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FORMULATION AND EVALUATION OF FAST DISINTEGRATING PIROXICAM TABLETS

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ABSTRACT

The study was carried to formulate and evaluate fast disintegrating tablet dosage form containing Piroxicam a Non-steroidal anti-inflammatory drug. The present study is an attempt to select best possible combination of diluents and disintegrants to formulate fast disintegrating tablet of Piroxicam which disintegrates within seconds in mouth, thereby reducing the time of onset of action. Here six formulations are prepared by using two polymers (Sodium starch glycolate and Crosspovidone) with different concentrations. Among the six formulations F3 gives maximum invitro drug release i.e 99%.All the formulated tablets were subjected for pre and post-compression. Evaluation parameters from the FTIR studies, the drug-polymers computability were confirmed. All the formulated tablets were shown satisfactory results which complies with official limits.

KEYWORDS

Piroxicam, Sodium starch glycolate, Crosspovidone and Fast disintegrating tablets.

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INTRODUCTION[1]

The oral route of drug administration is the most important method of administering drug for systemic effects. Except in certain case the parental route is not routinely used for self-administration, e.g. insulin. The topical route of administration has only recently been employed to deliver drugs to the body for systemic effect. The parental route of administration is important in treating medical

emergencies in which the subject is comatose or cannot swallow. Nevertheless it is probable that at least 90% of all drugs used to provide systemic effect are administered by oral route. When a new drug is discovered one of the first questions a pharmaceutical company ask is whether or not the drug can be effectively administered for its intended effect by oral route of drug that are administered orally, solid oral dosage forms represent the preferred class of product. Tablet and capsules represent unit dosage forms in which usual dose of drug has been accurately placed[1].

Fast disintegrating tablets are uncoated tablet that produce a uniform dispersion in water. They should disintegrate within three minutes and produce a uniform dispersion that passes through mesh No: 22 when dispersed in water. Fast disintegrating tablets are formulated for pediatric and geriatric use or for patients who has difficulty in swallowing tablets.

In this we are preparing fast disintegrating tablets of Piroxicam with different polymers i.e. Sodium starch glycolate and Crosspovidone in different ratios in to six formulations.

Ideal characteristics of Fast disintegrating tablets[2,3,4, 5]:-

- Should easily disintegrate and dissolve.
- Mask or overcome unacceptable taste of drug.
- They should have high drug loading.
- They should have pleasant feel in mouth.
- They should have negligible or no residue in oral cavity after administration.
- They should have low sensitivity against environment conditions like moisture, temperature etc.
- Ease of administration for patient who is mentally ill, disabled and uncooperative.

MATERIALS AND METHOD[5]

Materials and Chemical

Piroxicam, Micro crystalline cellulose, Lactose, Starch, Sodium starch glycolate, Pine apple, dry flavor, Crospovidone, Aspartame, Magnesium stearate and Talc.

Method

Direct Compression Method

The tablet Piroxicam dispersible tablets were prepared by direct compression method by using 9.5mm oval FFBE punches & with a break line on one side. The flow chart for direct compression method is given below. Different types of formulations prepared based on the given formula showed in table no. 1.

Flow chart for Piroxicam dispersible tablet by direct compression method

Weighing → Sifting→ Blending→ Lubrication → Tablet Compression.

EVALUATION PARAMETERS[1,2]

Pre-formulation Studies

Fourier Transform Infrared Spectroscopy

The Fourier transform infra-red analysis was conducted for the structure characterization. FTIR spectra of the pure drug, polymers and formulations were recorded by using BOMEN MB SERIES FTIR instrument. Approximately 5mg of samples were mixed with 50mg of spectroscopic grade KBr, samples were scanned in the IR range from 500 to 3500 cm^{-1}, with a resolution of 4 cm^{-1}.

The FT-IR results of pure drug and drug with polymers showed in figure No. 3, 4 and 5..

Pre-compression studies of tablet granules

Bulk density

3gm of granules were weighed separately and transferred into 100ml measuring cylinder, initial volume was measured and calculated according to the formula

Formula

Bulk density = Mass / Volume

Tapped density

Tapped density is determined by placing a graduated cylinder containing a known mass of granules and mechanical tapper apparatus, which is operated for a fixed number of taps until the powder bed volume has reached a minimum volume. Using the weight of the granules in the cylinder and this minimum volume, the tapped density may be computed.

Formula

Tapped density = Weight of granules/ Tapped volume of granules

Angle of Repose

The manner in which stresses are transmitted through a bead and the beads response to applied stress are reflected in the various angles of friction and response. The most commonly used of this in angle of repose, which may be determined experimentally by number of methods. The method used to find the angle of repose is to pour the powder a conical on a level, flat surface and measure the included angle with the horizontal.

Formula

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

Where,

θ = Angle of repose,

h = Height of the powder cone,

r = Radius of the powder cone.

Compressibility Index or Carr's Index

Carr's Index is measured using the values of bulk density and tapped density.

The following equation is used to find the Carr's Index,

$$CI = \frac{(TD-BD)}{TD} \times 100$$

Where, TD = Tapped density**,** BD = Bulk density

Hausner's Ratio

It indicates the flow properties of the powder and ratio of Tapped density to the Bulk density of the powder or granules.

All the flow properties results are measured and tabulated in table no.2.

Formula

Hausner's Ratio = Tapped density/Bulk density

Precompression parameters are showed in the table no.3.

Evaluation of tablets[3, 4, 5]

Hardness or Crushing strength Test

Hardness of the tablet was determined using the Monsanto hardness tester.

The force required to break the tablet is measured in kilograms and a crushing strength of 4Kg is usually considered to be the minimum for satisfactory tablets. Sustained release tablets have a hardness of 10 -20 kg ; however, Oral disintegrating tablets normally have a hardness of 4 to 10 kg and hypodermic and chewable tablets have a hardness of 3 kg.

Thickness Test

The thickness of the tablet is mostly related to the tablet hardness can be uses as initial control parameter. Ten tablets were randomly selected from each tablet thickness was determined using a Vernier calipers and the reading was recorded in millimeters.

Friability Test

The pre-weighed tablets were placed in the friabilator (EF-2, Electro lab, Mumbai) which was then operated for 100rpm, then dusted and reweighed. The Conventional compressed tablets that lose less than 0.5-1.0% of their weight are generally considered acceptable.

$$\text{Friability index} = \frac{I - F}{I} \times 100$$

Where,

I - Initial weight **F** - Final weight

The prepared matrix tablets were evaluated for hardness, weight variation, thickness, friability and drug content. Hardness of the tablets was tested using a Strong- Cobb hardness test. Friability of the tablets was determined in a Roche friabilator. The thickness of the tablets was measured by Vernier caliper. Weight variation test was performed according to the official method.

Post compression parameters are showed in the table no.4.

In-vitro release studies

The in-vitro release studies of PDT was carried out using USP dissolution apparatus type-II (paddle), at 50 rpm, at 370c ± 0.50c in 900 ml of phosphate buffer (pH 7.4) as dissolution medium. The sample was taken for every 3 min up to 15min and the drug content was estimated by UV method at 254 nm. Invitro results are showed in the figure No.6.

RESULTS AND DISCUSSION

The tablets were evaluated for different parameters like weight variation, thickness, hardness, drug

content and invitro evaluation studies and stability studies. Observations of all the formulations form physical characterization have shown that the formulations show optimum results.

Table No.1: Formula

S.No	Ingredients	F1	F2	F3	F4	F5	F6
1	Piroxicam	20	20	20	20	20	20
2	Micro crystalline cellulose	10	15	20	10	15	20
3	Sodium starch glycolate	5	10	15	-	-	-
4	Crosspovidone	-	-	-	5	10	15
4	Aerosil	5	5	5	5	5	5
5	Starch	25	25	25	25	25	25
6	Aspartame	5	5	5	5	5	5
7	Pineapple flavor	2	2	2	2	2	2
8	Magnesium stearate	5	5	5	5	5	5
9	Lactose	517	517	517	517	517	517
10	Talc	2	2	2	2	2	2

Table No.2: Standard curve of Piroxicam

S.No	Concentration (mcg/ml)	Absorbance
1	20	0.114
2	40	0.226
3	60	0.352
4	80	0.470
5	100	0.582

Table No.3: Precompression parameters

Formulation Trial no	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Compressibility Index (%)	Hausner's Ratio
F1	0.425	0.464	8.60	1.094
F2	0.416	0.459	9.36	1.103
F3	0.425	0.465	8.60	1.094
F4	0.421	0.459	8.27	1.090
F5	0.425	0.470	9.57	1.105
F6	0.430	0.481	10.60	1.118

Appearance of the tablet

White colored, oval uncoated, molted tablet with plain surface on one side and break line on other side.

Table No.4: Post Compression parameters of tablets

Formulation No	Wetting time (sec)	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Disintegration time (sec)	Uniformity of dispersion
F1	54.54	5.7	3.50	0.293	33.47	Pass
F2	55.56	5.7	3.48	0.293	31.56	Pass
F3	54.46	6.0	3.42	0.291	29.25	Pass
F4	56.37	5.8	3.71	0.428	35.42	Pass
F5	59.45	5.9	3.68	0.426	33.45	Pass
F6	59.35	5.7	3.66	0.426	29.41	Pass

Assay of prepared PDT

The results of the assay of Piroxicam were done as per procedure 5.10 and presented in the table no: 5.

Table No.5: Assay of Piroxicam

S. No	Formulation No	Assay of Piroxicam in % w/w
1	F1	98.3
2	F2	98.6
3	F3	99.0
4	F4	102.7
5	F5	102.5
6	F6	101.2

Table No.6: Invitro drug release of all formulations

Time(minutes)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
3	66.42	67.89	79	70.74	69.77	72.07
6	71.69	74.49	87.91	76.24	82.59	81.36
9	81.72	81.66	92.14	83.62	91.48	89
12	89.83	93.89	95.13	87.78	93.4	93.23
15	91.82	96.6	99.18	90.12	94.9	96.87

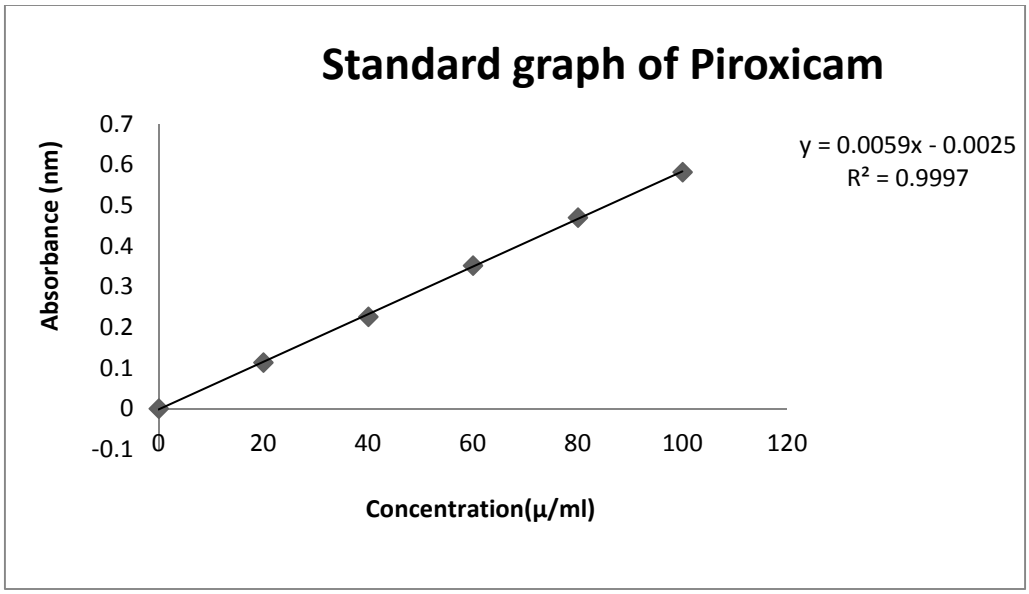

Figure No.1: Standard graph of Piroxicam

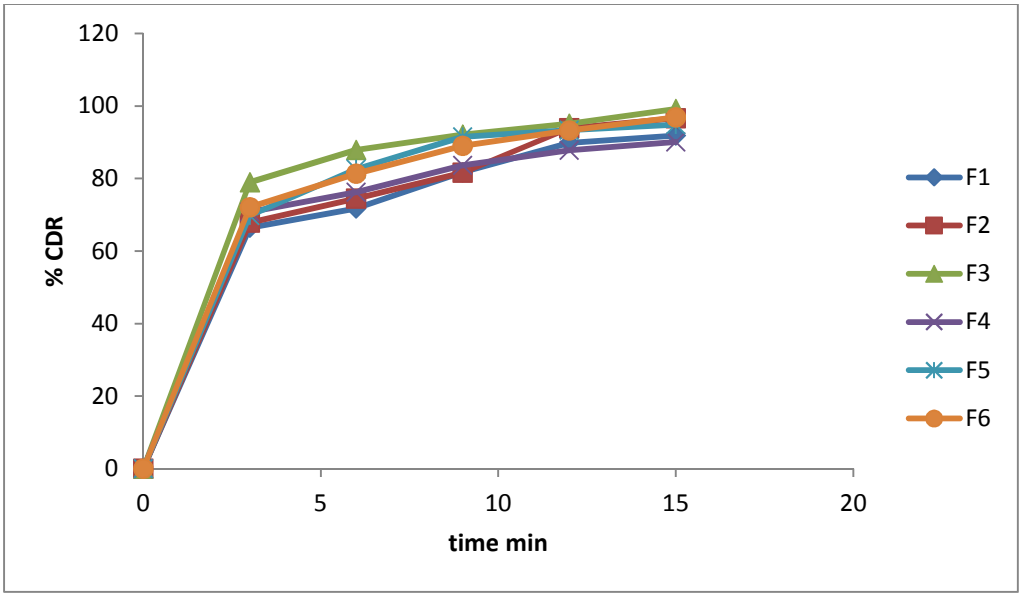

Figure No.2: Invitro Drug release of all formulations

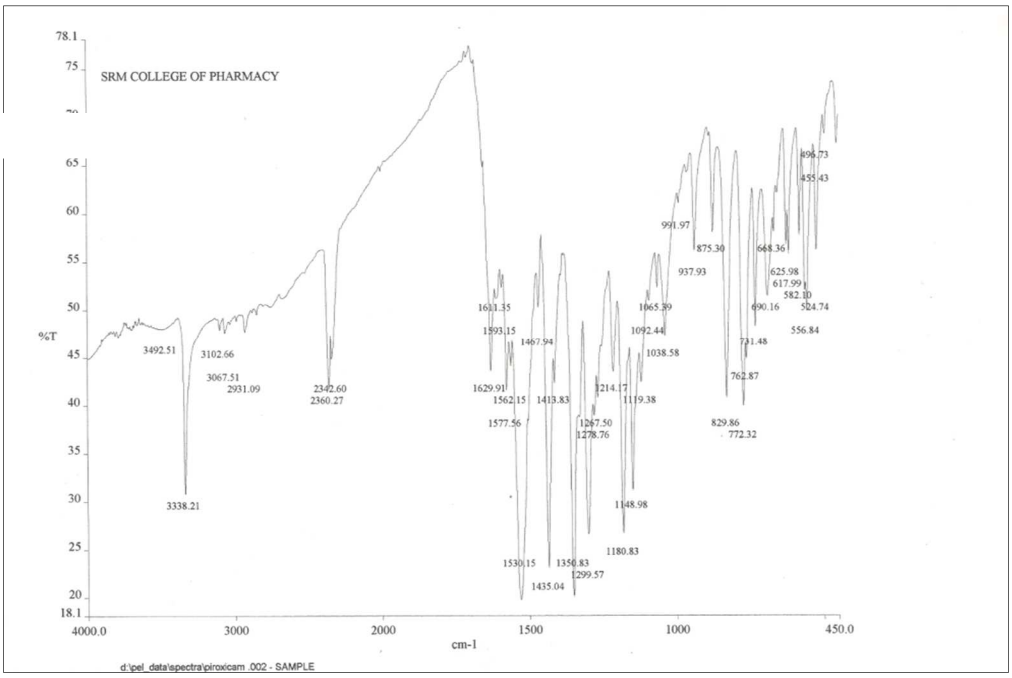

Figure No.3: Infra-Red Spectrum of Pure Piroxicam

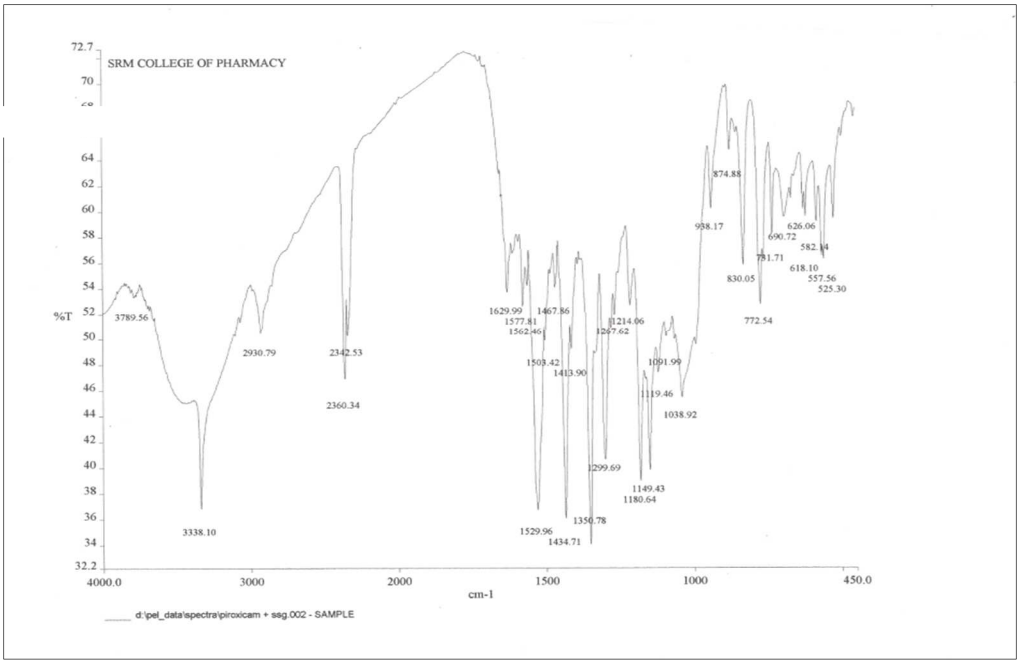

Figure No.4: Infra Red Spectrum of Piroxicam with Sodium Starch Glycolate

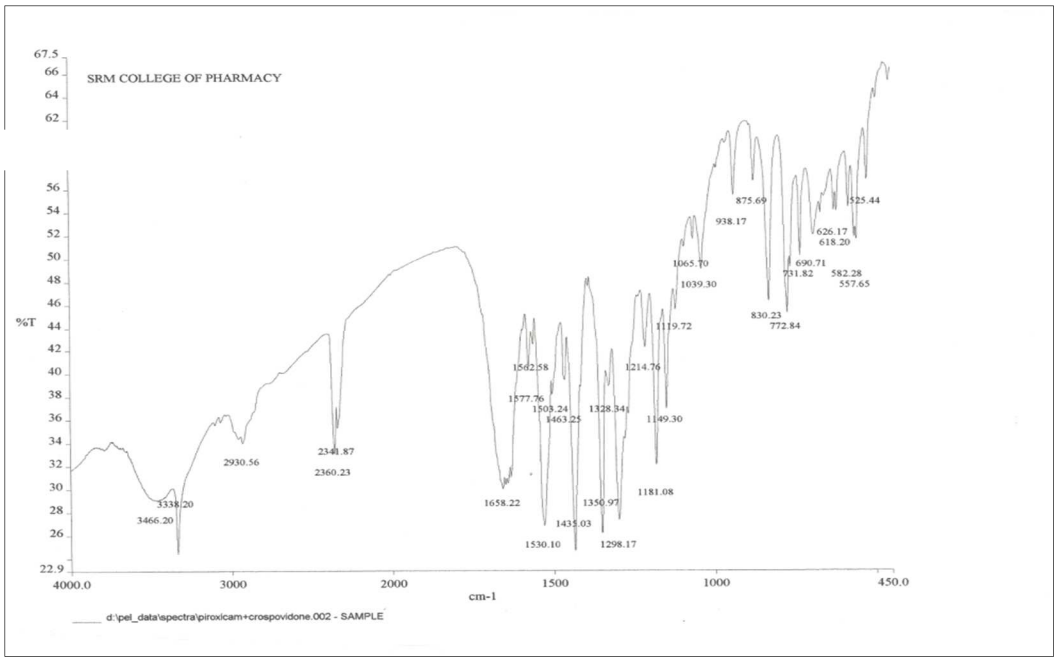

Figure No.5: Infra Red Spectrum of Piroxicam with Crospovidone

CONCLUSION

The study was carried to formulate and evaluate dispersible tablet dosage form containing Piroxicam a Non-steroidal anti-inflammatory drug. The present study is an attempt to select best possible combination of diluents and disintegrants to formulate dispersible tablet of Piroxicam which disintegrates within seconds in mouth, thereby reducing the time of onset of action.

Lactose is selected as diluents, Sodium starch glycolate, Crosspovidone, were selected as super disintegrants. Starch paste as a binder in all formulations in different concentrations. Aspartame as a sweetening agent, Magnesium stearate and Talc as a Lubricant, Aerosil as a Glidant.

- Direct Compression method was used to formulate the tablets.
- All the formulations were showed the acceptable flow properties and the precompression parameters like Bulk density, Tapped density and Hausner's ratio.
- The post compression parameters like Hardness, Friability, Disintegration time, Weight variation, wetting time, Dispersion time values were found to be within the IP limits.
- The percentage Drug content of all tablets was found to be between 98.3% - 102.7% of Piroxicam, which is within the limit.
- From the data obtained, it is observed from the formulation containing Sodium starch glycolate - 15mg, Micro crystalline cellulose - 20mg in Formulation F3, Disintegration time showed the 29 seconds, Percentage drug release of 99% at the end of 15 min which satisfied all the tablet evaluation parameters for dispersible tablet.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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