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Formulation and evaluation of fast disintegrating tablet of Piroxicam using superdisintegrant

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Abstract *— Piroxicam is a non-steroidal anti-inflammatory drug, classified in the Biopharmaceutics Drug Classification system as a Class II drug with low solubility and high permeability. It demonstrates a slow and gradual absorption via the oral route and has a long half-life of elimination, rendering a prolonged therapeutic action and a delayed onset of anti-inflammatory and analgesic effect. The basic objective of the present study is to formulate and evaluate the fast disintegrating tablet of Piroxicam. Fast Dissolving tablets can be prepared by conventional direct compression method using solvent deposition system (SDS) of piroxicam which shows increased solubility of piroxicam. For better Hardness, less friability, faster wetting time and less moisture uptake combination of both MCC and Mannitol are required in the formulation.*

Keywords *— Fast disintegrating tablet, Piroxicam, Sodium starch Glycolate (SSG)*

I. INTRODUCTION

Plain piroxicam preparations are indicated for osteoarthritis and rheumatoid arthritis but not for analgesia due to its delayed onset of pain relief (WangD et al., 2000). However, Fast Dissolving Formulation would be advantageous with regard to a rapid onset of action, especially in various painful conditions where an acute analgesic effect is desired. Hence the present work was aimed to increase rate of solubility of piroxicam and to prepare its rapid disintegrating tablets.

II. MATERIALS AND METHOD

Piroxicam was obtained from Vaishali Pharma Private Limited Maharashtra. Acetone, lactose, Sodium starch glycolate, Sodium carboxymethyl cellulose, Magnesium stearate, Mannitol and sodium sachharin was obtained from CDH® of analytical grade.

Formulation of solvent deposition system (SDS) of piroxicam:

Aqueous solubility of piroxicam will be enhanced by preparing solvent deposition system (SDS) by adsorbing it on lactose. SDS of piroxicam was prepared by taking piroxicam: lactose in the ratios of 1: 0, 1:0.5, 1:1 and 1:1.5, 1: 2. Piroxicam solution was prepared in acetone followed by dispersing the known quantity of lactose in it. The resulting dispersion was dried at room temperature. The dried SDS of piroxicam was passed through 60-mesh sieve and subjected for aqueous solubility determination. An excess different ratio of SDS was added in each four test tube containing 5 ml of water and shaking continuously. Then the solutions were centrifuged at 5000 rpm for a minute and the absorbance of the piroxicam test solutions was measured at the characteristic wavelength of 354nm by UV spectrophotometer (Shimadzu-1600).

Preparation of Rapid disintegrating tablets

Amount of SDS piroxicam was taken equivalent to 20 mg of piroxicam for each formulation. Sodium saccharin was used as sweetening agent to protect mild bitter after taste of piroxicam. All the ingredients were passed through 60- mesh sieve and mixed homogeneously in geometrical proportion. The resulted blend was compressed into tablets using 8 mm diameter die in single station tablet compression machine. The final weight of tablets was kept 200 mg. The prepared tablets has been stored in airtight container before evaluation

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7
SDS-P	40	40	40	40	40	40	40
SSG	20	-	-	10	-	10	6.66
SCMC	-	20	-	10	10	-	6.66
Starch1500®	-	-	20	-	10	10	6.66
Magnesium stearate	3	3	3	3	3	3	3
Mannitol	135.5	135.5	135.5	135.5	135.5	135.5	135.5
Sodium sachharin	1.5	1.5	1.5	1.5	1.5	1.5	1.5

Evaluation of tablets

The general appearance of a tablet, its visual identity and over all "elegance" is essential for consumer acceptance. The various evaluation testing includes tablet's size, shape, colour, presence or absence of an odour, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

Size and Shape

The size and shape of the tablet can be dimensionally described, monitored and controlled.

Thickness:

Tablet thickness was measured using a simple procedure. 5 tablets were taken and their thickness was measured using Varnier calipers (Shaikh S et al., 2010).

Hardness:

It is the force required to break a tablet by compression in the radial direction, it is an important parameter in formulation of mouth dissolve tablets because excessive crushing strength significantly reduces the disintegration time. In the present study the crushing strength of the tablet was measured using Pfizer hardness testers. An average of three observations is reported (Panigrahi R yet al., 2010).

Uniformity of weight:

I.P. procedure for uniformity of weight was followed, twenty tablets was taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity (Mahaveer PR et al., 1998).

Friability test:

Friability of the tablets was determined using Roche friability (Electrolab, Mumbai). This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Preweighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions (Modasiya MK et al., 2009).

In-vitro dispersion time test:

To determine dispersion time 10 ml measuring cylinder was taken in which 6 ml pH 6.8 phosphate buffer at 37±0.5˚ was added and tablet was dropped in it. Time required for complete dispersion was determined (Shirsand SB et al., 2010).

Disintegration time

The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 simulated salivary fluid at 37^{o}C ± 2^{o}C was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds. To comply the test all tablets should

disintegrate within 3 minutes (Khemariya P et al., 2010).

Content uniformity

Ten randomly selected tablets was weighed and average weight is calculated, the tablets was powdered in a glass mortar. The weight equivalent to 10 mg of piroxicam is weighed. The weighed amount is dissolved in solvent system in separate 100ml volumetric flask using magnetic stirrer, the volume is adjusted with buffer pH 6.8 in separate volumetric flasks in Lambert's-Beer's range. The drug content in formulation is determined very easily by UV sepectrophotometer (Shimadzu 1600) (Morales JO et al., 2010).

In-vitro drug release:

The development of dissolution methods for RDTs is comparable to the approach taken for conventional tablets, and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent RDT. Other media such as 0.1N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for ODT much in the same way as their ordinary tablet counter parts. The USP 2 Paddle apparatus has been used for this purpose which is the most suitable and common choice for rapid-disintegrating tablets, with a paddle speed of 50 rpm commonly used. Typically the dissolution of RDT is very fast when using USP monograph conditions; hence slower paddle speeds may be utilized to obtain a profile. The USP 1 Basket apparatus may have certain applications but sometimes tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles (Shirsand SB et al., 2010).

III. RESULTS AND DISCUSSION

The aqueous solubility of piroxicam is 0.027±0.02. On formulation of SDS of piroxicam, the aqueous solubility was found 5.568±0.03 to 11.21±0.04. So it was observed that aqueous solubility of piroxicam was increased upto 415 times by formulation of SDS of piroxicam on lactose surface. So SDS of Piroxicam prepared with Piroxicam: lactose in the ratio of 1:1. In further studies it will be selected to prepare the formulations.

Table no. 1: Results of aqueous solubility determination of SDS of piroxicam

S. No.	Piroxicam: Lactose	Aqueous solubility (mg/ml)
1	1:0	0.027 ± 0.02
2	1:0.5	5.568 ± 0.03
3	1:1	11.21 ± 0.04
4	1:1.5	10.22 ± 0.02
5	1:2	10.24 ± 0.02

Post compression results

Table no. 2: Results of Post compression evaluation

Evaluation parameter	Formulation Code						
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**
Thickness (mm)	2.91±0.02	2.85±0.01	2.96±0.01	2.82±0.02	**2.81±0.01**	2.59±0.02	3.12±0.01
Hardness (kg/cm2)	2.61±0.043	2.91±0.072	3.24±0.042	2.71±0.051	**2.81±0.021**	2.42±0.031	3.14±0.022
Friability (%)	0.93±0.02	0.72±0.02	0.74±0.03	0.79±0.02	**0.69±0.02**	0.54±0.03	0.76±0.01
Weight variation	Passes	Passes	Passes	Passes	**Passes**	Passes	Passes
Dispersion time	52± 06	61± 12	55± 98	44± 02	**25± 26**	42± 15	63± 06
Disintegration time (sec)	60.5±0.31	48.2±0.50	72.5±0.82	14.5±0.61	**11.5±0.71**	15.5±3.30	18.5±0.41
	R^2 = 0.6279	R^2 = 0.5714	R^2 = 0.3951	R^2 = 0.9230	**R^2 = 0.9514**	R^2 = 0.7676	R^2 = 0.2341
% Drug content	90± 0.76	88± 0.97	90± 0.25	95± 0.82	**96± 0.92**	95± 0.615	91± 0.28
% Drug Release	92±0.42	88± 0.19	88± 0.72	97± 0.13	**99± 0.71**	96± 0.72	93± 0.94
	R^2= 0.787	R^2= 0.683	R^2= 0.201	R^2= 0.859	**R^2= 0.945**	R^2= 0.230	R^2= 0.203

The average thickness of tablets was found in the range 2.59 mm to 3.12 mm respectively.

The hardness of tablets was ranged between 2.42±0.031 to 3.24±0.042 kg/cm^2. The friability of all the formulations was less than 1% indicating the ability of tablet to withstand abrasion in handling packaging and shipment. The average weight of the prepared tablets was found between 198 to 203 mg. with acceptable variation as per IP specifications i.e. below 7.5%. Dispersion time was found in the range of 25 to 63. Formulation F5 with starch1500 and NCMC disintegrants exhibit quick dispersion time compared to SSG, which indicated that this may be due to the low porosity of these disintegrants. All the formulations shows drug content in the range of 90± 0.25 to 96± 0.92 % as given in above table 2. Result also revealed that formulation F5 having high drug content 96%. Disintegration time of the prepared tablets was found in the range 11.5±0.71 to 72.5±0.82 seconds (R^2 = 0.2341 to 0.9514) respectively which was well within IP limit (IP limit is 180 seconds). Result also revealed that formulation F5 having quick disintegration in 11.5±0.71(R^2=0.9514) seconds.

In vitro drug release was found between 88 to 99 % within 30 min of the study.

IV. CONCLUSION

Quantitative solubility studies showed that the piroxicam poorly soluble in water. So solvent deposition system is used to increased the solubility of drug. The aqueous solubility of Piroxicam was enhanced after converting it into SDS. The solubility study indicated enhancement of aqueous solubility of Piroxicam by solvent deposition on lactose. SDS of Piroxicam prepared with Piroxicam: lactose in the ratio of 1:1.

The faster dissolution observed in the case of solvent deposition system was due to the molecular micronization of the drug particle, which gets coated over the extensive lactose surface. The formulation F5 containing Starch 1500® and Sodium carboxy methyl cellulose in equal proportion has shown highest drug release (99± 0.71, R^2 = 0.945 %) within 30 min. than other formulations. This can be attributed to the extent of water uptake and consequently the strong swelling power of these disintegrants caused sufficient hydrodynamic pressure to induce quick disintegration and dissolution of tablet. On the basis of results obtained from all evaluation parameters formulation F5 was considered as best formulation among all other formulations.

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