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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.

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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.[1] Due to the unique properties, the Fast dissolving drug delivery system (FDDDS) has great reputation in the pharmaceutical industry.[2] 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.[3, 4] Nowadays, the demand of fast disintegrating tablets has immensely increased as it has major impact on patient compliance.[5] 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.[4] 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.[6, 7] 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.[8, 9] 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.[10]

Piroxicam, an oxicam is a non-selective cyclooxygenase – 2 inhibitor, used in the treatment of rheumatoid arthritis,

osteoarthritis and other joint diseases but at high concentrations also inhibits polymorphonuclear leukocyte migration, decreases oxygen radical production, and inhibits lymphocyte function and it belongs to class-II of biopharmaceutical classification system which have low aqueous solubility.[11] Therefore, the present research work is to formulate and evaluate of fast dissolving tablets Piroxicam in order to provide faster on set of action and better patient compliance.

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 fine chemicals, New Delhi and all other chemicals/solvents used were of analytical grade.

Preformulation Studies

All the Preformulation studies like melting point, solubility study, and partition coefficient were carried out effectively.[12-14]

Determination of λ_{max} in methanol and phosphate buffer pH 6.8

The absorption maxima of Piroxicam was determined in methanol and phosphate buffer pH 6.8 by scanning the drug in the range of 400-200 nm using UV spectrophotometer.

Preparation of stock solution and calibration curve of Piroxicam

Standard stock solution (100 µg/ml) of Piroxicam was prepared in phosphate buffer pH 6.8. From this stock solution of phosphate buffer pH 6.8 different aliquots of various concentration (6, 8, 10, 12, 14, 16, 20 µg/ml) were prepared. For phosphate buffer pH 6.8 absorbance was measured at 344 nm, against similarly treated blank.

Compatibility Studies of Piroxicam

Dried samples were mixed with dried potassium bromide (KBr) powder. The sample discs were prepared using KBr press at pressure of 10000 to 15000 psi. The sample disc was placed in the sample holder and scanned from 4000 to 400 cm^{-1} at a resolution of 4 cm^{-1}.[15]

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 PXM 12 were prepared by sublimation method. Table 1 and Table 2 respectively.[16-18]

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

Pre-compression studies like bulk density, tapped density, angle of repose, carr's index and hausner ration were carried out successfully.[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. Average weight was calculated and comparison was made between individual weight and average weight of tablets.[24]

Thickness:

The thickness was measured by placing tablet between two arms of the Vernier Caliper.[25]

Hardness:

The hardness of tablets was measured by Monsanto hardness tester.[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 minute. After completion of 100 revolutions, the tablets were dusted and re-weighed.[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.[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 the disintegration of tablets was recorded by stopwatch. For accuracy, an average of six tablets was taken.[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.[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.[29] The water absorption ratio was calculated using the formula:

$$R = \frac{Wa - Wb}{Wa} \times 100$$

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) as a dissolution media and the temperature was maintained at 37 ± 0.5 ºC. 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 ºC, was added after each sampling to maintain the sink condition throughout the study.[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.[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 °C ± 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.[17]

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.

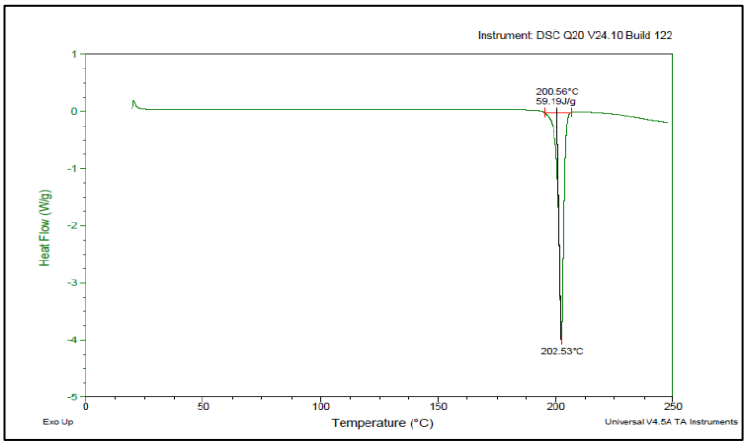

Figure 1: DSC Chromatogram of Piroxicam

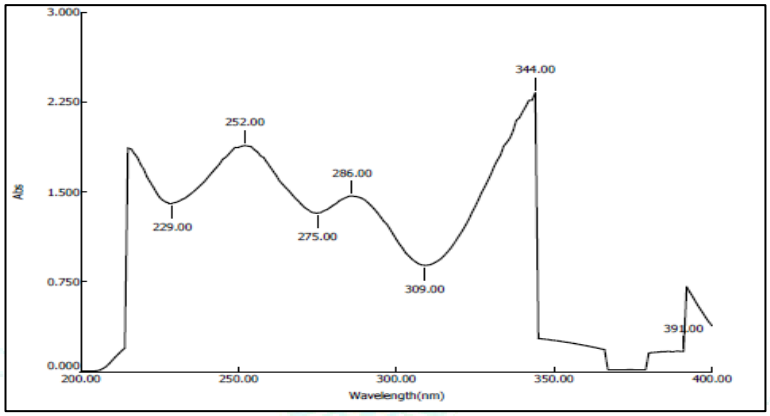

Figure 2: UV scan spectrum of Piroxicam in phosphate buffer pH 6.8

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

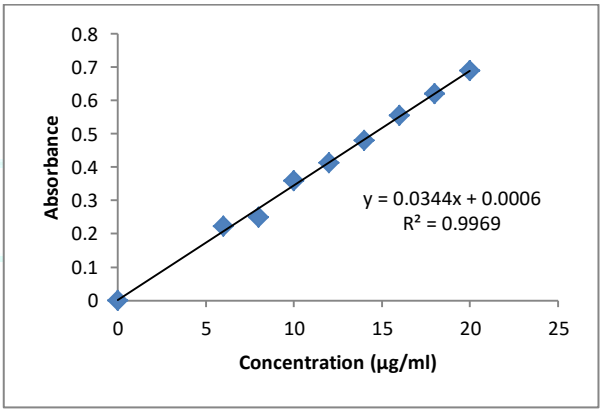

Figure 3: Calibration curve of Piroxicam in phosphate buffer pH 6.8

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-di substituted ring	773.46	775
2	SO_2-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.

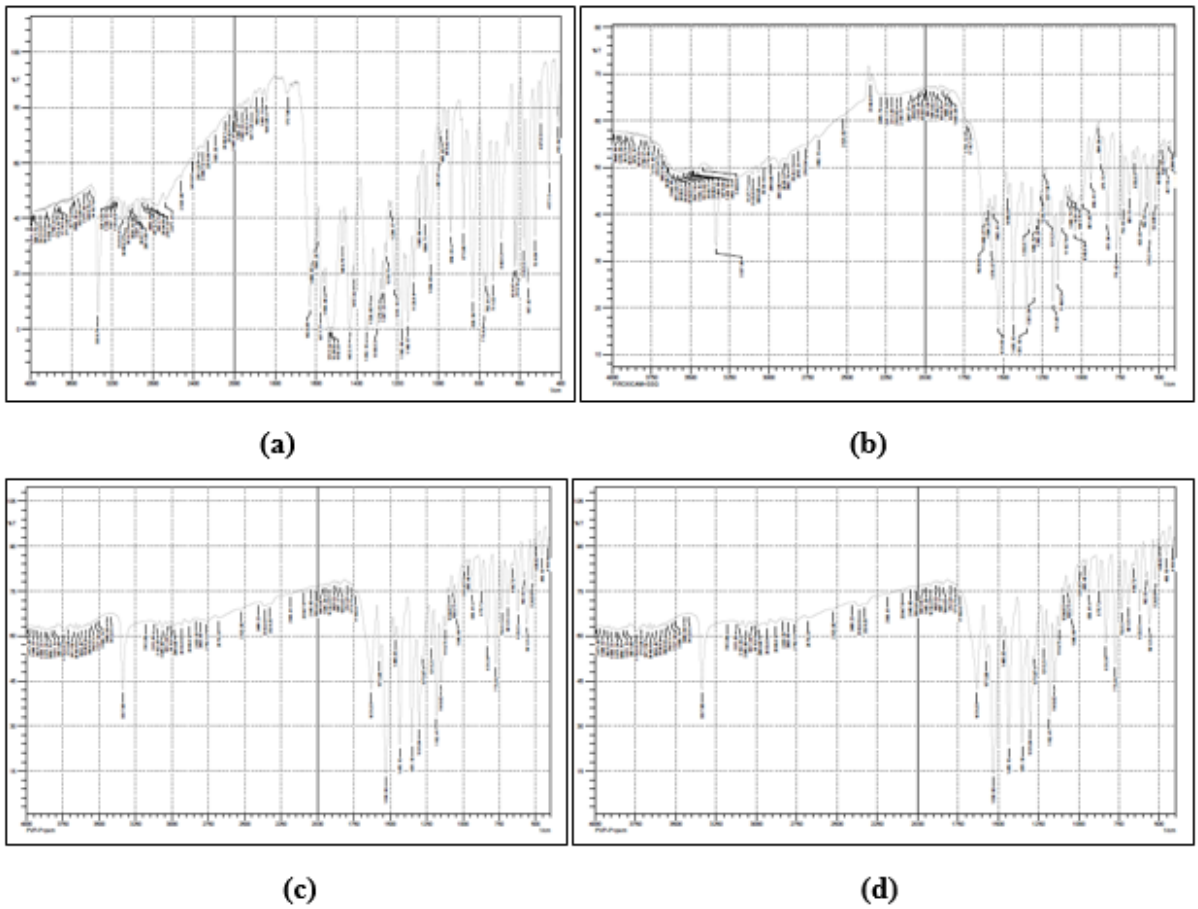

Figure 4: FTIR spectrum of (a) PXM, (b) SSG and PXM, (c) CP and PXM, (d) CCS and PXM

Table 7: Precompression parameters of powder blend

Formulation code	Angle of repose (θ)	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	0.558 ± 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/cm³)	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 showed 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	60.280 ± 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 ± 0.728	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),

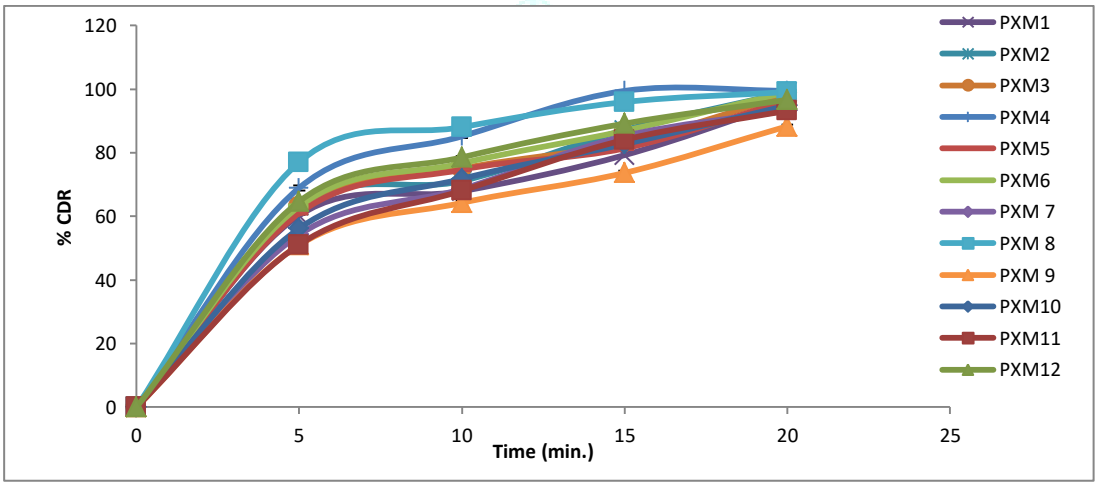

Figure 5: Comparison of percent cumulative drug release of all the formulations PXM1 to PXM12

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	81.737 ± 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

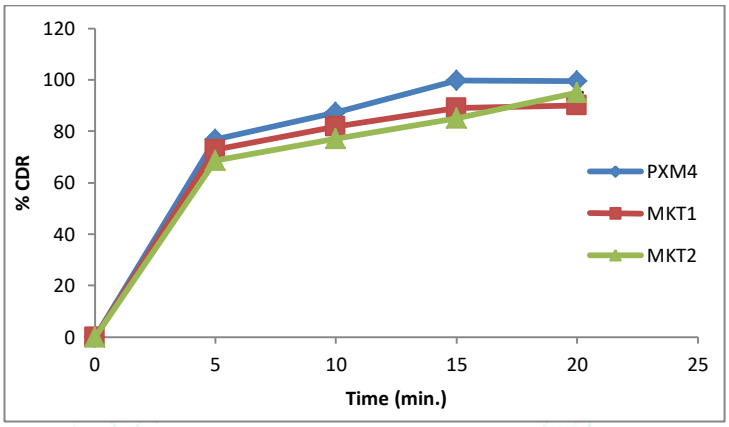

Figure 6: Comparison of the optimized formulation with the marketed formulations

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 compiles with Pharmacopeias 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 the 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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