapping was done for 50 times and the tapped volume was noted. Tapped density was calculated by using the following formula

$$Pt = M / Vt$$

Where, Pt-Tapped density, M - Weight of the sample in g, Vt - Tapped volume of blend in cm3.

**Compressibility index and hausners ratio:**

The compressibility index of the powder blend was determined by Carr's compressibility index and the Hausners ratio is calculated by using the formula [7]

Hausner'sRatio = Tapped density / Bulk density

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

TBD = Total bulk density, LBD = Loose bulk density

**IR Spectral Analysis:**

It was used to study the interactions between the drug and the excipients. The FT-IR method was used for preparation of sample and spectra were recorded over the wave number 4000 to 400cm in a BRUKUR- FT-ir spectrophotometer. IR spectral studies of Pure Piroxicam, Superdisintegrants and Piroxicam containing highest proportion of individual superdisintegrant were carried out.

**Evaluations of tablets**

**Weight Variation:**

Twenty tablets were randomly selected and individually weighed [8]. The average weight of tablets was calculated. Then the individual weight was compared with that of average weight.

**Hardness:**

The tablets to be tested are held between a fixed and a moving jaw of hardness test apparatus (Monsanto) and reading of the indicator is adjusted to zero [9]. The screw knob was moved forward until the tablet breaks and the force required breaking the tablet was noted.

**Friability:**

Friability test was performed using Roche friabilator. Ten tablets were weighed and placed in the friabilator, which was then operated for 25 revolutions per minute [10]. After 100 revolutions the tablets were dusted and reweighed. The percentage friability was determined using the formula,

$$\text{Percentage friability} = \frac{\text{Initial weight - Final weight}}{\text{Initial weight}} \times 100$$

***In-Vitro* disintegration time:**

The test was carried out in a disintegration apparatus using distilled water as disintegration medium (at $37^0$ C ± 0.50 C). A tablet was placed in each of six tubes of the apparatus and one disc was added to each tube [11]. The

 

time taken for complete disintegration of the tablet with no mass remaining in the apparatus was measured in seconds.

***In-vitro* dissolution test:**

Dissolution test can be carried in 0.1N HCl (ph-1.2). The USP 2 Paddle apparatus at 50 rpm is suitable for dissolution testing. Dissolution medium taking 900 ml. Sample is taken from the medium and measure the drug content in U.V. spectrophotometer [12-13].

**Table 2: Evaluation of powder blend**

| Formulation code | Angle of repose* | Bulk density (gm/cm3)* | Tapped density (gm/cm3)* | Compressibility Index (%)* | Hausner's ratio* |
|---|---|---|---|---|---|
| F1 | 32.63±1.42 | 0.57±.005 | 0.79±.011 | 14.71±1.67 | 1.30±.034 |
| F2 | 34.52±1.36 | 0.59±.026 | 0.79±.030 | 15.32±1.15 | 1.34±.005 |
| F3 | 31.72±1.52 | 0.52±.025 | 0.71±.060 | 14.26±1.49 | 1.29±.096 |
| F4 | 29.08±1.14 | 0.40±.066 | 0.56±.060 | 15.07±1.42 | 1.26±.011 |
| F5 | 28.13±1.02 | 0.38±.086 | 0.53±.085 | 13.17±1.20 | 1.31±.102 |
| F6 | 29.14±1.08 | 0.43±.005 | 0.61±.045 | 14.83±1.91 | 1.28±.121 |
| F7 | 32.11±1.15 | 0.42±.060 | 0.59±.059 | 14.75 ±1.54 | 1.32±.062 |
| F8 | 30.14±1.34 | 0.44±.041 | 0.59±.025 | 15.24±1.31 | 1.33±.075 |
| F9 | 29.81±1.32 | 0.47±.026 | 0.67±.017 | 13.83±1.32 | 1.32±.080 |
| F10 | 29.81±1.21 | 0.46±.040 | 0.65±.017 | 15.76±1.88 | 1.34±.073 |

**Table 3: Evaluation of Fast Dissolving Tablet of Piroxicam**

| Batch code | Weight variation (mg) | Thickness (mm) | Hardness ($kg/cm^2$) | Friability (%) | Disintegration time (sec) |
|---|---|---|---|---|---|
| **F1** | 200±1.2 | 3.59±.08 | 2.8±0.231 | .62±0.183 | 30±0.41 |
| **F2** | 200±1.3 | 3.47±.03 | 2.7±0.234 | .57±0.235 | 31±0.25 |
| **F3** | 201±1.3 | 3.66±.14 | 2.5±0.254 | .65±0.521 | 34±0.43 |
| **F4** | 200±1.1 | 3.62±.23 | 2.9±0.278 | .84±0.542 | 32±0.22 |
| **F5** | 202±1.4 | 3.74±.26 | 2.7±0.143 | .78±0.345 | 29±0.36 |
| **F6** | 199±1.2 | 3.48±.42 | 2.8±0.352 | .76±0.374 | 30±0.52 |
| **F7** | 201±1.3 | 3.82±.53 | 3.0±0.231 | .45±0.245 | 28±0.32 |
| **F8** | 200±1.2 | 3.86±.27 | 2.7±0.324 | .54±0.613 | 38±0.43 |
| **F9** | 200±1.1 | 3.31±.75 | 3.1±0.341 | .48±0.363 | 35±0.23 |
| **F10** | 200±1.5 | 3.42±.81 | 3.2±0.256 | .64±0.554 | 110±1.54 |

**Table 4: *in-vitro* dissolution test**

| Time (in min) | % Cumulative release of drug from FDT | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** | **F9** | **F10** |
| **0** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **10** | 57 | 56 | 69.4 | 70.38 | 64.12 | 66.89 | 65.67 | 63.64 | 73.82 | 23.65 |
| **20** | 65.12 | 75.13 | 74.43 | 78.8 | 70.31 | 70.25 | 71.21 | 69.71 | 79.04 | 29.98 |
| **30** | 78.67 | 80.61 | 81.9 | 85.29 | 78.21 | 75.31 | 75.51 | 76.80 | 81.58 | 34.32 |
| **40** | 83 | 87.55 | 88.9 | 84.88 | 81.78 | 81.48 | 82.79 | 83.22 | 86.22 | 43.02 |
| **50** | 92.49 | 94.16 | 89.91 | 93.58 | 90.32 | 88.42 | 87.39 | 92.65 | 90.64 | 49.45 |
| **60** | 98.14 | 96.68 | 94.27 | 99.18 | 96.36 | 98.26 | 99.13 | 98.65 | 97.35 | 56.18 |

 

**Release curve of FDT:**

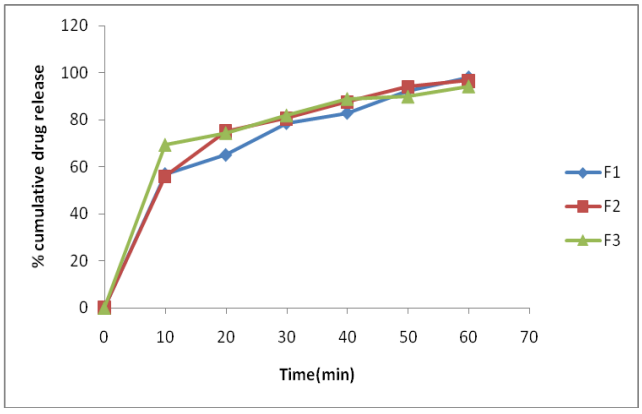


**Figure 1**: release curve with isapghula 4%, 5%, 6%.

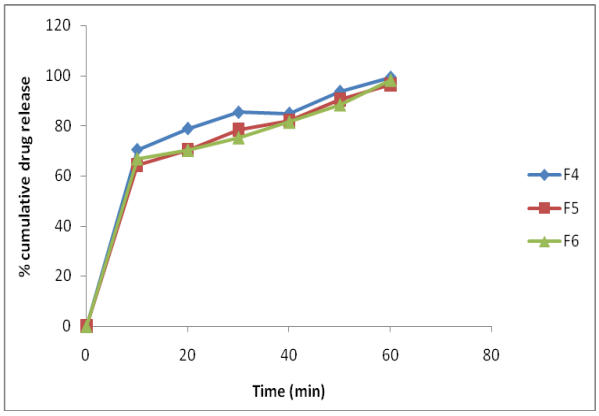


**Figure 2:** release curve with fenugreek 4%, 5%, 6%.

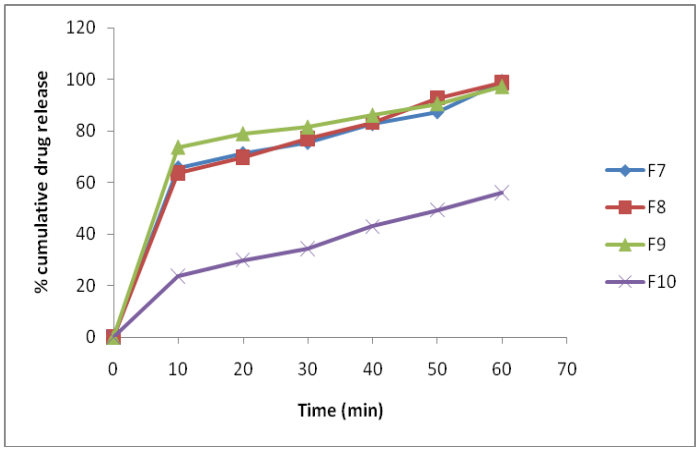


**Figure 3**: release curve with guar gum 4%, 5%, 6% and withought superdisintrigrants

FT-IR Spectra:

PIROXICAM: FT-IR

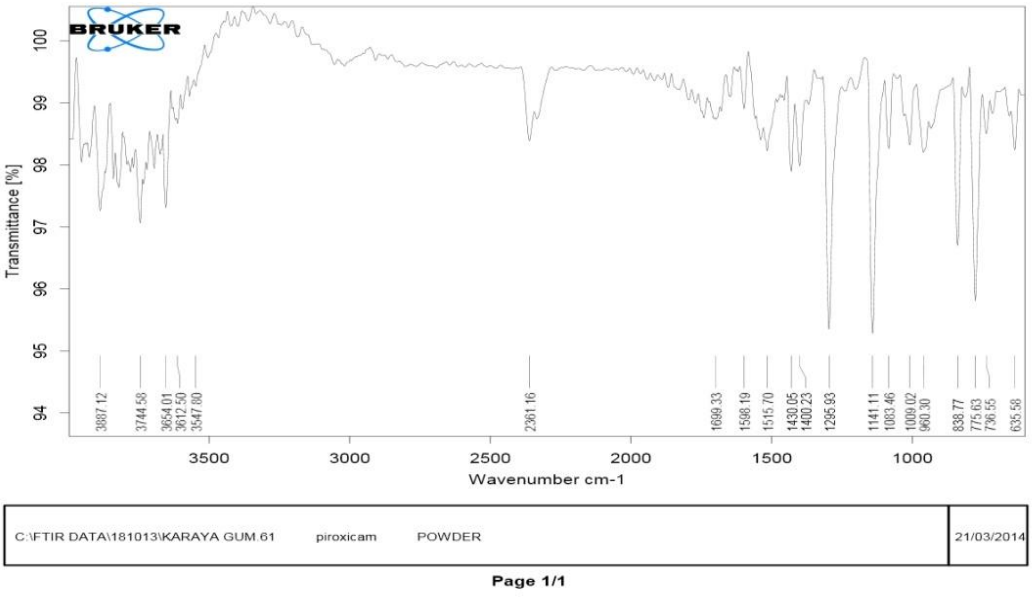


**Figure 4**: FT-IR of Piroxicam

 

**Table 5**: FT-IR interpetation Spectra of piroxicam

| Frequency(cm-1) | Assignment |
|---|---|
| 3654 | O-H Stretch |
| 2361 | C-H |
| 1430 | C-H Bend |
| 1141 | C-H Out of plane bend |

## RESULTS AND DISCUSSION:

It has been observed that Bulk density and tapped density of powder blend evaluated. The angle of repose for the entire formulations blend was found to be in the range28.13 to 34.63°. Formulations with Isapghula (F1-F3) as a disintegrant showed angle of repose values ≤ $30^{o.}$ Whereas formulation fenugreek containing (F4-F6) was showed angle of repose values ≥ $30^{o}$, Guar gum (F7-F9) was showed angle of repose values ≤$30^{o}$ indicating only fair flow property of the powder blend. Compressibility index was found to be in the range 13.61 % to 15.76 %. All formulations showed good flow properties. Hausner's ratio was found to be in the range 1.26 to 1.34and that indicated that all formulation has good flow properties. The batches F3, showed low hardness and F10 higher (2.5-3.2kg/$cm^2$). Higher friability F4 and low friability F7 (0.84- 0.45%).all parameters show weight variation, thickness, Disintegration time (sec) within standard limit. All formulation was subjected to dissolution. From all the above observations it was concluded that the formulation F9 containg guar gum 6% found to be better formulation in terms of rapid dissolution (73.82 ) and but maximum percentage drug release was found 99.18 of formulation F4, with fenugreek 4%.

## CONCLUSION:

It can be concluded from the whole study that fast dissolving tablets of Piroxicam drug. Natural Superdisintegrants can be used as pharmaceutical excipients for oral drug delivery.So natural superdisintegrant like fenugreek exhibited faster drug dissolution will lead to improve bioavailability, effective therapy, improve patient compliance, and satisfies all the criteria as fast dissolving tablet. It was concluded formulation f4 maximum percentage drug release was found 99.18, with fenugreek 4%.

## ACKNOWLEDGEMENT:

Authors are highly thankful to the Department of Pharmacy, School of Medical Allied Sciences, Galgotias University, and Greater Noida India for providing library facility during literature survey.

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