Formulation and Evaluation of Piroxicam Fast Dissolving Tablets Using Direct Compression and Sublimation Method

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ABSTRACT

Objective: In the present research work, fast dissolving tablets of Piroxicam were formulated by two different techniques i.e. direct compression method and sublimation method using different superdisintegrants.

Methods: Twelve formulations were prepared (PXM1 to PXM12) in which first six formulation were prepared by direct compression technique and other six formulation were prepared by sublimation method by using camphor as a sublimating agent.

Result and Discussion: All the formulations were subjected for precompression, post compression parameters, and shows all the data within the specific limits. Formulation PXM4 containing 5 % crospovidone showed 99.480 ± 0.291 % drug release in 20 min which was more than the drug release of rest of the formulations. The optimized formulation PXM4 was compared with the marketed formulation and it revealed that drug release of PXM4 was found to be 99.397 ± 0.751 % in 20 min, which was greater than the marketed formulation. Finally, results were statistically analysed by the application of one way ANOVA and t-test. The stability study of the optimized formulation PXM4 showed no significant changes in, drug content, disintegration time and in-vitro drug release.

Conclusion: Piroxicam can be successfully prepared using direct compression technique and it will enhance the drug dissolution, which will further increase absorption and bioavailability of the drug.

Keywords: Direct compression, fast dissolving tablets, sublimation, Piroxicam.

INTRODUCTION

A modern enhancement in Novel Drug Delivery System (NDDS) goals to improve safety and efficiency of formerly used drug molecule by formulating a suitable dosage form to achieve better patient acquiescence and ease of administration with enhanced bioavailability and enhanced efficacy, thus reducing the dose to reduce the side effects. Due to the unique properties, the Fast dissolving drug delivery system (FDDDS) has great reputation in the pharmaceutical industry. FDDDS in most cases is a tablet that dissolved in oral mucosa within seconds without need of water that makes them extremely attractive to pediatric and geriatric patients. Nowadays, the demand of fast dissolving tablets has immensely increased as it has major impact on patient compliance. According to European Pharmacopoeia, rapidly disintegrating tablets are those, which are placed in the oral cavity and disperse before swallowing in less than three minutes. The property of dispersibility is due to the addition of superdisintegrants to the dosage form, thus increasing the bioavailability by releasing the drug in mouth. There are various conventional approaches to formulate the fast dissolving tablets. Addition of superdisintegrants is the basic approach that plays a vital role in the dissolution and disintegration for the development of the fast dissolving tablets. This is the most popular technique due to its cost effectiveness and easy implementation. Drugs which are poorly water soluble (Class II) having slower rate of absorption, high permeability and low bioavailability due to less dissolution, so there is need to improve the dissolution rate of such drugs which may lead to the improvement of bioavailability and hence faster onset of action of drugs is achieved. Piroxicam, an oxicam is a non-selective cyclooxygenase – 2 inhibitor, used in the treatment of rheumatoid arthritis,
Materials and Methods

Piroxicam was obtained as gift sample from Lark laboratories, Bhiwadi, India. Sodium starch glycolate, croscarmellose sodium, microcrystalline stearate were obtained as gift sample from Maple biotech, Pune. Talc, camphor, mannitol and aspartame were procured from CHD laboratories, Bhiwadi, India. Sodium starch glycolate, CP was obtained as gift sample from Lark laboratories (Sodium starch glycolate, crospovidone and croscarmellose sodium) with different concentration. In the present work, total 12 formulations were prepared i.e. PXM1 to PXM12 in which formulations PXM1 to PXM6 were prepared by direct compression method and PXM7 to PXM12 were prepared by sublimation method. Table 1 and Table 2 respectively.

Formulation of Tablets

Fast dissolving tablets of Piroxicam were formulated by direct compression method and sublimation method using sublimating agent i.e. camphor. Different superdisintegrants were used (Sodium starch glycolate, crospovidone and croscarmellose sodium) with different concentration. In the present work, total 12 formulations were prepared i.e. PXM1 to PXM12 in which formulations PXM1 to PXM6 were prepared by direct compression method and PXM7 to PXM12 were prepared by sublimation method. Table 1 and Table 2 respectively.

Table 1: Composition of different batches of fast dissolving tablets of Piroxicam (Direct compression method)

| S. No. | Ingredients   | PXM1 (mg) | PXM2 (mg) | PXM3 (mg) | PXM4 (mg) | PXM5 (mg) | PXM6 (mg) |
|--------|---------------|-----------|-----------|-----------|-----------|-----------|-----------|
| 1      | Piroxicam     | 20        | 20        | 20        | 20        | 20        | 20        |
| 2      | SSG           | 6         | 10        | -         | -         | -         | -         |
| 3      | CP            | -         | -         | 6         | 10        | -         | -         |
| 4      | CCS           | -         | -         | -         | -         | 6         | 10        |
| 5      | MCC           | 102       | 98        | 102       | 98        | 102       | 98        |
| 6      | Mannitol      | 60        | 60        | 60        | 60        | 60        | 60        |
| 7      | Aspartame     | 8         | 8         | 8         | 8         | 8         | 8         |
| 8      | Magnesium stearate | 2 | 2 | 2 | 2 | 2 | 2 |
| 9      | Talc          | 2         | 2         | 2         | 2         | 2         | 2         |
| 10     | Menthol       | q.s       | q.s       | q.s       | q.s       | q.s       | q.s       |

Table 2: Composition of different batches of fast dissolving tablets of Piroxicam (Sublimation method)

| S. No. | Ingredients   | PXM7 (mg) | PXM8 (mg) | PXM9 (mg) | PXM10 (mg) | PXM11 (mg) | PXM12 (mg) |
|--------|---------------|-----------|-----------|-----------|-----------|-----------|-----------|
| 1      | Piroxicam     | 20        | 20        | 20        | 20        | 20        | 20        |
| 2      | SSG           | -         | -         | 6         | 10        | -         | -         |
| 3      | CP            | 6         | 10        | -         | -         | -         | -         |
| 4      | CCS           | -         | -         | -         | -         | 6         | 10        |
| 5      | MCC           | 96        | 92        | 96        | 92        | 96        | 92        |
| 6      | Mannitol      | 60        | 60        | 60        | 60        | 60        | 60        |
| 7      | Aspartame     | 8         | 8         | 8         | 8         | 8         | 8         |
| 8      | Magnesium stearate | 2 | 2 | 2 | 2 | 2 | 2 |
| 9      | Talc          | 2         | 2         | 2         | 2         | 2         | 2         |
| 10     | Camphor       | 6         | 6         | 6         | 6         | 6         | 6         |

SSG-Sodium starch glycolate, CP-Crospovidone, CCS-Croscarmellose sodium, MCC-Microcrystalline cellulose.
Pre-compression studies like bulk density, tapped density, angle of repose, Carr’s index and Hausner ratio were carried out successfully.\(^\text{19-23}\)

**Post Compression Studies**

The prepared tablets were evaluated for post compression studies, which are as follows:

**Weight variation:**

Randomly 20 tablets were selected from each formulation and weighed individually. The average weight was calculated and comparison was made between individual weight and average weight of tablets.\(^\text{24}\)

**Thickness:**

The thickness was measured by placing tablet between two arms of the Vernier Caliper.\(^\text{25}\)

**Hardness:**

The hardness of tablets was measured by Monsanto hardness tester.\(^\text{26}\)

**Friability:**

Randomly twenty tablets were selected and weighed. These tablets were placed in the Roche friabilator test apparatus, which was then operated at 25 revolutions in a min. After completion of 100 revolutions, the tablets were dusted and re-weighed.\(^\text{27}\) The percent friability was calculated from the formula:

\[
\text{Friability} \% = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100
\]

**Drug content:**

Ten tablets from each formulation were crushed and the blend equivalent to one tablet was taken. The blend equivalent to one tablet was taken in a 100 ml volumetric flask and volume was made up to mark with phosphate buffer (pH 6.8). The flask was shaken for 24 hrs using a water bath shaker. The solution was filtered and the filtrate was analyzed at 344 nm against similarly treated blank using UV-VIS spectrophotometer.\(^\text{28}\)

**In-vitro disintegration time**

Six tablets were taken from all formulations and maintaining the water temperature at 37.0 ± 0.5 °C. Time taken for complete disintegration of tablets was recorded by stopwatch. For accuracy, an average of six tablets was taken.\(^\text{29}\)

**Wetting time:**

To determine the wetting time of tablets, five pieces of circular tissue paper was placed in the petri dish of diameter 10 cm containing 2 ml of amaranth dye and 10 ml of simulated saliva. The amaranth dye was used to identify complete wetting of the tablet surface. Now, the tablet was placed on the surface of the tissue paper in the petri dish containing dye at room temperature. The time-required dye to reach the upper surface of the tablets and the complete wetting of tablet was noted as the wetting time.\(^\text{29}\)

**Water absorption ratio:**

For the determination of water absorption ratio, firstly weighed the tablets from each formulation before placing them into the petri plate containing 2 ml of amaranth dye and 10 ml of simulated saliva. Tablets were carefully removed from petri dish and weigh the wetted tablet.\(^\text{29}\) The water absorption ratio was calculated using the formula:

\[
R = \frac{W_a - W_b}{W_a} \times 100
\]

Where, R is water absorption ratio, Wb is weight of tablet before water absorption, and Wa is weight of tablet after water absorption.

**In-vitro dissolution studies:**

In-vitro dissolution study was carried out using USP dissolution test apparatus II at 50 rpm in 900 ml of phosphate buffer (pH 6.8). The samples were withdrawn at fixed time intervals of 0, 5, 10, 15, 20 min. Aliquots (10 ml) were withdrawn, filtered and analyzed spectrophotometrically using UV spectrophotometer at 344 nm. An equal amount of fresh dissolution medium, pre-warmed at 37 ± 0.5 °C, was added after each sampling to maintain the sink condition throughout the study.\(^\text{30}\) The premising formulation was compared with the two different brands of marketed formulation by comparing in-vitro drug release.

**Statistical analysis**

The optimized formulation was analyzed using graph pad prism 7.0 version to generate statistical data. ANOVA was used to identify the significant effect. One way ANOVA, Brown-Forsythe test and Bartlett’s test was used to analyze the data and the P value was calculated at P < 0.05 to identify the significant effect.\(^\text{31}\)

**Stability study of optimized batch**

To determine the drug and formulation stability, stability studies was performed according to ICH guideline under accelerated storage conditions. Tablets from the optimized batch were stored in stability chamber at temperature 45.0 ± 2.0 °C and 75 % ± 5 % RH conditions for the period of 90 days. After 90 days, the tablets were evaluated for the physical appearance, drug content, and disintegration time and in-vitro drug release.\(^\text{32}\)

**RESULTS AND DISCUSSION**

**Pre-formulation parameters**

Piroxicam was observed for organoleptic properties like physical appearance, odor, and melting point. The drug was identified with the help of UV and FTIR and exhibited absorption maxima at 344 nm when phosphate buffer 6.8pH was used as a solvent as mentioned in the literature. Differential scanning calorimeter shows endothermic fusion peak at 202.3°C, which was corresponding to the melting point of Piroxicam.
Figure 1: DSC Chromatogram of Piroxicam

Figure 2: UV scan spectrum of Piroxicam in phosphate buffer pH 6.8

Table 3: Calibration curve data of Piroxicam in phosphate buffer pH 6.8

| Concentration (µg/ml) | Absorbance ± SD (n=3) |
|-----------------------|------------------------|
| 0                     | 0                      |
| 6                     | 0.222 ± 0.001          |
| 8                     | 0.249 ± 0.001          |
| 10                    | 0.359 ± 0.001          |
| 12                    | 0.413 ± 0.001          |
| 14                    | 0.480 ± 0.001          |
| 16                    | 0.554 ± 0.001          |
| 18                    | 0.620 ± 0.001          |
| 20                    | 0.689 ± 0.001          |

Table 4: Solubility studies of Piroxicam in different solvents

| Sr. NO. | Solvent used       | Solubility (mg/ml) | Solubility profile     |
|---------|--------------------|--------------------|------------------------|
| 1       | Methanol           | 7.26               | Soluble                |
| 2       | Water (pH 7.0)     | 0.022              | Very slightly soluble  |
| 3       | Phosphate buffer pH 6.8 | 0.236          | Slightly soluble       |
| 4       | pH 4.0             | 0.029              | Very slightly soluble  |
| 5       | pH 7.0             | 0.556              | Slightly soluble       |
| 6       | 0.1N HCl           | 0.417              | Slightly soluble       |
Drug excipient compatibility study by FTIR

The IR spectrum of physical mixture of pure drug and excipients were recorded by IR spectroscopy. The IR spectrum of drug and excipients did not show any significant change in the characteristic peaks of drug, which showed that superdisintegrants and drug were compatible with each other (Figure 4).

### Table 5: Infrared spectral band of Piroxicam

| Sr.No. | Functional group          | Observed peaks (cm⁻¹) | Reported peaks (cm⁻¹) |
|--------|---------------------------|-----------------------|-----------------------|
| 1      | Ortho-đ substituted ring  | 773.46                | 775                   |
| 2      | SO₂-NH group              | 1149.57               | 1149                  |
| 3      | Pyridine                  | 1300.02               | 1298                  |
| 4      | Methyl                    | 1435.04               | 1435                  |
| 5      | Tertiary amine group      | 1525.69               | 1524                  |
| 6      | Amide carbonyl            | 1629.85               | 1629.85               |
| 7      | Cubic polymorphic form    | 3338.78               | 3338.78               |

### Table 6: FTIR studies of Piroxicam with superdisintegrants

| IR spectra       | Peak of functional groups [Wave length (cm⁻¹)] |
|------------------|-----------------------------------------------|
|                  | N-H stretch | C–H stretch | C=C stretch | OH bend |
| Standard spectra | 3339.028    | 2933.879    | 1529.315    | 939.582 |
| Piroxicam        | 3338.78     | 2931.88     | 1525.69     | 939.33  |
| Piroxicam + CCS  | 3337.96     | 2932.89     | 1529.62     | 938.41  |
| Piroxicam + crospovidone | 3337.96 | 2933.85 | 1530.58 | 938.41 |
| Piroxicam + SSG  | 3337.96     | 2932.89     | 1531.55     | 938.41  |

Precompression parameters

The values of precompression parameters evaluated were found to be within the prescribed limits and indicated good free flowing property. Data are tabulated in Table 7.
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Table 7: Precompression parameters of powder blend

| Formulation code | Angle of repose (°) | Bulk density (g/ml) | Tapped density (g/ml) | Hausner’s ratio | Carr’s index (%) |
|------------------|---------------------|--------------------|-----------------------|-----------------|-----------------|
| PXM1             | 31.63 ± 0.563       | 0.326 ± 0.009      | 0.376 ± 0.011         | 1.15 ± 0.010    | 13.37 ± 0.495   |
| PXM2             | 30.55 ± 0.527       | 0.376 ± 0.018      | 0.437 ± 0.017         | 1.15 ± 0.012    | 13.89 ± 0.870   |
| PXM3             | 28.58 ± 0.450       | 0.342 ± 0.019      | 0.423 ± 0.021         | 1.23 ± 0.005    | 19.143 ± 0.491  |
| PXM4             | 28.15 ± 0.30        | 0.357 ± 0.015      | 0.411 ± 0.018         | 1.13 ± 0.030    | 13.13 ± 0.253   |
| PXM5             | 27.88 ± 0.627       | 0.444 ± 0.013      | 0.526 ± 0.015         | 1.173 ± 0.001   | 14.75 ± 0.108   |
| PXM6             | 25.41 ± 0.685       | 0.457 ± 0.015      | 0.553 ± 0.018         | 1.21 ± 0.003    | 17.367 ± 0.220  |
| PXM7             | 30.240 ± 0.617      | 0.561 ± 0.003      | 0.646 ± 0.006         | 1.152 ± 0.005   | 13.197 ± 0.336  |
| PXM8             | 28.990 ± 0.298      | 0.620 ± 0.006      | 0.705 ± 0.004         | 1.136 ± 0.004   | 12.007 ± 0.332  |
| PXM9             | 33.170 ± 0.706      | 0.478 ± 0.002      | 0.550 ± 0.003         | 1.167 ± 0.003   | 14.383 ± 0.224  |
| PXM10            | 26.880 ± 0.355      | 0.508 ± 0.002      | 0.624 ± 0.018         | 1.182 ± 0.006   | 15.427 ± 0.42   |
| PXM11            | 27.967 ± 0.182      | 0.410 ± 0.005      | 0.493 ± 0.009         | 1.197 ± 0.005   | 16.497 ± 0.341  |
| PXM12            | 27.697 ± 0.405      | 0.517 ± 0.007      | 0.590 ± 0.007         | 1.140 ± 0.008   | 12.263 ± 0.617  |

Mean ± SD (n=3)

Post compression parameters

Post-compression evaluations of all formulations were carried out successfully and data are tabulated Table 8 and Table 9 respectively.

Table 8: Post compression parameters of prepared fast dissolving tablets

| Formulation code | Hardness (kg/cm²) | Friability (% age) | Thickness (mm) | Weight variation | Drug content (%) |
|------------------|-------------------|-------------------|----------------|-----------------|-----------------|
| PXM1             | 3.500 ± 0.300     | 0.534 ± 0.093     | 3.546 ± 0.069  | Pass            | 98.730 ± 0.611  |
| PXM2             | 3.067 ± 0.208     | 0.568 ± 0.034     | 3.569 ± 0.068  | Pass            | 99.36 ± 0.959   |
| PXM3             | 3.467 ± 0.115     | 0.480 ± 0.076     | 3.464 ± 0.053  | Pass            | 100.24 ± 0.641  |
| PXM4             | 3.500 ± 0.173     | 0.375 ± 0.144     | 3.552 ± 0.045  | Pass            | 100.19 ± 0.386  |
| PXM5             | 3.900 ± 0.100     | 0.659 ± 0.191     | 3.425 ± 0.034  | Pass            | 99.850 ± 0.200  |
| PXM6             | 3.800 ± 0.300     | 0.672 ± 0.016     | 3.457 ± 0.038  | Pass            | 99.250 ± 0.522  |
| PXM7             | 3.467 ± 0.896     | 0.593 ± 0.042     | 3.376 ± 0.053  | Pass            | 97.033 ± 0.533  |
| PXM8             | 3.500 ± 0.781     | 0.579 ± 0.049     | 3.390 ± 0.047  | Pass            | 99.157 ± 0.400  |
| PXM9             | 3.630 ± 0.551     | 0.775 ± 0.056     | 3.392 ± 0.040  | Pass            | 99.037 ± 0.352  |
| PXM10            | 4.430 ± 0.777     | 0.787 ± 0.027     | 3.367 ± 0.026  | Pass            | 99.020 ± 0.052  |
| PXM11            | 3.760 ± 0.379     | 0.643 ± 0.049     | 3.418 ± 0.059  | Pass            | 98.773 ± 0.336  |
| PXM12            | 3.860 ± 0.306     | 0.654 ± 0.024     | 3.369 ± 0.040  | Pass            | 99.497 ± 0.517  |

Mean ± SD (n=3),

Table 9: Post compression parameters of prepared fast dissolving tablets

| Formulation code | Disintegration time (sec) | Wetting time (sec) | Water Absorption Ratio (%) |
|------------------|---------------------------|--------------------|---------------------------|
| PXM1             | 54.787 ± 0.514           | 23.987 ± 0.991     | 64.813 ± 0.836            |
| PXM2             | 46.23 ± 0.404            | 19.840 ± 0.643     | 73.397 ± 0.309            |
| PXM3             | 33.8 ± 0.625             | 26.050 ± 0.821     | 73.420 ± 0.305            |
| PXM4             | 18.667 ± 0.577           | 10.410 ± 0.637     | 94.997 ± 0.154            |
| PXM5             | 58.35 ± 0.673            | 57.66 ± 0.577      | 71.070 ± 0.298            |
| PXM6             | 60.700 ± 0.608           | 42.673 ± 0.769     | 62.127 ± 0.633            |
| PXM7             | 51.200 ± 0.779           | 56.267 ± 0.681     | 65.867 ± 0.351            |
| PXM8             | 38.100 ± 0.850           | 43.467 ± 0.961     | 83.700 ± 0.458            |
| PXM9             | 66.300 ± 0.557           | 68.600 ± 0.794     | 55.100 ± 0.624            |
| PXM10            | 59.900 ± 0.500           | 62.067 ± 0.513     | 62.133 ± 0.351            |
| PXM11            | 71.067 ± 0.416           | 72.700 ± 0.458     | 69.600 ± 0.700            |
| PXM12            | 64.367 ± 0.416           | 66.400 ± 0.300     | 60.600 ± 0.458            |
Dissolution studies were conducted for all the formulation via USP dissolution apparatus II paddle type, using phosphate buffer pH 6.8 as dissolution medium. It had been observed from the drug release profile more than 90% drug was released within 20 min. Tablets which were formulated by the direct compression method showed more than 75% of the drug release within 15 min. Formulation PXM4 containing 5% crospovidone showed 99.450 ± 0.260% drug release within 15 min which was formulated by the direct compression method. Formulation PXM8 that was formulated by sublimation method containing 5% crospovidone and 3% camphor as sublimating agent showed 95.94 ± 0.205% drug release within 15 min that was less as compared to the formulation PXM4. Cumulative percent drug release of all formulations is tabulated below in Table 10. Comparative drug release of the all the formulations were shown in the Figure 5.

Table 10: In-vitro dissolution profile data of formulations PXM1-PXM12

| Formulation Code | Time (min) | 0   | 5   | 10  | 15  | 20  |
|------------------|------------|-----|-----|-----|-----|-----|
| PXM1             | 0          | 60.290 ± 0.567 | 67.893 ± 0.787 | 79.260 ± 0.910 | 96.043 ± 0.614 |
| PXM2             | 0          | 63.240 ± 0.490 | 71.107 ± 0.510 | 87.113 ± 0.345 | 99.040 ± 0.445 |
| PXM3             | 0          | 63.050 ± 0.790 | 75.050 ± 0.753 | 83.193 ± 0.710 | 98.057 ± 0.819 |
| PXM4             | 0          | 68.950 ± 0.785 | 85.163 ± 0.550 | 99.450 ± 0.260 | 99.480 ± 0.291 |
| PXM5             | 0          | 60.980 ± 0.516 | 74.667 ± 0.451 | 81.370 ± 0.488 | 96.427 ± 0.407 |
| PXM6             | 0          | 63.14 ± 0.651  | 76.687 ± 0.539 | 86.920 ± 0.570 | 99.087 ± 0.619 |
| PXM7             | 0          | 54.22 ± 0.477  | 68.60 ± 0.484  | 85.24 ± 0.514  | 93.26 ± 0.462  |
| PXM8             | 0          | 77.06 ± 0.385  | 88.04 ± 0.118  | 95.94 ± 0.205  | 99.09 ± 0.140  |
| PXM9             | 0          | 51.00 ± 0.811  | 64.25 ± 0.715  | 73.66 ± 0.729  | 88.34 ± 0.558  |
| PXM10            | 0          | 56.22 ± 0.293  | 71.80 ± 0.210  | 82.73 ± 0.400  | 94.83 ± 0.401  |
| PXM11            | 0          | 51.10 ± 0.394  | 68.08 ± 0.346  | 84.07 ± 0.681  | 93.20 ± 0.433  |
| PXM12            | 0          | 64.67 ± 0.548  | 78.55 ± 0.513  | 89.17 ± 0.201  | 96.64 ± 0.557  |

Mean (%CDR) ± SD (n=3).

From the above data, it was observed that formulation PXM 4 containing 5% crospovidone formulated by the direct compression method showed fastest drug release when compared with the all other formulations. The best-selected formulation PXM 4 was chosen for comparison with marketed formulations. Formulation PXM4 was compared with two different marketed formulations of different brands. Comparison indicated that the prepared formulation PXM4 containing 5% crospovidone showed 99.667 ± 0.244% drug release in 15 min whereas marketed formulation MKT1 and MKT2 showed 89.017 ± 0.091 % and 85.013 ± 0.119 % drug release within 15 min that was less than formulation PXM4. The comparison of percent drug release of optimized formulation with marketed formulation is shown in the Table 11 and in Figure 6.
Table 11: Comparison of the optimized formulation with the marketed formulations

| Time (min.) | PXM4       | MKT1       | MKT2       |
|------------|------------|------------|------------|
| 0          | 0          | 0          | 0          |
| 5          | 76.900 ± 0.324 | 72.993 ± 0.206 | 68.530 ± 0.426 |
| 10         | 87.330 ± 0.361 | 81.37 ± 0.555  | 76.993 ± 0.111  |
| 15         | 99.667 ± 0.244 | 89.017 ± 0.091  | 85.013 ± 0.119  |
| 20         | 99.397 ± 0.751 | 90.950 ± 0.060  | 95.003 ± 0.179  |

Figure 6: Comparison of the optimized formulation with the marketed formulations

Statistical analysis
It was found to be significant indicating there is no significant difference in the release profile of formulated FDTs and marketed formulations.

Stability study of optimized formulation
The optimized formulation PXM4 The fast dissolving tablets were packed in suitable packaging and stored at 40.0 °C ± 2.0 °C and RH 75 % ± 5 % for 90 days. After 90 days the tablets were evaluated for physical appearance, drug content, disintegration time, wetting time and in-vitro drug release studies. Stability data for the optimized formulation is shown in the Table 12. No significant changes were seen in drug content, disintegration time, wetting time and in-vitro drug release. Stability study of optimized formulation PXM4 was found to be stable and complies with Pharmacopoeias standards.

Table 12: Drug release from the formulation PXM4 during stability studies

| Sampling time (90 days) | Time (min.) | % CPR ± SD (n=3) |
|-------------------------|-------------|-----------------|
|                         | 0           | 0               |
|                         | 5           | 66.163 ± 0.280  |
|                         | 10          | 82.257 ± 0.435  |
|                         | 15          | 94.320 ± 0.802  |
|                         | 20          | 97.120 ± 0.147  |

CONCLUSION
Fast dissolving tablets were prepared in two different methods viz. direct compression and sublimation. Pre-formulations parameters like the physical characterization of the drug were evaluated. All the Piroxicam fast dissolving tablets were showed more than 80 % drug release within 15 min. Formulation PXM4 containing 5 % crospovidone prepared by direct compression was found to be better in terms of rapid disintegration and maximum percentage drug release when compared with all other formulations and marketed formulation. It shows disintegration time of 18.667 ± 0.577 sec and 99.450 ± 0.260 % drug release in 15 min. Stability studies revealed that there were no significant changes seen in physical appearance, drug content, disintegration time and in-vitro drug release during the storage of optimized formulation PXM4 for 90 days. Thus, Piroxicam can be successfully prepared using direct compression technique and it will enhance the drug dissolution, which will further increase absorption and bioavailability of the drug.

CONFLICT OF INTEREST: None declared

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