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Original Research Article

Formulation And Evaluation of Fast Dissolving Tablets of Piroxicam Using Various Concentration of Different Super Disintegrating Agents

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Abstract:

Fast-dissolving tablets (FDTs) offer several advantages and disadvantages, making them a unique pharmaceutical dosage form suitable for specific applications. The current study attempted to create and assess a fast-dissolving tablet containing Piroxicam employing several superdisintegrants in order to increase its therapeutic efficiency along with patient compliance. Piroxicam is a nonsteroidal anti-inflammatory medicine used to treat osteoarthritis, rheumatoid arthritis, as well as ankylosing spondylitis. It is classed as a Class II drug in the Biopharmaceutical drugs Classification system. Here are some of the key advantages and disadvantages of fast-dissolving tablets. Directed compression method was utilized for the preparation of FDTs and nine formulations were formulated using Cross Povidone, Pre gelatinized starch & Microcrystalline Cellulose at different concentration. Different types of evaluation parameters are mentioned below. Results of all the evaluation parameters of all formulations were satisfactory and within limit. It may be concluded that a mouth dissolving tablet of Piroxicam can be produced utilizing Cross Povidone to increase therapeutic efficiency and patient compliance.

Key Words: Fast-dissolving tablets, osteoarthritis, Cross Povidone, therapeutic efficiency.

Introduction

Recent advancements in novel drug delivery systems (NDDS) seek to enhance patient compliance by developing an easy-to-administer form of dosage that will raise the medicinal molecule's safety and effectiveness. The "fast disintegrating tablet" is one such method. [1,2]

Fast-dissolving tablets, also known as orally disintegrating tablets (ODTs) or orally dissolving tablets, are a pharmaceutical dosage form designed to disintegrate or dissolve rapidly in the mouth without the need for water. These tablets have gained popularity in the pharmaceutical industry due to their numerous advantages, making them a preferred choice for certain patient populations.[3]

Fast-dissolving tablets are typically composed of active pharmaceutical ingredients (APIs) and various excipients,

including superdisintegrants, binders, and fillers. Superdisintegrants play a crucial role in promoting the rapid disintegration of the tablet in the saliva. [4]

Benefits offered by FDTs

1. FDTs are designed to disintegrate and dissolve rapidly in the mouth without the need for water.
2. FDTs enhance patient compliance, as they eliminate the need to swallow large or solid tablets.
3. The rapid disintegration and dissolution of FDTs in the oral cavity result in quicker drug absorption, leading to a faster onset of action compared to traditional oral dosage forms.
4. The high surface area exposed to saliva allows for better drug dissolution, potentially improving drug bioavailability.
5. In comparison to liquids FDTs have accurate dosage.
6. In regards to administration and transportation, FDTs are preferable to liquid medications. [5,6]

Limitations With Fast Dissolving Tablets

1. FDT formulations often have limitations in terms of the amount of drug that can be incorporated, which may be insufficient for some high-dose medications.
2. The rapid disintegration and exposure to moisture in the mouth can pose stability challenges, particularly for moisture-sensitive drugs. Special packaging and storage conditions may be required to maintain product integrity.
3. Some FDT formulations may have a chalky or gritty mouthfeel, and the taste of certain drugs may still be noticeable despite taste-masking efforts. This can affect patient acceptance.
4. The development and production of FDTs can be costlier compared to conventional tablets or capsules. [7,8]

Materials and Methods:

Piroxicam, Sodium Carboxy Methyl Cellulose, Cross Povidone, Pre gelatinized starch, Microcrystalline Cellulose, Mannitol, Lactose, Magnesium strearate, Aspartame along with Talc were employed for the preparation of FDTs of Piroxicam.

The direct compression process was used to create piroxicam fast dissolving tablets. All of the components were individually sieved using a 60-mesh sieve. The medication and microcrystalline cellulose were combined together by taking a small amount of each and combining it until a homogenous combination was obtained and set aside. The materials were then weighed and combined in geometrical sequence, and tablets of 8mm diameters flat round punch were crushed to create tablets using the Rimek Compression Machine.

Evaluation of Prepared Tablets (FDTs)

Shape and Size

Diameter and thickness of prepared FDTs were determined using Vernier callipers. Three tablets from each formulation were taken and average was calculated. [9,10]

Thickness variation

Thickness of prepared FDTs were determined using Vernier callipers. Three tablets from each formulation were taken and average was calculated.

Hardness

Hardness of tablets is the amount of force needed to split them. Monsanto's hardness tester, Pfizer's hardness tester, and others are used to determine the tablet hardness. Hardness is measured in kilograms or pounds.

Both Monsanto and Pfizer hardness tester were used to determine the hardness of the formulated tablets. The hardness was calculated as kg/cm^2. Three tablets from

each formulation were taken and average was calculated. [11]

Weight variation

This test is performed to check the uniformity of weight of the prepared tablets, as drug content is directly related to the weight of tablet. In this process, 20 tablets were weighed individually. The average weight of one tablet was calculated by taking average mean. As per IP, not more than two tablets deviate by more than the limit prescribed and none tablets deviate by more than twice of the limit prescribed in individual monograph.

Friability

The friability of the tablet is determined using the friability test instrument. Friability is used to determine the amount to which tablets break during physical stress situations such as packaging, handling, transportation, and so on. The % weight reduction is estimated by comparing the pre- and post-operative weight of 20 tablets.

The Roche friabilator was used to measure friability of the formulated tablets. Weight of 20 tablets was measured and placed in the friabilator chamber. The friabilator was rotated at speed of 25 rpm for 4 min. After completion of 100 revolutions, the tablets were weighted again and % weight loss is calculated, which corresponds to friability.

$$\%\ Friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

Drug content

The drug content was calculated by triturating ten tablets in a mortar with pestle to get fine powder. Powder equivalent to weight of one tablet was taken and was dissolved in distilled water. Measure the absorbance of diluted sample of MS at 283 nm using UV-Visible Spectrophotometer. The drug content was calculated by using standard calibration curve. [12]

Wetting time

The wetting time was calculated by placing the tablets in Petri dish containing wet tissue paper. Wet tissue was placed in a petri dish and the tablet was placed over it. The time required for complete wetting of tablets was noted

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. 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. [13,14]

***In vitro* disintegration time**

The process of breakdown of a tablet into smaller particles is called as disintegration. The in-vitro disintegration time of a tablet was determined using disintegration test apparatus as per I.P. specifications.

I.P. Specifications: Place one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using pH 6.8 (simulated saliva fluid) maintained at 37°±2°C as the immersion liquid. The assembly should be raised and lowered between 30 cycles per minute in the pH 6.8 maintained at 37°±2°C. The time in sec. taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

***In vitro* dissolution Test**

Dissolution testing measures the extent and rate of solution formation from a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. Dissolution of prepared mouth dissolving tablets was determined in

phosphate buffer pH 6.8 using paddle apparatus, 50 RPM at 37^0C. [15,16]

Result and Discussion.

Table 1: Evaluation parameters: thickness, diameter, average hardness and average weight.

Formulation code	Thickness (mm)	Diameter(mm)	Average hardness (kg/cm2) (Mean±S.D.*)		Average weight (mg)
			Monsanto type	Pfizer type	
F1	3.437± 0.031	8.01±0.03	3.7±0.1	202.70±1.30	202.70±1.30
F2	3.440±0.027	8.04±0.04	3.6±0.2	199.40±1.60	199.40±1.60
F3	3.456±0.037	8.03±0.02	3.5±0.2	201.10±1.90	201.10±1.90
F4	3.461±0.055	8.06±0.04	3.4±0.4	203.80±1.59	203.80±1.59
F5	3.456±0.046	8.03±0.02	3.5±0.3	201.60±1.68	201.60±1.68
F6	3.498±0.043	8.04±0.03	3.5±0.2	199.20±1.85	199.20±1.85
F7	3.424±0.065	8.04±0.02	4.0±0.3	200.20±1.75	200.20±1.75
F8	3.435±0.052	8.04±0.03	3.9±0.2	203.90±1.65	203.90±1.65
F9	3.439±0.061	8.00±0.02	3.8±0.2	201.60±1.32	201.60±1.32

The diameter was found to be 8.06±0.04 to 8.00±0.02 mm and thickness was found to be 3.498±0.043 mm to 3.424±0.065 mm for all the formulations.

The average hardness of prepared tablets was found to be 4.0 – 3.4 kg/cm^2 with Monsanto type and 4.1- 3.4 kg/cm^2 with Pfizer type, which are within the standard limits. It may be inferred that hardness is optimum for mouth dissolving tablets. None of the tablet deviated by the limit prescribed (5%). Therefore, the prepared tablets pass the test for weight variation.

Table 2: Evaluation parameters: friability, % drug content, wetting time, water absorption ratio and disintegration time.

Formulation code	Friability (%)	% Drug Content (Mean±S.D.*)	Wetting time (second)	Water Absorption Ratio	Disintegration time (Sec.)
F1	0.46±0.06	97.35±1.52	45	35.87±1.3	47±6
F2	0.41±0.03	96.70±2.42	43	35. 25±1.5	42±7
F3	0.36±0.04	96.80±2.23	51	36.49±2.1	33±4
F4	0.36±0.05	97.48±1.22	34	34.11±1.7	34±5
F5	0.35±0.07	98.40±2.81	36	34.97±2.5	29±4
F6	0.31±0.04	98.90±1.65	31	33.09±1.3	23±3
F7	0.45±0.02	96.25±3.43	35	34.01± 2.2	52±5
F8	0.38±0.04	95.40±2.12	39	34. 87±1.9	46±6
F9	0.33±0.03	97.90±1.04	42	35.23±2.1	39±2

* Standard Deviation, n=3

The friability of prepared tablets was found to be 0.31±0.04 to 0.46±0.06 %, which are less than the standard limits (1%). The % drug content of prepared tablets was found to be 95.40±2.12 to 98.90±1.65%, which is within the prescribed limits. The results revealed that the content of Piroxicam was within the acceptable limits in all the formulations. Therefore, the prepared mouth dissolving tablets pass the test for drug content (content uniformity).

The wetting time of prepared tablets was found to be 31 - 51 second, which are optimum for mouth dissolving tablets. Formulation F6 showed minimum wetting time (31 second) among all the formulations.

The water absorption ratio of all the formulation were determined and it was between 36.49±2.1 to 33.09±1.3. All the outcomes were within limit.

The Disintegration time of prepared tablets was found to be 23 seconds – 52 seconds, which is optimum for mouth dissolving tablets. Formulation F6 showed minimum Disintegration time 23 Seconds among all the formulations. Specification limit of disintegration time for uncoated tablet from I.P is NMT 15 minutes. Disintegration time of all formulations were found within the time as specified in the I.P and passed the disintegration test. When we increase the concentration of superdisintegrants, disintegration time also reduce.

***In vitro* dissolution test**

Dissolution of prepared mouth dissolving tablets was determined in phosphate buffer pH 6.8 using paddle apparatus, 50 RPM at 37^0C. The outcomes of the test are tabulated below.

Table 3: *In vitro* dissolution test of formulations

Time (Min.)	Formulations								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0	0	0	0	0	0	0	0	0	0
1	7.57	10.29	14.4	9.67	14.76	17.35	7.21	9.44	15.64
3	22.01	25.51	29.18	21.61	29.54	32.73	21.26	28.42	33.59
5	37.97	38.71	42.93	32.43	39.65	44.46	34.73	39.54	41.56
7	46.48	49.59	53.86	44.23	52.17	61.98	41.26	50.86	52.78
9	59.75	63.85	69.52	59.91	66.94	75.78	56.67	62.88	68.28
11	72.34	77.76	79.23	70.84	73.57	85.38	64.29	71.51	74.65
13	82.49	85.78	90.67	84.17	86.04	93.69	70.12	82.59	87.92
15	93.59	95.61	98.33	94.74	96.45	99.42	89.8	93.02	95.75

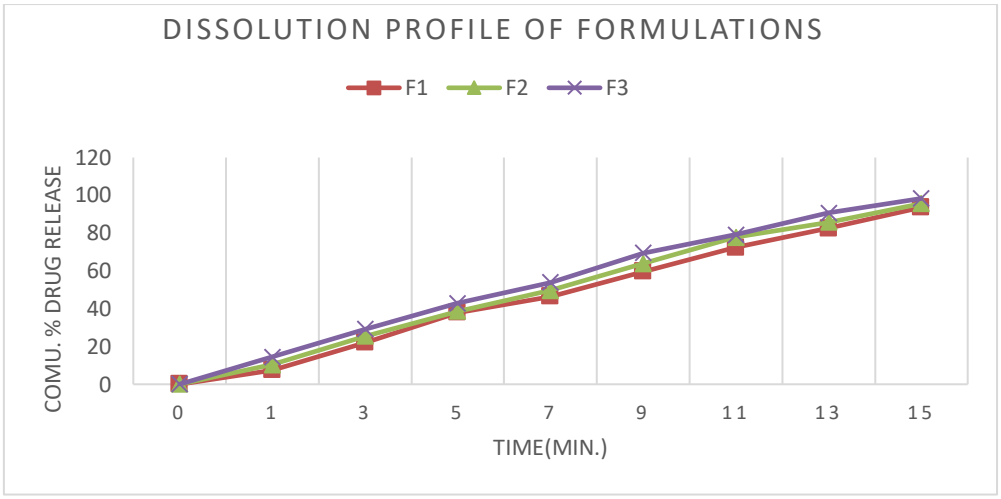

Fig. 1: In-vitro dissolution of F1, F2 and F3

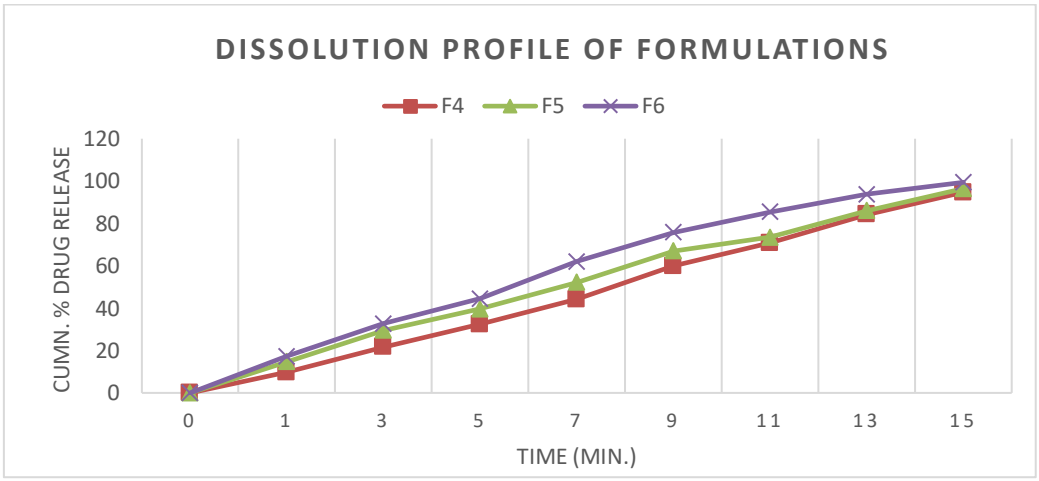

Fig. 2: In-vitro dissolution of F4, F5 and F6

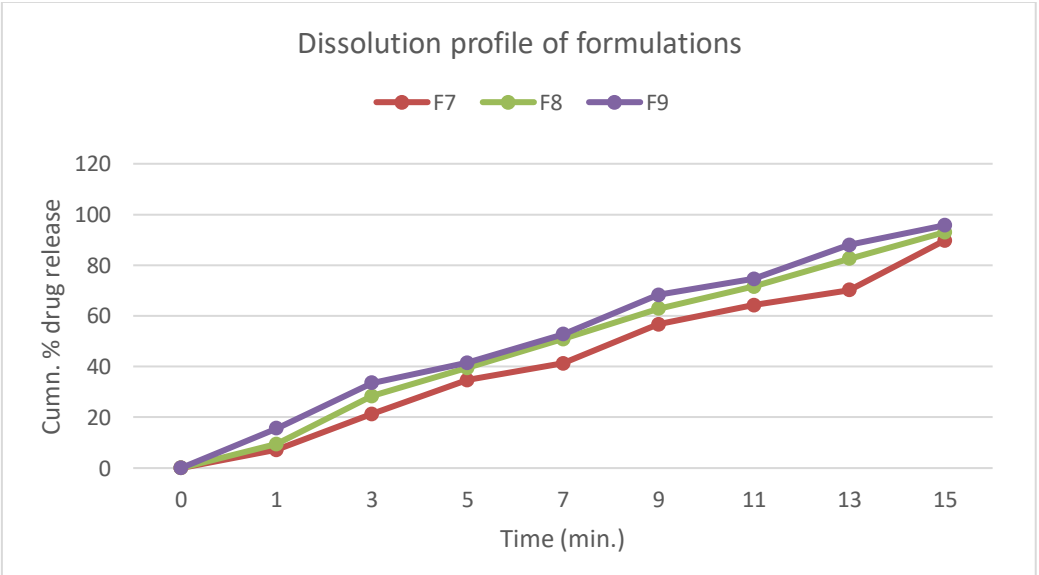

Fig. 3: In-vitro dissolution of F7, F8 and F9

Dissolution of Piroxicam starts immediately when the tablet is added to the dissolution media. The drug release of formulation F1 to F9 was found to be 89.8 to 99.42 % at 15 minutes. The acceptable in vitro dissolution limit for Piroxicam as per IP is NLT 75% dissolution in 45 min

Conclusion

In the present investigation an attempt was made to formulate and evaluate fast dissolving tablet of Piroxicam by using different superdisintegrants and to improve its therapeutic efficiency and their by improving patient compliance. Total 9 formulation were prepared using different concentration of superdisintegrating agents and then evaluated utilizing parameters like thickness, hardness, weight variation, friability, content uniformity and in-vitro release. All the results after evaluation of the prepared formulation were within limits. it was concluded that formulation F6 was selected as the best formulation among all. Finally, it can be concluded that mouth dissolving tablet of Piroxicam can be formulated using Cross Povidone to improve its therapeutic efficiency and their by improving patient compliance.

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