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Formulation, Development and Evaluation of Fast Disintegrating Tablet of Piroxicam using Solid Dispersion Technique

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ABSTRACT

The solubility behavior of drugs remains one of the most exigent aspects in formulation development. With the advent of combinatorial chemistry and high throughput screening, the number of poorly water soluble compounds has dramatically increased. Among all the newly discovered chemical entities, about 40-45% drugs fail to reach market due to their poor water solubility. Because of solubility problem, bioavailability of drugs gets affected and hence solubility enhancement becomes necessary. In present study the attempts have been made to increase the dissolution of BCS class 2 drug Piroxicam using hydrophilic polymers namely polyethylene glycol (PEG) 6000 and sodium lauryl sulphate as a surfactant by using solid dispersion technique. In solid dispersion microwave induced solid dispersion and conventional fusion method is compared. Drug-polymer complex was prepared using batch method. Maximum dissolution rate was obtained of the complex prepared from (Piroxicam + PEG6000 + SLS). A successful solubility enhancement of drug complex was confirmed by taking drug release in phosphate buffer pH 6.8. The drug was characterized according to different compendial methods, on the basis of identification by UV spectroscopy, organoleptic properties and other tests. After that among the all formulation batches, solid dispersion (F16) was selected for further tablet formulation batches, nine formulations were developed and studied. The values of pre-compression parameters was evaluated, results were within prescribed limits and indicated good free flowing properties. The data obtained of post-compression parameters such as weight variation, hardness, friability, wetting time, water absorption ratio, content uniformity, disintegration time and dissolution was found to superior over conventional formulation. The F9 batch with disintegrating time 10 ± 0.52 second and dissolution 93.20 ± 0.61 % was selected as optimized formulation and was found superior over other formulation. Batch F9 was also subjected to stability studies for three months and was tested for its disintegrating time, drug contents and dissolution behavior monthly. F9 formulation after stability study was found to be stable.

KEYWORDS: *Piroxicam, Solid dispersion, Solubility, Dissolution, Microwave Induced fusion Method*

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INTRODUCTION

Solid dispersions have attracted considerable interest as an efficient means of improving the dissolution rate and hence the bioavailability of drugs. There are various methods available to improve the solubility of the new drug in which solid dispersion emerged promising. A Solid dispersion generally composed of

two components the drug and the polymer matrix. Hence, this approach is expected to form a basis for the commercialization of many poorly water-soluble and water-insoluble drugs in their solid-dispersion formulations in the near future. These poorly water soluble drugs i.e. BCS class II drugs absorption from the gastrointestinal tract can be limited by a number of factors; most significant contributors are poor aqueous solubility & poor membrane permeability of the drug molecule. Therefore, the improvement of drug solubility thereby its oral bioavailability remains one of most challenging aspects of drug development process especially for oral drug delivery system. Out of many categories, Non steroidal anti-inflammatory drugs, Analgesic drugs are the most widely prescribed medication. Piroxicam is an Analgesic and non steroidal anti inflamatory drug commonly used to relieve the pain and inflammation. Piroxicam belongs to BCS class II drugs which has low solubility and high permeability. Piroxicam mostly permeable through stomach but due to its solubility limitation it can't enter into systemic circulation. After this time Piroxicam goes in to small intestine where it is solubilized but can't permeate through its membrane (Piroxicam having pH depended solubility and permeability). So, to improve dissolution of such drug is challenging and rational. Recently a totally unique approach supported the use of microwave irradiation has been proposed for the preparation of SD. Microwaves irradiation (MW) could also be a well-known method for heating and drying materials. Microwaves, with their ability to penetrate any substance, allow the assembly of heat in any point of the sample at the same time this is often because of the presence in it of molecules characterized by a dipolar moment able to absorb microwave energy and convert it into heat. This phenomenon occurs when the microwave frequency is on the brink of the resonance frequency of the polar molecules. The efficient heating of materials by microwaves depends on the capacity of a selected material to soak up microwave energy. Microwave energy has been employed to vary the crystalline state of a drug, instead of conventional heating. [1, 2]

MATERIALS AND METHODS

Materials

All materials used in present research were commercial samples. Active pharmaceutical ingredient: Piroxicam (Aarti Pharma, Mumbai) Hydrophilic polymers: Polyethylene glycol 6000, Sodium lauryl sulphate (Research lab Fine chem. Industry, Mumbai), Excipients: Sodium starch glycolate, Croscarmellose Sodium, Crospovidone, (Research lab fine chem. Islampur), Microcrystalline cellulose, Magnesium stearate, Mannitol, Talc (Research lab fine chem. Mumbai).

Preformulation Studies of Piroxicam

Organoleptic Evaluation, Melting point, Solubility profile and Loss on drying of Piroxicam drug for identification and authentication of received sample for further formulation studies of solid dispersion [3, 4]

Scanning of Piroxicam in Phosphate Buffer pH 6.8 Solution

The standard solution (10ug/mL) was scanned from 200-400 nm on UV spectrophotometer (Shimadzu UV-1800). Primary standard solution of Piroxicam was prepared by dissolving 10 mg of Piroxicam in 100 mL of the phosphate buffer pH 6.8 solutions to obtain a solution of 100 ug/mL Aliquot of 0.5 mL, 1.0 mL, 1.5 mL, 2.0 mL and 2.5 mL from the standard stock solution were transferred to 10mL volumetric flask and the volume was adjusted up to the mark with phosphate buffer pH 6.8 to obtain a concentration of 5ug/mL, 10ug/mL, 15ug/mL, 20ug/mL and 25ug/mL The absorbance was determined at 354 nm against blank. The calibration curve is shown in Figure (2) and absorbances of different concentration of Piroxicam are reported in Table (4) [7, 8, 9, 17]

Drug Excipient Compatibility Studies by using FTIR Spectroscopy of Piroxicam and PEG 6000 and SLS

Piroxicam, polymer and solid dispersion was prepared and mixed with suitable quantity of Potassium bromide. About 100mg of this sample was compressed to form a transparent pellet using a hydraulic press at 10 tons pressure. It was scanned from 4000 to 600 cm^{-1} FTIR Spectrophotometer. The interaction between drug-excipients was observed from IR spectral studies by observing any shift in peaks of drug in the spectrum of physical mixture of drug. [11, 12, 13]

Formulation and Development of Solid Dispersion of Piroxicam

Solid dispersion of drug and polymer was prepared by using Microwave induced fusion method and conventional fusion method in various ratios such as Piroxicam + PEG 6000 (1:1), Piroxicam + PEG 6000 + SLS (1:1:0.75), Piroxicam + PEG6000 (1:2), Piroxicam+PEG6000 + SLS (1:2:0.75), Piroxicam + PEG 6000 (1:3), Piroxicam + PEG 6000 + SLS (1:3:0.75) Piroxicam + PEG 6000 (1:4), Piroxicam + PEG 6000 + SLS (1:4:0.75) and Solid dispersion prepared by conventional fusion method were F1, F2, F3, F4, F5, F6, F7, F8 and solid dispersion prepared by microwave induced fusion method F9, F10, F11, F12, F13, F14, F15 and F16 respectively.[11]

Table 1 Formulation of Drug and Polymer

Formulations / Batches	Composition	Method	Ratio
F1	Piroxicam+ PEG 6000	Conventional Fusion Method	1:1
F2	Piroxicam +PEG 6000 +SLS	Conventional Fusion Method	1:1:0.75
F3	Piroxicam + PEG 6000	Conventional Fusion Method	1:2
F4	Piroxicam +PEG 6000 +SLS	Conventional Fusion Method	1:2:0.75
F5	Piroxicam +PEG 6000	Conventional Fusion Method	1:3
F6	Piroxicam + PEG 6000+SLS	Conventional Fusion Method	1:3:0.75
F7	Piroxicam +PEG 6000	Conventional Fusion Method	1:4
F8	Piroxicam + PEG 6000+SLS	Conventional Fusion Method	1:4:0.75
F9	Piroxicam+ PEG 6000	Microwave Induced Fusion Method	1:1
F10	Piroxicam +PEG 6000 +SLS	Microwave Induced Fusion Method	1:1:0.75
F11	Piroxicam + PEG 6000	Microwave Induced Fusion Method	1:2
F12	Piroxicam +PEG 6000 +SLS	Microwave Induced Fusion Method	1:2:0.75
F13	Piroxicam +PEG 6000	Microwave Induced Fusion Method	1:3
F14	Piroxicam +PEG 6000 +SLS	Microwave Induced Fusion Method	1:3:0.75
F15	Piroxicam +PEG 6000	Microwave Induced Fusion Method	1:4
F16	Piroxicam + PEG 6000+SLS	Microwave Induced Fusion Method	1:4:0.75

Conventional Fusion Method

In conventional fusion method the polymer was heated to molten mass and to this weighed amount of Piroxicam was added with continuous stirring with or without SLS until mixture get melt completely and drug molecules are get dispersed uniformly in polymer occur. Solidification was allowed to occur at room temperature. The product was stored in a dessicator for 24 h and then pulverized using a porcelain mortar and pestle. The pulverized powder was passed through 100# sieve to get uniform particle size. [11]

Microwave Induced Fusion Method

In microwave induced fusion method microwave energy used to prepare solid dispersion. The drug and hydrophilic polymer will get fused together to form solid dispersion. Solid dispersion is prepared by placing the mixture of drug and polymer in porcelain dish and subjected to microwave radiation. Only one sample is place at a time inside the microwave oven. Only one sample is placed at a time inside the microwave oven. Porcelain dish is place in room temperature to solidify molten mass. The solid dispersion is placed in desiccators for 24 hr. and then product is pulverize using a porcelain mortar and pestle. The pulverize powder is pass through 100# sieve. [11]

Comparative Solubility and Dissolution Study to Select the Optimum Batch of Solid Dispersion

Comparative solubility and dissolution study of Piroxicam and Solid dispersion batches to select the optimum batch of solid dispersion for further studies.

Solubility study of Solid Dispersion and Piroxicam

Solubility measurement of Piroxicam were performed according to a published method. The amount of solid dispersion powder containing 2.5mg equivalent Piroxicam was weighed accurately in volumetric flask was dissolved 5ml distilled water by sonication for 15 min subsequently, the solutions were filtered through a Whatman filter paper no. 1 Filtered solution was diluted properly with distilled water. The diluted solution was analyzed for the Piroxicam in UV at 354nm.[11]

In vitro Dissolution Study of Pure Drug and Solid Dispersion Using Conventional Fusion Method and Microwave Induced Fusion Method.

Dissolution profiles of Piroxicam and solid dispersion were determined using the USP Type II Dissolution test apparatus (Electrolab Model TDT-08L) set with a paddle speed of 50 rpm. Dissolution was performed in 900 ml of phosphate buffer pH 6.8 maintained at $37^0 \pm 0.5^0$C. The 20 mg of Piroxicam, and The solid dispersion containing equivalent of 20mg of Piroxicam and PEG 6000 (1:1, 1:0.75, 1:2, 1:2:0.75, 1:3, 1:3:0.75, 1:4, 1:4:0.75) Conventional Fusion Method and Microwave Induced Fusion Method batches of solid dispersion from F1 to F16 was taken in a muslin cloth and tied to the rotating paddle kept in vessel of dissolution apparatus the paddle was rotated at 50 rpm. Aliquot of dissolution medium, 5 ml was withdrawn at specified time and filtered through Whatmann filter paper. The amount of drug dissolved was determined by UV-Visible spectrophotometer by measuring the absorbance of the sample at 354 nm. An equal volume of fresh medium,

prewarmed at 37^0C was replaced into the dissolution medium after each sampling to maintain the constant volume throughout the test. Three trials for each batch were performed and average percentage drug release. [11]

Comparative Dissolution Study of Piroxicam and solid dispersion

The dissolution of pure drug is compare with solid dispersion by conventional fusion method (F8) and microwave induced fusion method (F16) which is shown in Table 12 and graph was plotted to show % drug release which was represented in Figure 10

Selection of Optimum Batch of Solid Dispersion for formulation of Fast Disintegrating Tablet

For Selection of the optimum batch Solid Dispersion Technique, the dissolution of the pure drug Piroxicam and its Solid Dispersion by Conventional Fusion Method and Microwave Induced Fusion Method is compare.

EVALUATION OF SOLID DISPERSION [11, 13]

Physical appearance

Visual inspection of all batches of solid dispersions such as color and appearance.

Percentage yield Study of Solid Dispersion

Percentage yield was calculated with respect to dry product. Based on the practical yield (P.Y) obtained a0nd the calculated theoretical yield (T.Y), % yield was calculated by using the following formula:

PY (%) = [Practical weight/Theoretical weight (Drug +Carrier)] ×100 .....Eq^{n}1

Where,
a = Practical weight of solid dispersion obtained
b = Theoretical weight of solid dispersion preparation.

Drug Content

Determination of drug content in solid dispersion powder solid dispersion equivalent to 20 mg of Piroxicam was accurately weighed and transferred to a 100 ml volumetric flask. About 30 ml of distilled water was added and flask was shaken to dissolve the contents completely and the volume was made up to the mark with distilled water. The concentration of this resulting solution was 100µg/ml. From this solution, 1 ml of solution was taken in another 10 ml volumetric flask, and volume was made up to 10 ml with distilled water. The solution was analyzed spectrophotometric at 354 nm against corresponding reagent blank. The analysis was carried out in triplicate and drug contents were determined. [11, 14]

Characterization of Microwave Induced Solid Dispersion

FT-IR Spectroscopy

Infrared spectra matching approach was used for the detection of any possible chemical reaction between the drug and the excipients. Piroxicam, polymer and solid dispersion was prepared and mixed with suitable quantity of Potassium bromide. The interaction between drug-excipients was observed from IR spectral studies by observing any shift in peaks of drug in the spectrum of mixture of drug. [14]

Differential Scanning Calorimetry (DSC)

In drug formulation it is essential to evaluate the possible interactions between the active principle and the excipients, as the choice of the excipients should be performed in relation to the drug delivery, to their compatibility with the same drug and to the stability of the final product. Piroxicam powder was mixed with various excipient and the resulting mixture was kept in sealed glass vials. Mixture should be examined under Nitrogen to eliminate oxidative and pyrolytic effect at a standard heating rate (2, 5 or 10^0C per minute) on DSC. Thermograms of pure drug are used as a reference. [14]

XRD STUDIES

X-ray powder diffractometry was carried out to investigate the effect of complexation process on crystallinity of drug. Powder X-ray diffractometry were carried out using a D8 Advance (Bruker) scanner with filter Ni, Cu, Kα radiation, voltage 40kV and a current of 20 mA. The scanning rate employed was 1°/min over the 5° to 50° diffraction angle (2θ) range. The XRPD patterns of drug powder and drug-polymer complex were recorded. The comparative XRPD patterns of pure drug and drug- polymer complex were given in Figures 14 and 15 [11, 14]

FORMULATION OF FAST DISINTEGRATING TABLET OF PIROXICAM USING SOLID DISPERSION TECHNIQUE

After evaluation of solid dispersion of Piroxicam prepared by conventional fusion method and microwave induced fusion method, fast dissolving tablets were prepared according to formula given in Table 2 [15, 16]

Table 2 Formulation of Fast Disintegrating Tablet

Formulations	F1	F2	F3	F4	F5	F6	F7	F8	F9
Ingredient	Unit Formula (mg per tablet)								
Solid Dispersion complex equivalent to 20 mg Piroxicam	118.55	118.55	118.55	118.55	118.55	118.55	118.55	118.55	118.55
Sodium starch glycolate	6	10.5	15	-	-	-	-	-	-
Crosscarmellose sodium	-	-	-	6	10.5	15	-	-	-
Crospovidone	-	-	-	-	-	-	6	10.5	15
Microcrystalline cellulose	120	115.5	111	120	115.5	111	120	115.5	111
Mannitol	50	50	50	50	50	50	50	50	50
Magnesium Stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Total	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**

EVALUATION OF POWDER BLEND FOR FAST DISINTEGRATING TABLET

Method: Accurate quantity of drug and all ingredients were weighed according to formula and powder except mannitol and magnesium sterate was blended homogeneously in mortar and pestle for 15 minutes. Prepared powder blend was passed through sieve No. #60. Finally, mannitol and magnesium sterate passed through sieve No. #30 was added and further mixed for 10 minutes. The powder blend was evaluated for angle of repose, bulk density, Tapped density, Compressibility Index and Hausner's ratio. [7, 11]

MANUFACTURING OF FAST DISINTEGRATING TABLET OF PIROXICAM CONTAINING SOLID DISPERSION BY DIRECT COMPRESSION METHOD

The fast disintegrating tablets were prepared by direct compression method with the use of different superdisintegrants namely Croscarmellose sodium, Sodium starch glycolate, Crospovidone. Microcrystalline cellulose, Mannitol was used as a diluents and Mg. Stearate was used as lubricant.. Accurate quantity of drug and all ingredients were weighed according to formula and powder except mannitol and Magnesium sterate was blended homogeneously in mortor and pestle for 15 minutes. Prepared powder blend was passed through sieve no. #60. Finally, mannitol and Magnesium sterate passed from sieve no. #30 added and was further mixed for10 minutes. Accurately weighed 300 mg homogeneously mixed powder blend was fed manually and compressed with constant compression force and hardness on 16 stations tablet compression machine with 5 mm, breakthrough, and flat faced punches. Total nine formulations were prepared.

EVALUATION OF FAST DISINTEGRATING TABLET

The prepared tablets of piroxiam were evaluated for post cimression parameters like

Appearance

The tablets were visually observed for capping, chipping and lamination. [11,17]

Thickness

Three tablets were selected randomly from each batch and thickness was measured by using Vernier Caliper. [11,17]

Hardness

Hardness or tablet crushing strength (F_o) the force required to break a tablet in a diametric compression was measured using Pfizer Hardness Tester. For each formulation, the hardness of 6 tablets was determined using the Pfizer hardness tester. The tablet was held along its oblong axis in between the two jaws of the tester. At this point, reading should be zero kg/cm^2. Then constant force was applied until the tablet fractured. The value at this point was noted in kg/cm^2. [7,11,17]

Friability

Friability of the tablets was determined using Roche Friabilator. This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and roping the tablets height of 6 inches in each revolution. [7]

Previously weighed sample of tablets was placed in the riabilator and were subjected to 25 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed, the friability (F) is given by the formula.

Drug Content

Content uniformity test is used to ensure that every tablet contains the amount of drug substance intended with little variation among tablets within a batch. Five tablets were selected randomly and average weight was calculated. Tablets were crushed in a mortar and accurately weighed and the amount of average tablet was taken from the crushed blend. then, the sample was transferred to the 100ml volumetric flask and was diluted up to the mark with pH 6.8 phosphate buffer. the content was shaken periodically and kept for 24 hours for dissolution of drug completely. The solution was filtered and appropriate dilutions were made. The drug content in each tablet was estimated at 354nm against pH 6.8 phosphate buffer as a blank reference and reported. [11, 17, 18]

Weight Variation Method

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation test if not more than two of the individual tablet weight deviate from the average weight. [7, 17]

% F = (Initial wt. - Final wt. / Initial wt.) × 100. ……..Eq^{n}2

Disintegration time Method

The disintegration time of tablet was determined by using Disintegration test apparatus. Tablets were placed in disintegration test assembly and disc was placed was placed on tablets in each glass tube of assembly. The assembly was dipped in a vessel containing 900ml phosphate buffer pH 6.8 at 37^{0}C. The time for disappearance of tablet residue above mesh was noted as disintegration time. [7]

Wetting time of water absorption Ratio

Wetting Time: wetting time of dosage form is related with the contact angle. wetting time of the mouth dissolving tablets is another Important parameter, which needs to be assessed to give an insight into the disintegration properties of the tablets; a lower wetting time cause faster disintegration of the tablet can be measured using a simple procedure. [7, 17, 18]

Method: five circular tissue papers of 10 cm diameter were placed in a petri dish. 10ml of water was added to petri dish, a tablet was carefully placed on the surface of the tissue paper. the time required for water to reach upper surface of the tablet was noted as wetting time.

Water absorption ratio(R): the weight of the tablet before keeping in the petri dish was noted (Wb). The wetted ablet from the petri dish was taken and re weighed (Wa) using the same.

R=100×Wa- Wb/Wb ……Eq^{n}3

Where,
Wb =Weight of tablet before water absorption
Wa = Weight of tablet after water absorption

In-vitro Dissolution studies

Dissolution profiles of piroxicam tablets were determined using the USP Type II Dissolution test apparatus set with a paddle speed of 100 rpm. Dissolution was performed in 900 ml of maintained at 37^{0} ± 0.5^{0} C. Aliquot of dissolution medium, 5 ml was withdrawn at 5, 10, 15, 20, 25, 30 and 40 min with 5 minutes interval, and filtered through Whatmann filter paper. The amount of drug dissolved was determined by UV-Visible spectrophotometer by measuring the absorbance of the sample at 354 nm. An equal volume of fresh medium, prewarmed at 37^{0}C was replaced into the dissolution medium after each sampling to maintain the constant volume throughout the test. Three trials for each batch were performed and average percentage drug release was calculated by using disso software. [7, 11, 13]

STABILITY STUDY

Stability of a formulation can be defined as the time from date on manufacture of the formulation until its chemical or biological activity is not less than a predetermined level of labeled potency and its physical characteristics have not changed appreciably or deleteriously. Formulation and the development of a pharmaceutical product are not complete without proper stability analysis, carried out on it to assess the physical and chemical stability and the safety. The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time. Under the influence of a variety of environmental factors such as temperature, humidity and light, enabling recommended storage conditions, re-test periods and shelf lives. Generally, the observation of the rate at which the product degrades under normal room temperature requires a long time. To avoid the undesirable delay, the principles of accelerated stability studies are adopted.

The International Conference on Harmonization (ICH) Guidelines titled "Stability testing of new drug substance and products" (QIA) describes the stability test requirements for drug registration application in the European Union, Japan and United States of America. ICH specifies the length of study and storage conditions.

Long-term testing $25^0C \pm 2^0C/60$ % RH ± 5% for 12 months.

Short term testing $30^0C \pm 2^0C/65$ % RH ± 5% for 1 month.

Accelerated testing $40^0C \pm 2^0C/75$ % RH ± 5% for 6 months.

Stability studies for the present work carried out at $40^0C \pm 2^0C/75\% \pm 5\%$ RH for the selected formulation for 3 months.

Method

The selected formulations were packed in tightly closed container which were tightly plugged with cotton and capped. They were then stored at $40^0C \pm 2^0C$ /75 % RH ± 5% for 3 months and evaluated for their physical appearance, hardness, disintegrate time, dissolution testing and drug content at specified intervals of time. The drug solutions were further scanned to observe any possible spectral change. [11]

Result and Discussion

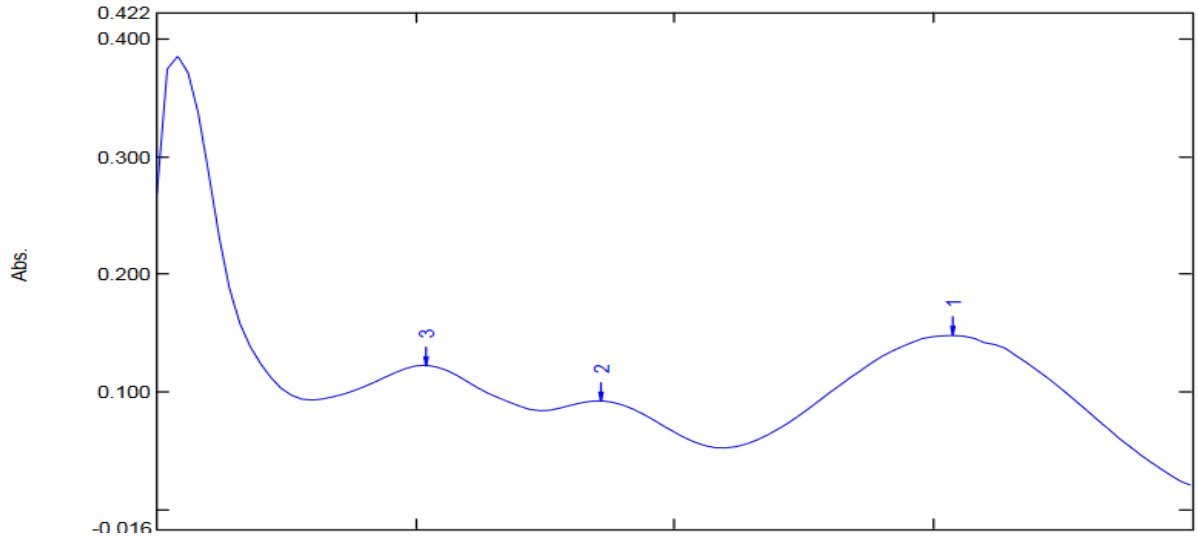
Preformulation Studies of Piroxicam

Organoleptic properties received sample of piroxicam oduorless, fine off white to light yellow powder. The melting point of piroxicam was found to be 199-201^{0}C. The reported melting point of Piroxicam was 198-200^{0}C. The Piroxicam is practically insoluble in water and freely soluble in methanol and chloroform. The percentage loss on drying after 4 hours was found to be 0.5%. The sample passes test for loss on drying as per the limits specified in I.P. (N.M.T. 0.4%) all results are complies as per I.P.

Scanning of Piroxicam in Phosphate Buffer pH 6.8 Solution

The absorption maxima were found to be at 354 nm in phosphate buffer pH 6.8.

Figure 1 Scanning of Piroxicam in Phosphate Buffer pH 6.8 Solution



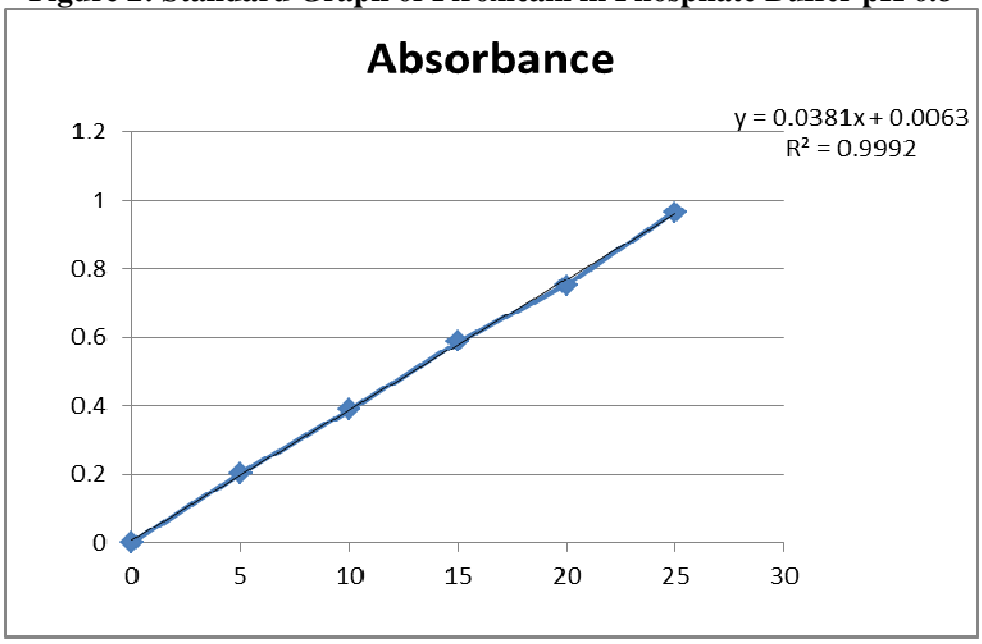
Calibration Curve of Piroxicam in Phosphate Buffer pH 6.8

Standard curve of Piroxicam was determined by plotting absorbance Vs concentration at 354nm. Using solution prepared in Phosphate Buffer pH 6.8 at 354nm; it follows Beer's law. The R^2 value was found to be 0.9992. Absorbance value were depicted in Table 3

Table 3 Calibration Curve of Piroxicam in Phosphate Buffer pH 6.8

Sr.no.	Concentration (µg/ml)	Absorbance
1	5	0.203
2	10	0.389
3	15	0.587
4	20	0.751
5	25	0.965

Figure 2: Standard Graph of Piroxicam in Phosphate Buffer pH 6.8



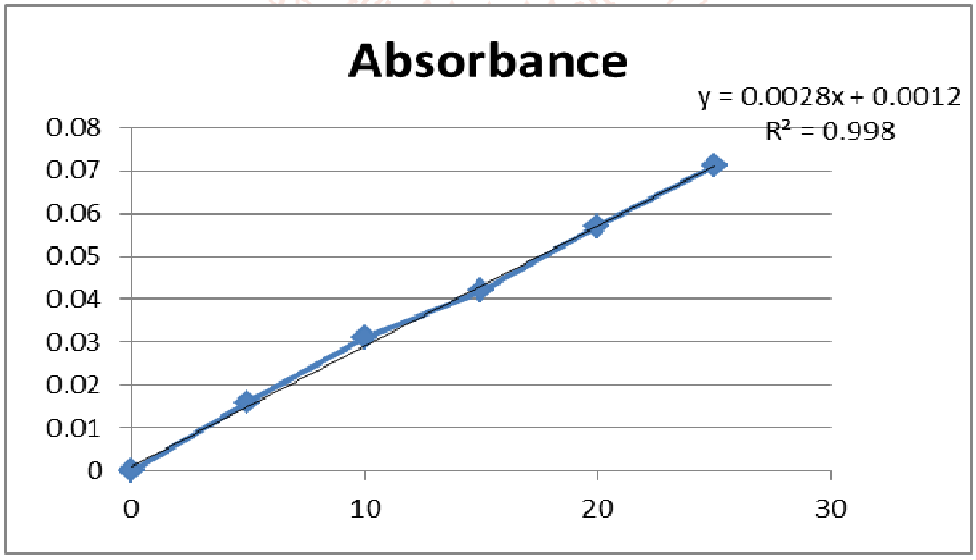
Calibration Curve of Piroxicam in Distilled Water

Standard curve of Piroxicam was determined by plotting absorbance Vs concentration at 354nm. Using solution prepared in Distilled water at 354nm; it follows Beer's law. The R^2 value was found to be 0.998. Absorbance value were depicted in Table 4

Table 4 Calibration Curve of Piroxicam in Distilled Water

Sr.no.	Concentration (µg/ml)	Absorbance
1	5	0.016
2	10	0.031
3	15	0.042
4	20	0.057
5	25	0.071

Figure 3 Calibration Curve of Piroxicam in Distilled Water



Drug Excipient Compatibility Studies Using Fourier Transform Infra red Spectroscopy of Piroxicam and PEG 6000 and SLS

Major functional groups present in Piroxicam show characteristic peaks in IR spectrum. Table 5 shows peaks observed at different wave numbers and the functional group associated with these peaks. The major peaks are identical to functional group of Piroxicam. Hence, the sample was confirmed as Piroxicam.

FTIR Studies of Piroxicam

Figure 4 FTIR Spectrum of Piroxicam

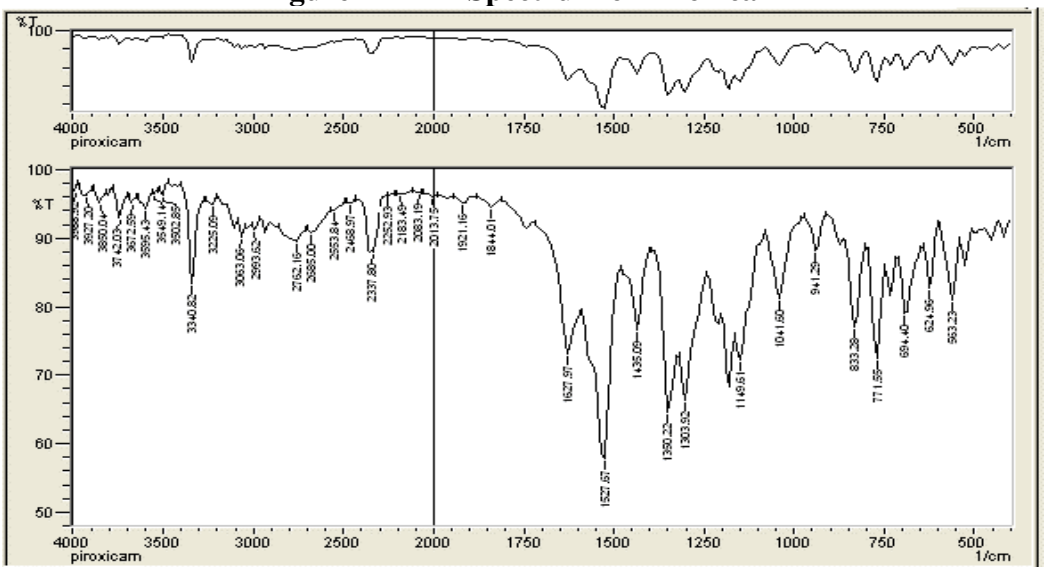


Table 5 Interpretation of FTIR Spectrum of Piroxicam

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Reported Peak Wavenumber(cm^{-1})	Functional Group
1	773.45	771.55	Ortho-di substituted ring
2	1149.57	1149.61	SO_2-NH group
3	1300.02	1303.92	Pyridine
4	1435.04	1435.09	Methyl
5	1525.69	1527.67	Tertiary amine group
6	1629.85	1627.97	Amide carbonyl
7	3338.78	3340.82	Cubic polymorphic form

FTIR Studies PEG 6000

Figure 5 FTIR Spectrum of PEG 6000

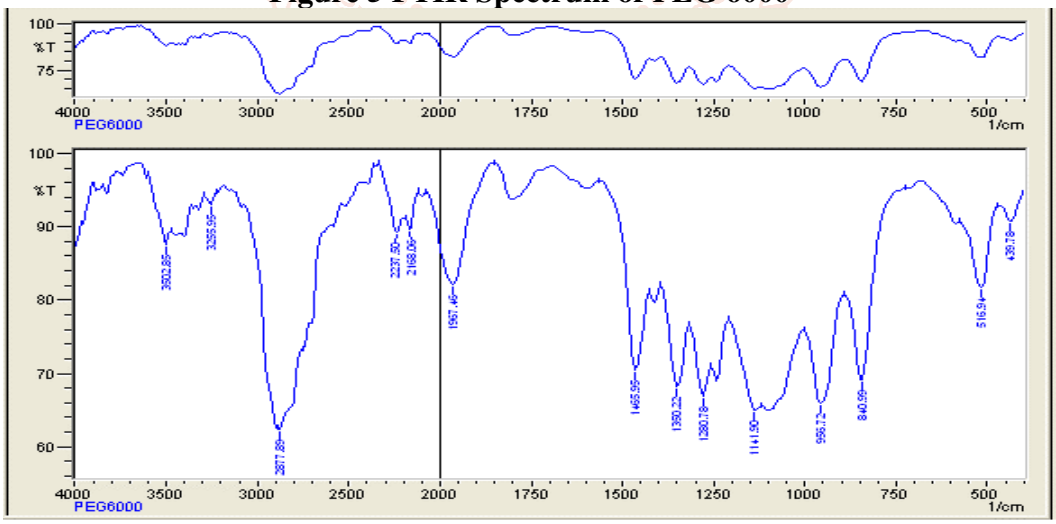


Table 6 Interpretation of FTIR Spectrum of PEG 6000

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	3500-3000	3502.85	O-H Stretching
2	3000-2500	2885.60	OH Bending
3	2000-1500	1350.22	C-H stretching
4	1500-1000	1141.90	C=O Stretching

FTIR Studies Sodium lauryl Sulphate

Figure 6 FTIR Spectrum of SLS

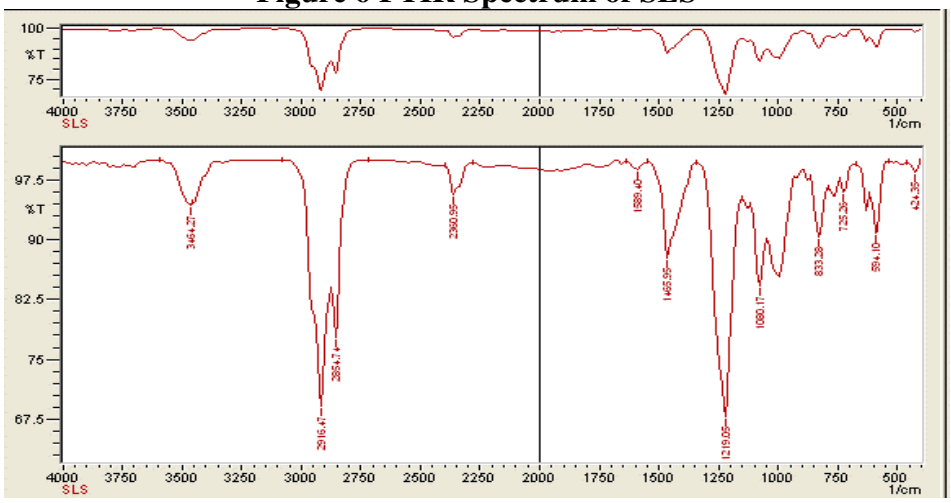


Table 7 Interpretation of FTIR Spectrum of SLS

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	1350-1140	1216.64	S=O Sulphate
2	1375-1450	1372.1	C=N Stretching of pyridine
3	3000-2800	2916.96	C-H Stretching
4	1300-1000	1078.26	O-H (Alcohol H-bonded) stretching
5	1465	1466.67	C-H Alkane stretching

Mixture of Piroxicam, PEG 6000 and SLS

Figure 7 FTIR Spectrum of Piroxicam, PEG 6000 and SLS Mixture

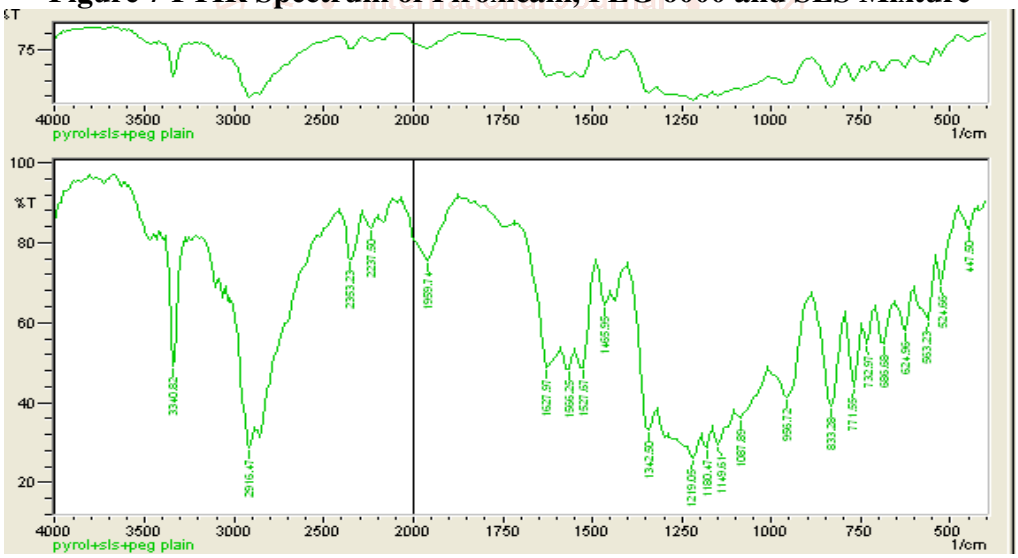


Table 8 Interpretation of FTIR Spectrum of Piroxicam, PEG 6000 and SLS Mixture

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Reported Peak Wavenumber(cm^{-1})	Functional Group
1	773.45	771.55	Ortho-di substituted ring
2	1149.57	1149.61	SO2-NH group
3	1300.02	1342.50	Pyridine ring
4	1435.04	1465.09	Methyl group
5	1525.69	1527.67	Tertiary amine group
6	1629.85	1627.97	Amide carbonyl
7	3338.78	3340.82	Cubic polymorphic form

In spectrum of pure drug and polymer is showed in figure 4 - 7. In above IR spectra the peak of drug and polymer are showed in Table 5 - 8. All these peaks have appeared in physical mixture indicating no chemical interaction between Piroxicam and polymer.

The formulation of solid dispersion prepared by both methods i.e., Conventional Fusion Method and Microwave induced Fusion method in various ratios such as Piroxicam and PEG with and without SLS (1:1, 1:1:0.75, 1:2, 1:2:0.75, 1:3, 1:3:0.75 1:4, 1:4:0.75) Solid dispersion prepared by conventional Fusion Method were F1, F2, F3, F4, F5, F6, F7, F8 and solid dispersion prepared by microwave Induced Fusion Method F9, F10, F11, F12, F13, F14, F15 and F16 respectively.

Solubility study of various solid dispersion trial batches was performed. Solid dispersion prepared by microwave induced fusion method improved solubility of Piroxicam as compared to pure drug and solid dispersion prepared by conventional fusion method. The batch F16 was more soluble than pure drug and other formulation batches.

Table 9 Solubility Study of Solid Dispersion

Formulations	Drug: Carrier	Solubility (µg/ml)
Pure drug	Pure drug	2.285
F1	Piroxicam + PEG 6000 (1:1)	9.428
F2	Piroxicam + PEG 6000 (1:1:0.75)	20.85
F3	Piroxicam + PEG6000 (1:2)	17.28
F4	Piroxicam + PEG 6000 + SLS (1:2:0.75)	29.42
F5	Piroxicam + PEG6000 (1:3)	25.14
F6	Piroxicam + PEG 6000 + SLS (1:3:0.75)	40.14
F7	Piroxicam + PEG 6000 (1:4)	34.42
F8	Piroxicam + PEG 6000 (1:4:0.75)	51.57
F9	Piroxicam + PEG 6000 (1:1)	13.714
F10	Piroxicam + PEG 6000 (1:1:0.75)	28.71
F11	Piroxicam + PEG6000 (1:2)	24.42
F12	Piroxicam + PEG 6000 + SLS (1:2:0.75)	37.28
F13	Piroxicam + PEG6000 (1:3)	31.57
F14	Piroxicam + PEG 6000 + SLS (1:3:0.75)	47.91
F15	Piroxicam + PEG 6000 (1:4)	42.28
F16	Piroxicam + PEG 6000 + SLS (1:4:0.75)	63.71

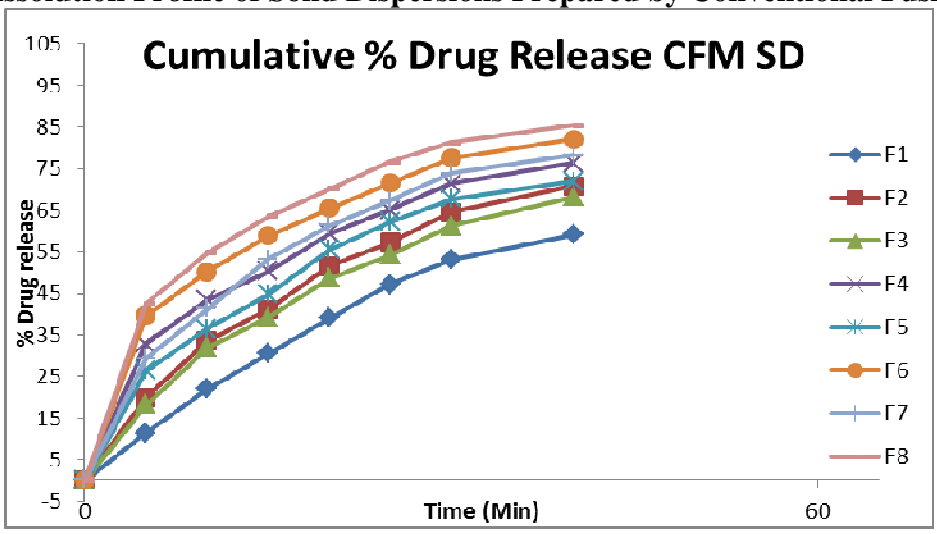
Out of eight formulations F8 shown maximum drug release i.e., 85.47±0.19%. Solid dispersion (F8) of Piroxicam, PEG 6000 with and without SLS prepared by conventional fusion method significantly improved its solubility and dissolution rate.

Table 10 Dissolution profile of solid dispersions prepared by conventional fusion Method

Time (min)	Cumulative % Drug Release							
	F1	F2	F3	F4	F5	F6	F7	F8
0	00	00	00	00	00	00	00	00
5	11.35 ± 0.81	19.94 ± 1.22	18.24 ± 0.73	32.89 ± 1.21	26.45 ± 1.14	39.63 ± 1.24	31.39 ± 1.19	42.48 ± 0.93
10	22.06 ± 0.63	33.57 ± 1.13	31.89 ± 0.62	43.52 ± 0.64	36.44 ± 0.93	50.23 ± 1.15	40.35 ± 0.75	54.77 ± 0.64
15	30.63 ± 0.44	41.21 ± 0.96	39.23 ± 0.26	50.36 ± 0.49	43.83 ± 0.52	58.92 ± 1.29	51.46 ± 0.82	63.54 ± 1.04
20	39.09 ± 0.36	51.60 ± 0.56	48.73 ± 0.84	59.41 ± 0.52	55.54 ± 0.63	65.46 ± 1.65	59.46 ± 0.95	70.19 ± 1.14
25	47.26 ± 0.59	57.21 ± 0.66	54.19 ± 0.63	65.12 ± 0.47	62.16 ± 0.67	71.46 ± 1.33	67.28 ± 0.61	76.56 ± 0.85
30	53.11 ± 1.09	64.57 ± 0.75	61.23 ± 0.34	71.45 ± 0.71	67.64 ± 0.83	77.63 ± 0.23	72.69 ± 0.91	81.26 ± 0.98
40	59.22 ± 0.26	70.89 ± 0.64	68.47 ± 1.05	76.32 ± 0.33	72.88 ± 1.34	82.12 ± 0.44	78.29 ± 1.13	85.47 ± 0.79

*Result are mean of three determinations

Figure 8 Dissolution Profile of Solid Dispersions Prepared by Conventional Fusion Method



*Result are mean of three determinations

Out of eight formulations F16 showed maximum drug release i.e., 96.24±0.04 %. Solid dispersion (F16) of Piroxicam with polymer PEG 6000 and surfactant SLS prepared by microwave induced fusion method significantly improved its solubility and its dissolution rate.

Table 11 Dissolution profile of solid dispersion prepared by microwave induced fusion method.

Time (min)	Cumulative % Drug Release							
	F9	F10	F11	F12	F13	F14	F15	F16
0	00	00	00	00	00	00	00	00
5	16.28 ± 0.66	23.14 ± 1.12	22.17 ± 0.69	34.17 ± 0.80	30.11 ± 0.62	46.05 ± 1.44	37.03 ± 0.96	54.33 ± 0.82
10	26.99 ± 0.63	37.40 ± 0.80	34.30 ± 0.46	46.61 ± 0.72	41.86 ± 1.23	56.44 ± 0.41	48.36 ± 0.77	63.12 ± 0.64
15	34.36 ± 0.52	48.39 ± 0.46	42.78 ± 1.13	55.96 ± 0.64	52.63 ± 0.73	65.97 ± 1.07	57.21 ± 1.25	72.55 ± 0.44
20	43.87 ± 1.14	56.89 ± 1.06	49.53 ± 1.21	63.41 ± 0.75	60.63 ± 1.14	73.19 ± 1.06	66.59 ± 1.27	79.88 ± 0.95
25	52.69 ± 0.61	63.59 ± 1.11	57.01 ± 1.04	70.55 ± 0.61	68.74 ± 0.44	78.51 ± 1.15	73.42 ± 0.60	84.57 ± 1.02
30	61.47 ± 1.32	71.23 ± 0.63	66.79 ± 1.17	78.60 ± 1.33	73.99 ± 0.92	83.48 ± 1.26	79.34 ± 1.35	89.11 ± 1.28
40	68.77 ± 0.94	76.09 ± 1.21	74.56 ± 0.94	81.20 ± 0.92	79.24 ± 0.83	87.96 ± 0.72	84.44 ± 1.29	96.24 ± 0.84

*Result are mean of three determinations

Figure 9 Dissolution Profile of Solid Dispersions Prepared by Microwave Induced Fusion Method

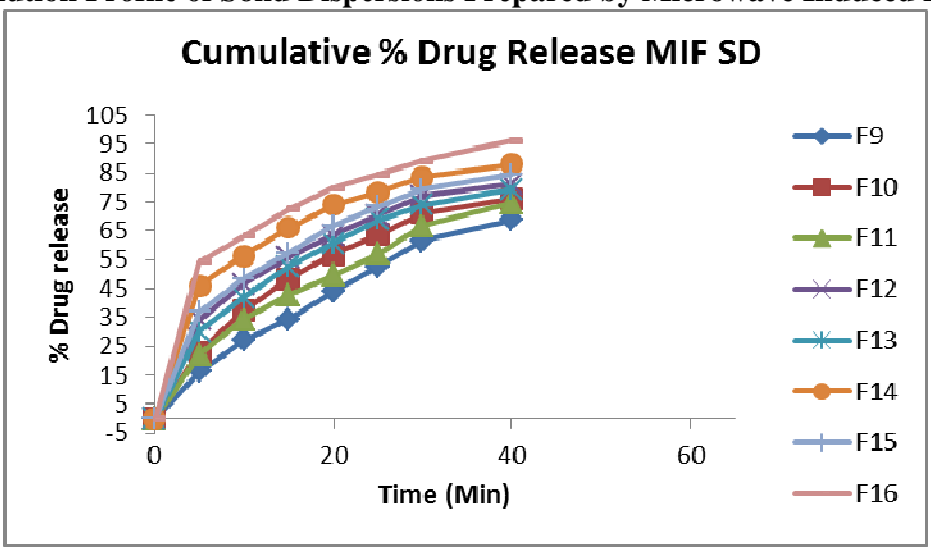
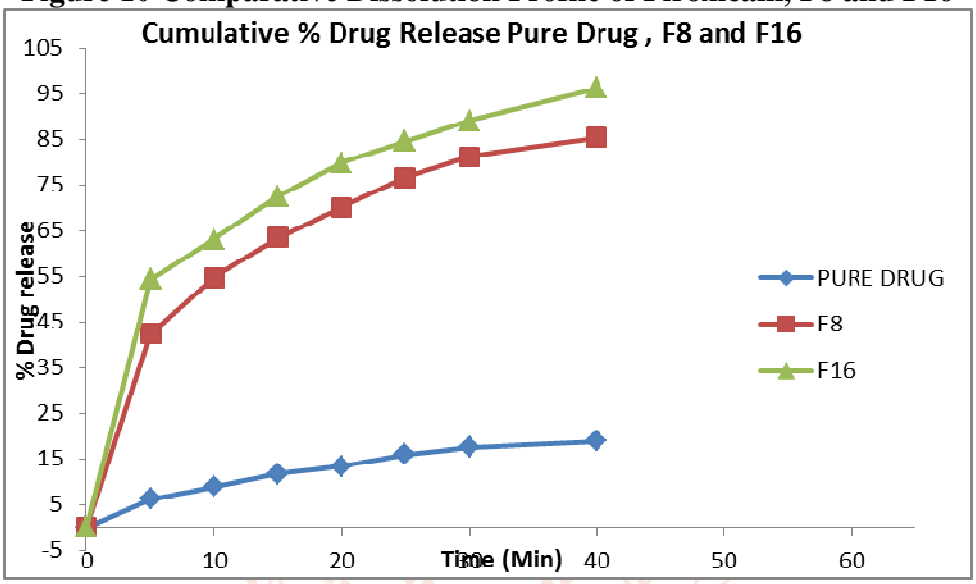


Table 12 Percent drug release of Piroxicam and solid dispersion by conventional fusion method (F8) and microwave induced fusion method (F16)

Time (Min)	Cumulative % Drug Release		
	Pure Drug	F8	F16
0	0.00	00	00
5	06.21 ± 0.34	42.48 ± 0.93	54.33 ± 0.82
10	08.91 ± 0.52	54.77 ± 0.64	63.12 ± 0.64
15	11.75 ± 0.63	63.54 ± 1.04	72.55 ± 0.44
20	13.38 ± 0.92	70.19 ± 1.14	79.88 ± 0.95
25	15.92 ± 0.45	76.56 ± 0.85	84.57 ± 1.02
30	17.51 ± 0.61	81.26 ± 0.98	89.11 ± 1.28
40	18.95 ± 0.95	85.47 ± 0.79	96.24 ± 0.84

*Result are mean of three determination

Figure 10 Comparative Dissolution Profile of Piroxicam, F8 and F16



It was concluded that the F16 formulation gives highest drug release i.e. 96.24% in 40 min, in Phosphate Buffer pH 6.8 whereas the F8 formulation and pure drug was found to be 81.26% and 18.95% drug release in Phosphate Buffer pH 6.8 in 40 min. In that comparative study microwave induced solid dispersion exhibit significant improvement in solubility and dissolution rate compared to that of pure drug.

Selection of Optimum Batch of Solid Dispersion for formulation of Fast Disintegrating Tablet

From solubility and dissolution studies all batches of microwave induced fusion method shows improved drug solubility and dissolution rate than conventional fusion method, Hence F16 formulation of microwave induced fusion method is selected for further formulation of fast disintegrating tablet.as shown in table no 10, 11, 12.

All batches of Piroxicam solid dispersion are off white colored and amorphous powder in nature. It is further confirmed by x ray diffraction studies.

Different trial batches of solid dispersion show % practical yield from range 86.79 to 97.63%. Batch F16 Showed 97.63 % practical yield.

Table 13 Percentage Practical Yield of Solid Dispersion

Formulation	Ratio	Initial weight (mg)	Final Weight (mg)	% Practical Yield
F1	1:1	2000	1.899	94.96
F2	1:1:0.75	2.750	2.6367	95.88
F3	1:2	3000	2.883	96.11
F4	1:2:0.75	3.750	3.517	93.80
F5	1:3	5000	4.722	94.44

F6	1:3:0.75	4.750	4.745	95.31
F7	1:4	5000	4.804	96.09
F8	1:4:0.75	5.750	5.543	96.40
F9	1:1	2000	1.952	97.63
F10	1:1:0.75	2.750	2.697	98.09
F11	1:2	3000	2.896	96.56
F12	1:2:0.75	3.750	3.646	97.23
F13	1:3	4000	3.873	96.83
F14	1:3:0.75	4.750	4.689	97.89
F15	1:4	5000	4.868	97.36
F16	1:4:0.75	5.750	5.529	98.16

(Drug is taken in 1000 mg)

The drug Content of Solid Dispersion of Piroxicam optimized formulation F16 Piroxicam + PEG 6000 + SLS (1:4:0.75) was found to be 97.00 % indicating good content in solid dispersion.

In spectrum of pure drug and microwave induced solid dispersion is showed in figure 4 and 11 In above IR spectra the peak of drug and polymer are showed in Table 5 - 8. All these peaks have appeared in formulation and physical mixture indicating no chemical interaction between Piroxicam and polymer.

Figure 11 FTIR Studies of Microwave Induced Fusion Solid Dispersion

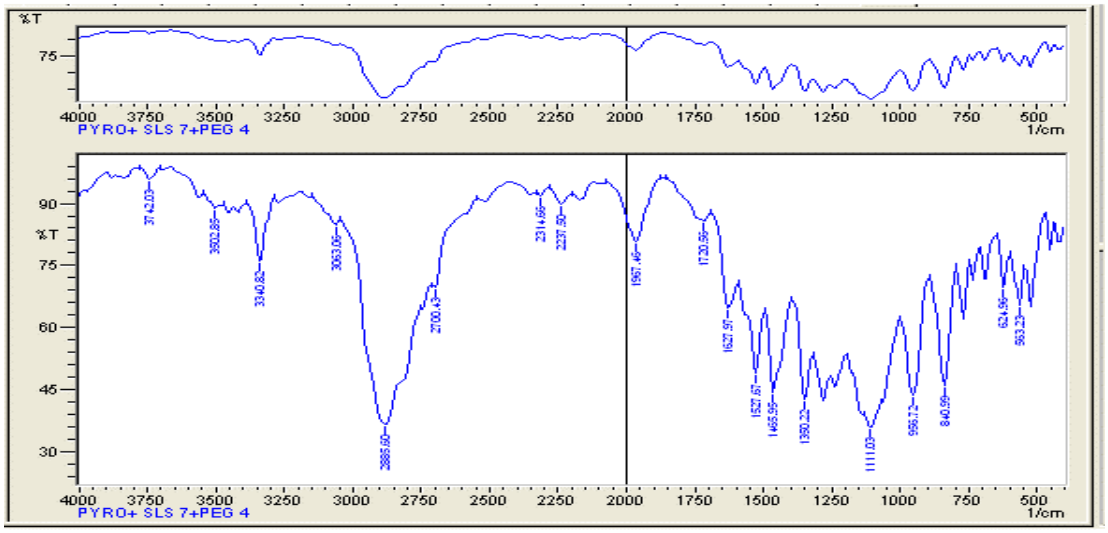
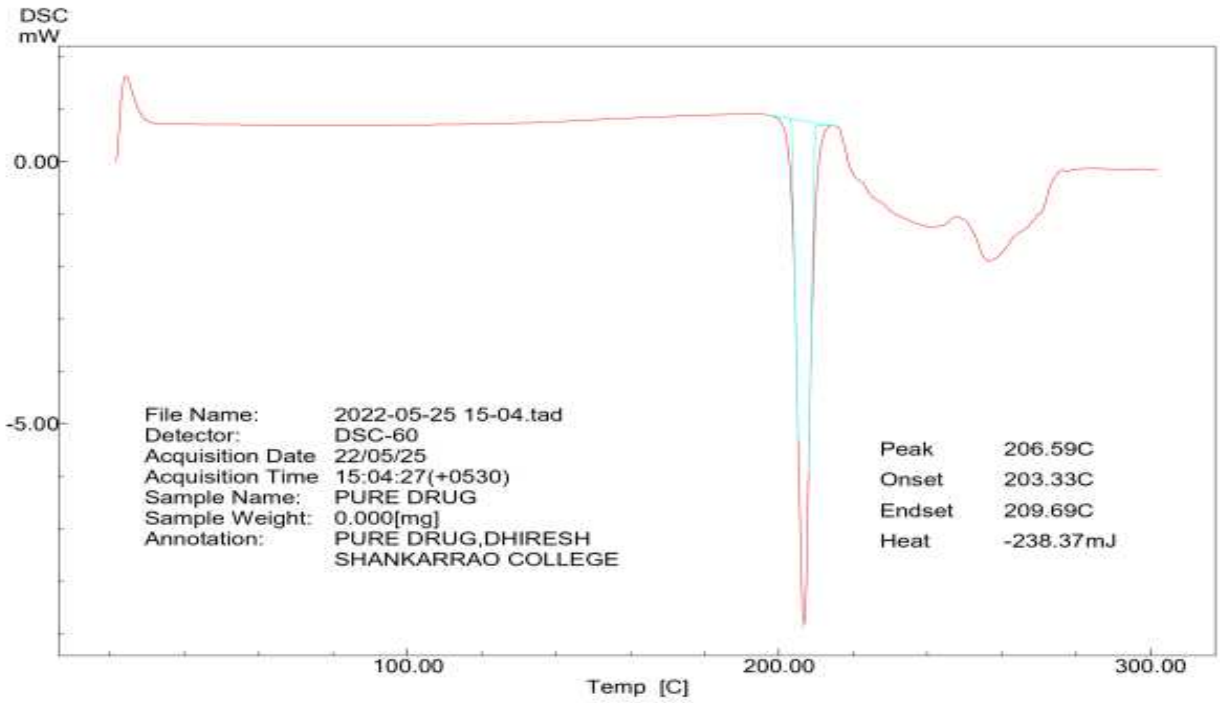


Table 14 Interpretation of FTIR Spectrum of Microwave Induced Fusion Method

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Reported Peak Wavenumber(cm^{-1})	Functional Group
1	773.45	771.55	Ortho-di substituted ring
2	1149.57	1149.61	SO_2-NH group
3	1300.02	1303.92	Pyridine ring
4	1435.04	1435.09	Methyl group
5	1525.69	1527.67	Tertiary amine group
6	1629.85	1627.97	Amide carbonyl
7	3338.78	3340.82	Cubic polymorphic form

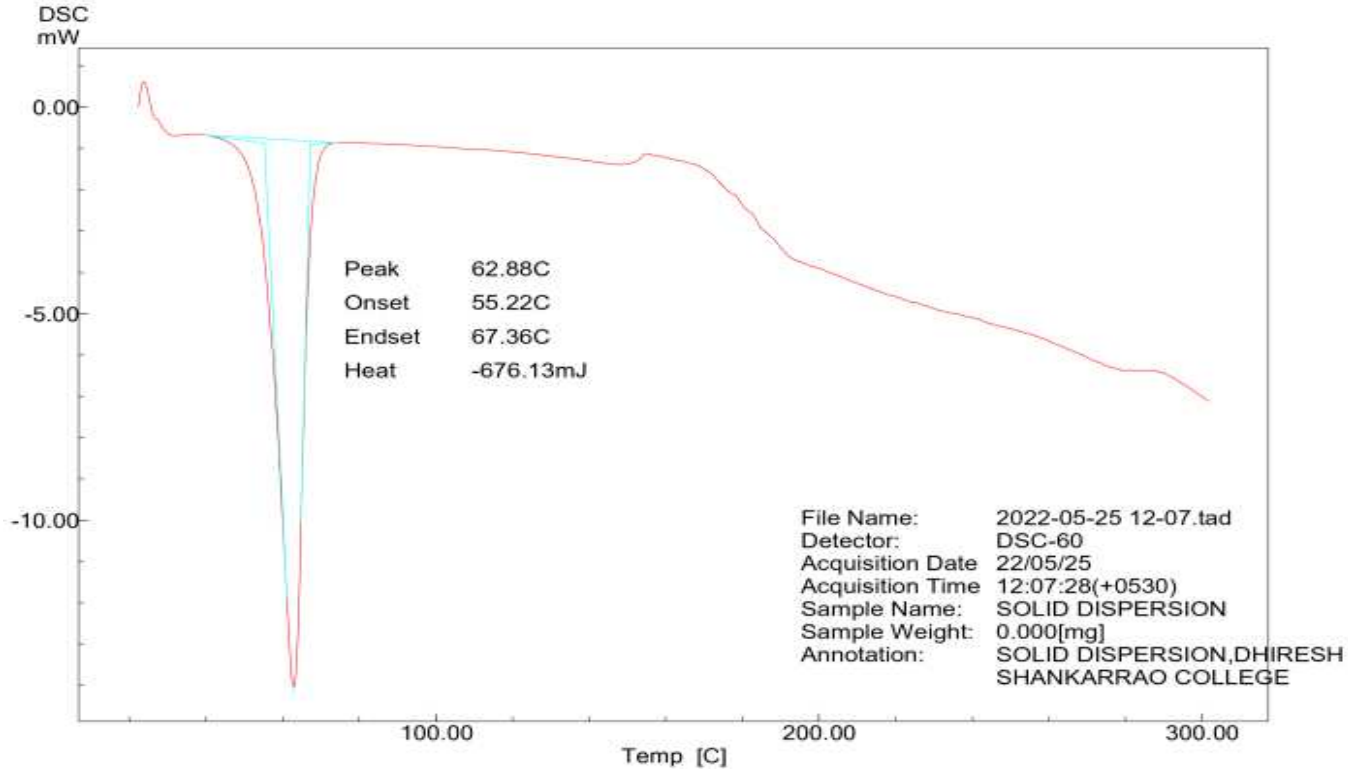
The DSC of Piroxicam shown in Figure 12 Piroxicam showed a characteristic sharp endothermic peak at 203.33°C which is near to its standard reported melting point. From this it is confirms that given drug sample is of Piroxicam is in pure form.

Figure 12 DSC Studies of Piroxicam



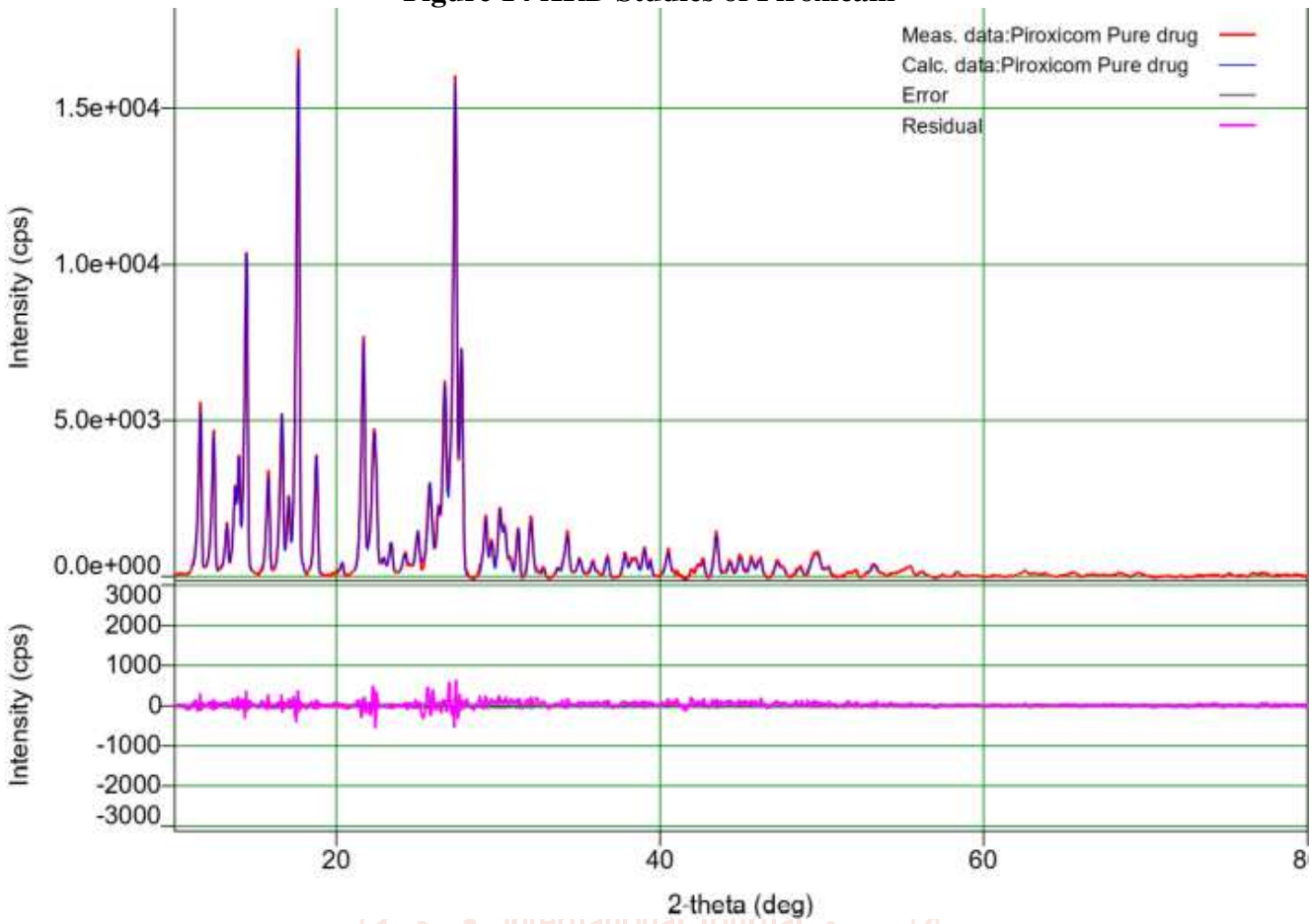
The DSC curve of pure piroxicam exhibited a single endothermic response corresponding to the melting of drug. Onset of melting was observed at 203.33°C, where as pure PEG 6000 showed a melting endotherm at 55.22°C. Thermograms of SDs showed the absence of a piroxicam peak, suggesting that piroxicam is completely soluble in the liquid phase of polymer or absence of crystalline nature of piroxicam. However, the melting peak of PEG 6000 in SDs was observed at slightly lower temperature (52-57°C) than that of pure PEG 6000. The Formulation of piroxicam, SLS and PEG 6000 also showed no endothermic peak of piroxicam. It is speculated that piroxicam dissolved in PEG 6000 during the DSC measurement, only one endothermic peak at 55.22°C corresponding to PEG 6000 was observed. The crystalline piroxicam is converted to its amorphous form which is confirmed by DSC and further by XRD study. (Fig.15

Figure 13 DSC Studies of Microwave Induced Fusion Solid Dispersion



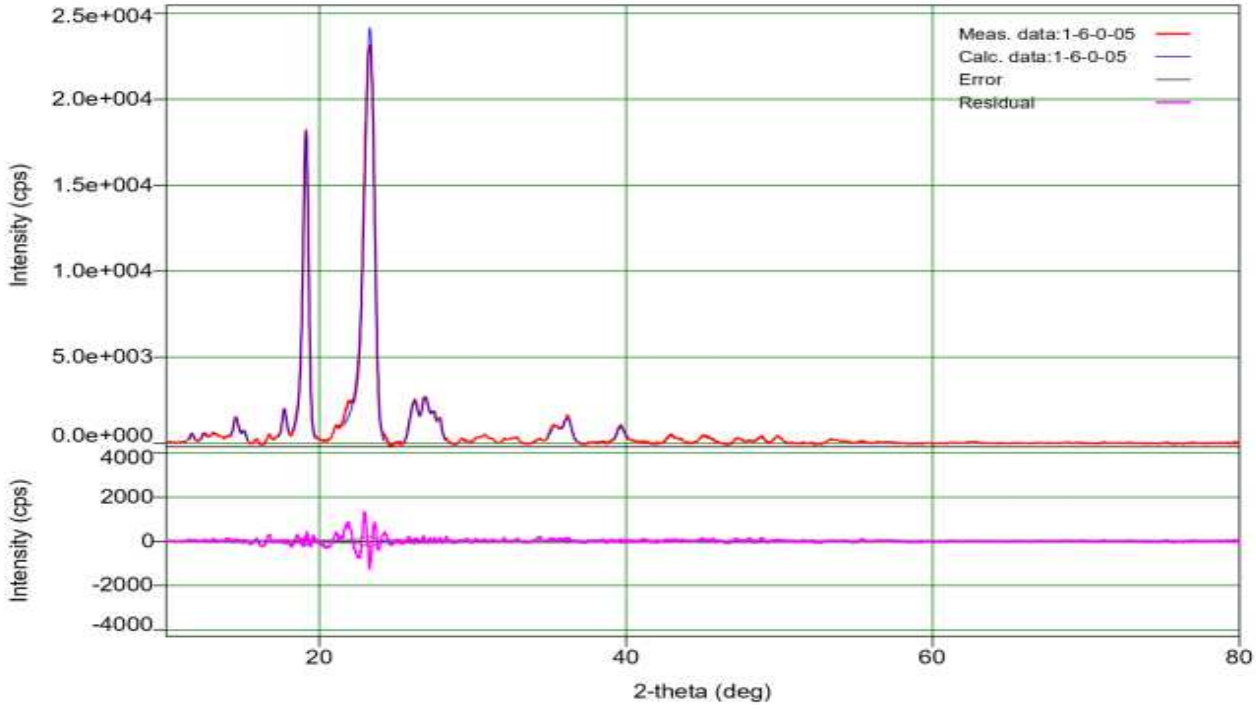
X-ray diffraction of piroxicam displayed five major peaks shows at diffraction angles ($2Ø^0$) 14.46°, 17.65°, 19.69^0, 26.68° and 27.32° were observed with intense peak at 17.65^0 and 27.32^0indicating the crystalline nature of Piroxicam. (Fig-14)

Figure 14 XRD Studies of Piroxicam



The absence of sharp peaks in the solid dispersion indicates the crystalline nature of Piroxicam is converted into amorphous nature absence of a piroxicam peak, suggesting that Piroxicam is completely soluble in the liquid phase of polymer or absence of crystalline nature of Piroxicam. It is confirmed that piroxicam is solubilized or fused with polymer and also confirms the amorphous nature of Piroxicam. (Fig.14)

Figure 15 XRD Studies of Microwave Induced Fusion Solid Dispersion



EVALUATION OF POWDER BLEND FOR FAST DISINTEGRATING TABLETS

The characterization of mixed blend was done for determination of mass-volume relationship parameter. The evaluated parameter angle of repose, bulk density, tapped density, hausner's ratio and compressibility index was reported in Table 15.

Table 15 Evaluation of powder blend for fast disintegrating tablets

Formulations	Angle of repose (Θ)	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Hausner's Ratio (H_R)	Carr's Compressibility index (%)
F1	25.58 ± 0.63	0.44 ± 0.010	0.51 ± 0.043	1.15 ± 0.42	13.72 ± 0.20
F2	27.67 ± 0.65	0.47 ± 0.019	0.53 ± 0.029	1.12 ± 0.32	11.32 ± 0.39
F3	25.53 ± 0.49	0.45 ± 0.023	0.51 ± 0.016	1.13 ± 0.38	13.72 ± 0.45
F4	26.42 ± 0.45	0.44 ± 0.029	0.52 ± 0.014	1.16 ± 0.20	15.38 ± 0.42
F5	25.78 ± 0.23	0.46 ± 0.078	0.53 ± 0.031	1.15 ± 0.16	15.21 ± 0.36
F6	28.04 ± 0.57	0.44 ± 0.096	0.52 ± 0.039	1.18 ± 0.22	13.20 ± 0.16
F7	26.65 ± 0.13	0.47 ± 0.056	0.54 ± 0.010	1.14 ± 0.71	12.96 ± 0.47
F8	27.66 ± 0.49	0.44 ± 0.063	0.51 ± 0.021	1.15 ± 0.38	13.72 ± 0.67
F9	25.79 ± 0.39	0.46 ± 0.076	0.52 ± 0.026	1.13 ± 0.28	11.53 ± 0.41

* Result are mean of three dimensions

MANUFACTURING OF FAST DISINTEGRATING TABLET OF PIROXICAM CONTAINING SOLID DISPERSION BY DIRECT COMPRESSION METHOD

EVALUATION OF FAST DISINTEGRATING TABLETS

All the formulations were subjected for weight variation, thickness, hardness, friability, drug content, in vitro disintegration time, wetting time, water absorption ratio, in vitro dissolution studies were carried out. All the formulations were passed the parameter which was reported in Table 16

Table 16 Evaluation of Fast Disintegrating Tablets

Formulations	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Drug Content (%)	Weight variations (mg)	Disintegration time (sec)	Wetting time (sec)	% Water absorption ratio
F1	4.39 ± 0.02	3.26 ± 0.31	0.72 ± 0.25	95.85 ± 0.89	300 ± 1.51	59 ± 0.3	24 ± 0.57	81.26 ± 1.08
F2	4.44 ± 0.03	3.36 ± 0.55	0.81 ± 0.34	96.21 ± 0.44	302 ± 1.02	48 ± 0.5	20 ± 0.41	90.28 ± 0.69
F3	4.30 ± 0.03	3.24 ± 0.44	0.69± 0.33	96.25 ± 0.56	300 ± 0.93	37 ± 0.6	17 ± 0.33	114.40 ± 1.015
F4	4.32± 0.01	3.36 ± 0.86	0.63± 0.18	95.89 ± 0.96	298 ± 1.15	42 ± 0.3	49 ± 0.56	78.45 ± 0.96
F5	4.36 ± 0.05	3.33 ± 0.45	0.79± 0.22	96.50 ± 0.11	303 ± 0.89	34 ± 0.2	43 ± 0.41	84.34 ± 0.61
F6	4.49 ± 0.1	3.22 ± 0.92	0.72± 0.31	96.83 ± 0.63	299 ± 0.96	26 ± 0.4	38 ± 0.22	93.12 ± 1.55
F7	4.38 ± 0.05	3.30 ± 0.59	0.62± 0.42	96.40 ± 0.56	301 ± 0.65	23 ± 0.2	22 ± 0.47	84.24 ± 093
F8	4.41 ± 0.05	3.39 ± 0.43	0.50± 0.26	96.15 ± 0.23	300 ± 0.96	16 ± 0.5	18 ± 0.42	96.66 ± 0.85
F9	4.40 ± 0.03	3.25 ± 0.71	0.71 ± 0.29	97.00 ± 0.11	300 ± 0.49	10 ± 0.6	13 ± 0.52	119.80 ± 0.76

*Results are mean of three determinations.

***In vitro* % Drug Release of Drug from Tablet**

All the nine formulations were subjected for the in vitro dissolution studies using tablet dissolution apparatus (USP). Phosphate Buffer pH 6.8 was used as dissolution medium. The sample were withdrawn at different time intervals, Filter and analyzed at 354nm. Cumulative % drug release was calculated on the basis of mean amount of Piroxicam present in respective table. The result obtained in the in vitro drug release for all formulations F1 to F9 are tabulated in Table 17 The plots are presented in figure no 10.17. The superdisintrgrants such as crospovidone (2%, 3.5% and 5%), SSG (2%, 3.5% and 5%), and CCS (2%, 3.5% and 5%), were used in different proportions.

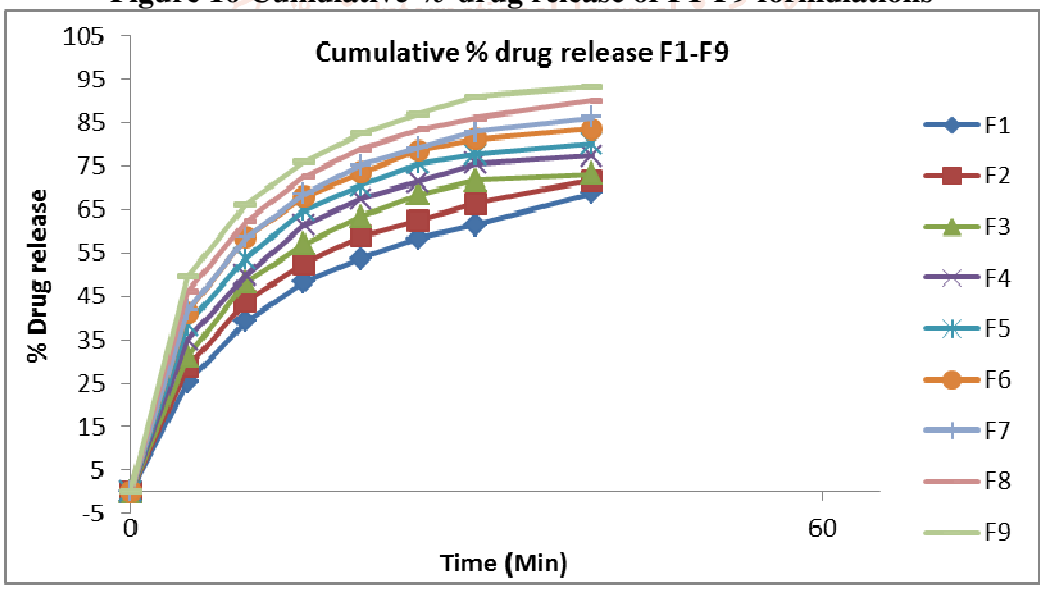
Table 17 *In vitro* Cumulative % Drug Release from Tablets

Time (min)	Cumulative % Drug Release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	00	00	00	00	00	00	00	00	00
5	25.24 ± 0.76	28.74 ± 1.21	31.12 ±0.71	35.02 ± 1.12	38.42 ± 0.94	41.23 ± 0.76	43.76 ± 0.79	48.12 ± 0.7 4	52.36 ± 0.81
10	39.26 ± 0.65	43.92 ± 1.02	48.22 ± 0.66	49.78 ± 0.64	53.75 ± 0.65	58.63 ± 0.69	58.49 ± 0.65	62.26 ± 0.89	66.22 ± 0.36
15	48.25± 0.91	52.47 ± 0.66	57.02 ± 0.86	61.36 ± 0.96	64.81 ± 0.89	67.84 ± 0.81	68.45 ± 0.66	72.55 ± 0.65	75.98 ± 0.85
20	53.66 ± 0.63	58.81 ± 0.42	63.44 ± 0.94	67.47 ± 0.41	70.48 ± 0.65	73.45 ± 0.99	75.18 ± 0.71	79.01 ± 0.62	82.61 ± 0.92
25	58.44± 0.59	62.47± 0.97	68.55 ± 1.27	71.42 ± 1.18	75.64 ± 0.64	78.64 ± 1.02	79.22 ± 0.69	83.47 ± 0.93	87.06 ± 0.69
30	61.56 ± 0.48	66.56 ± 0.62	71.85 ± 1.26	75.64 ± 0.69	77.63 ± 0.92	81.24 ± 1.5	83.03 ± 0.46	86.17 ± 0.73	91.02 ± 0.72
40	68.77± 0.74	71.73 ± 1.31	73.25 ± 1.10	77.32 ± 0.89	80.12 ± 1.22	83.63 ±1.23	86.34 ± 0.91	90.11 ± 0.49	93.20 ± 0.61

*Results are mean of three dimensions

The rapid dissolution was observed in formulation F9 releases 93.20% ± 0.61 at the end of 40 minutes. Rapid dissolution might be due to fast breakdown of particles and rapid absorption of drugs. The drug release was completely achieved in shorter duration of time. In all the formulations the drug release within 40 minutes. High dissolution may occur due to faster breakdown.

Figure 16 Cumulative % drug release of F1-F9 formulations



In comparative study F9 formulation gives higher percent drug release compare to other remaining eight formulations at the end of 40 minutes and graphical representation is shown in Figure 16 Therefore, it was concluded that the best optimized batch was found to be F9 because of lesser disintegration time and highest percentage drug release at the end of 40 min among all the formulations. Because it containing crosspovidone superdisintegrant with fast wetting time and highest swelling property.

STABILITY STUDY

The Fast disintegrating tablet of solid dispersion of Piroxicam, F9 batch were subjected to stability study at temperature 40°C ± and relative humidity 75% ± for three months. After each month tablet were analyzed for hardness, friability, disintegration time, dissolution time and drug content. The results are as follows.

Table 18 Stability Study of Fast Disintegrating Tablets of Optimized Formulation F9 at $40^0C \pm 2^0C$ /75 % RH ± 5%

Formulation	Parameters Evaluated	Initial	After 1 Month	After 2 Month	After 3 Month
F9	Hardness (Kg/Cm^2)	3.25 ± 0.71	3.23 ± 0.89	3.18 ± 0.68	3.12 ± 0.41
	Friability (%)	0.71± 0.29	0.71 ± 0.79	0.83 ± 0.25	0.69 ± 0.89
	Disintegration Time (sec)	10 ± 0.6	10 ± 0.4	11 ± 0.5	11 ± 0.3
	Content Uniformity (%)	97.00 ± 0.11	97.00 ± 0.30	96.36 ± 0.23	96.22 ± 0.75
	Cumulative % Drug Release	93.20 ± 0.61	93.14 ± 0.39	92.42 ± 0.36	92.11 ± 0.56

*Results are the mean of three determinations

From the results of Table 18 it is concluded that, the fast disintegrating tablets of solid dispersion of Piroxicam from tablet F9 batch are physically stable and retained their original properties when stored at temperature $40^0C \pm 2^0C$, 75 % RH ± 5% and after three months there was no significant difference in disintegration time, cumulative % drug release, hardness, friability and drug content.

Conclusion

Overall, the results concluded that suitable formulated solid dispersion F9 of Piroxicam with polymer Polyethylene glycol 6000 and surfactant as sodium lauryl sulphate prepared by microwave induced fusion method in the ratio (1:4:0.75), improved its solubility and dissolution rate. Alteration of surface property of drug particles may be responsible for enhanced dissolution rate of Piroxicam from solid dispersion compared to pure Piroxicam. It was decided to prepare fast dissolving tablets of solid dispersion of Piroxicam by direct compression method. In the formulation of tablets, sodium starch glycolate, and croscarmellose, crospovidone were used as super disintegrants. Prior to compression, the powder blend were evaluated for angle of repose, bulk density, tapped density, compressibility index, Hausner's ratio. The compressed tablets were also evaluated for weight variation, hardness, friability, drug content, disintegration time, wetting time, in vitro drug release and stability studies In the above studies, F9 formulation showed promising results. The stability studies were carried out for the optimized batch F9 for 90 days and it showed acceptable results. So F9 formulation was considered as the optimized formulation. Among F1 to F16 batches of solid dispersions prepared, F16 was found to be optimized. The study shows that the dissolution rate of Piroxicam can be enhanced to a great extent by solid dispersion technique using microwave induced fusion method in the ratio (1:4:0.75) Hence, Piroxicam sodium starch glycolate, croscarmellose & crospovidine systems can be considered for formulating fast disintegrating tablets of Piroxicam. The fast disintegrating tablets of Piroxicam batch (F9) shows highest drug release as compared to other formulations. From above results it can be concluded that the solid dispersion technique can be used to enhance the solubility, dissolution rate and oral bioavailability of water insoluble drugs.

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