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# Formulation, Development and Evaluation of Fast Disintegrating Piroxicam Tablets

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## Abstract

Piroxicam is a non-steroidal anti-inflammatory drug used in the treatment of osteo arthritis, rheumatoid arthritis, ankylosing spondylitis, classified in the Bio pharmaceutics Drug Classification system as a Class II drug because it has 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. Thus an attempt is made to formulate piroxicam fast disintegrating tablet so that it helps to render faster onset of anti inflammatory and analgesic effect. To increase the solubility of piroxicam solid dispersion method is opted in the present investigation. Study proposes the use of PVPk30 to prepare solid dispersion of piroxicam and comparison of its in-vitro dissolution with pure piroxicam. Fast Dissolving tablets can be prepared by conventional direct compression method using solid dispersion. For better Hardness, less friability, faster wetting time and less moisture uptake combination of both MCC and Mannitol are used in the formulation.

## Introduction

### Fast disintegration drug delivery system

In this period, fast disintegrating drug delivery system (FDDDS) began to gain popularity and acceptance since they can disintegrate/dissolve quickly in the oral cavity upon contact with saliva, resulting in solutions or suspensions form of the administered medicine .Fast disintegrating drug delivery systems (FDDSs) are the systems which disintegrate even in the absence of additional water and release the active ingredient quickly. The development of pharmaceutical technology in past years has presented the development of alternative dosage forms for patients who may have difficulty in swallowing of conventional tablets. Among the drug delivery systems the fast disintegrating tablets (FDTs) are the more acceptable form because of its convenience of self-administration, compactness. Pediatric and geriatric patients, who have difficulty in swallowing, uncooperative patients, where the traditional tablets and capsules administration is inconvenient, the fast dissolving/disintegrating tablets are perfect alternative. According to European Pharmacopoeia, the FDT disintegrate in less than three minutes. The basic approach used in development of FDT is the use of superdisintegrants which provide instantaneous disintegration and thereby releasing the drug in saliva. Taste of the drug is one of the most important parameters which should be considered for the development of FDTs. Oral administration of bitter drugs with an acceptable degree of palatability can be achieved by taste masking approach. The Zydis (Catalent Pharma Solutions, Somerset, NJ) based on lyophylization technology is the first approved FDDDS.

## Drug Profile

Piroxicam is a non steroidal anti-inflammatory drug (NSAID) of the oxicam class and is used to relieve the symptoms of painful inflammatory conditions like arthritis. Piroxicam works by preventing the production of endogenous prostaglandins which are involved in the mediation of pain, stiffness, tenderness and swelling.

**IUPAC NAME:** 4-hydroxy-2-methyl-1,1-dioxo-N-pyridin-2-yl-1?6,2-

benzothiazine-3-carboxamide

**MOLECULAR FORMULA:** $C_{15}H_{13}N_3O_4S$

**MOLECULAR WEIGHT**: 331.3 g/mol

**CHEMICAL PROPERTIES**

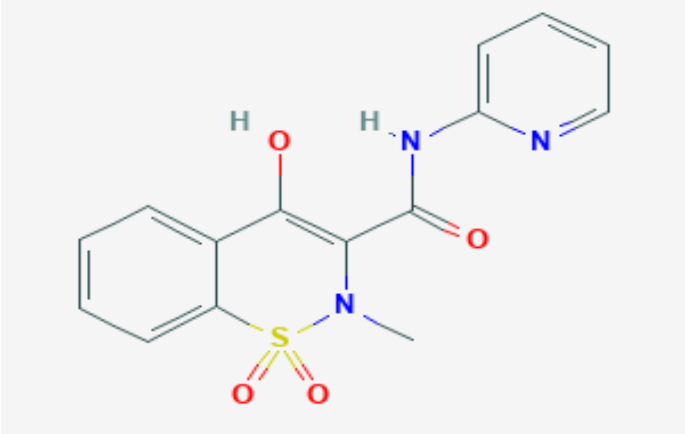
Piroxicam exists as alkenol tautomer in organic solvents

Piroxicam exists as zwitter ionic form in water

**MECHANISM OF ACTION**

Piroxicam is an NSAID and, as such, is a non-selective COX inhibitor possessing both analgesic and antipyretic properties.

**CHEMICAL STRUCTURE OF PIROXICAM FIG No:3.1**




## Pharmacokinetic activity of piroxicam

Piroxicam is highly bound (approximately 99%) to plasma proteins and has a small distribution volume. Despite its high plasma binding, the drug readily penetrates into synovial fluid. Piroxicam has a long elimination half-life of about 50 h. Elimination of the parent drug is mainly the result of biotransformation. The elimination of piroxicam is impaired in some elderly patients, resulting in a high interindividual variability in average steady state levels following a standard 20 mg/day dosage regimen.

# Methodology

## Preparation of solid dispersions

Preparation of solid dispersion: 20mg of piroxicam is taken in a beaker. It is dissolved in 10ml chloroform then required quantity of pvp k30 is added and kept for magnetic stirring for 2 hrs. Allowed it to dry untill the solvent evaporates completely. the obtained solid dispersion is used in further process.

Formulation of solid dispersions are as follows **Table No-3.3**

| FORMULATION | PIROXICAM | PVPK30 |
|---|---|---|
| SD1(1:1) | 20mg | 20mg |
| SD2(1:0.5) | 20mg | 10mg |
| SD3(1:1.5) | 20mg | 30mg |

**Evaluation of solid dispersions:** evaluation tests for solid dispersion were done to choose the better, cost reductive and effective proportion of polymer and drug. Following are the evaluation tests for solid dispersions.

**Determination of solubility:** Solubility of piroxicam was performed in solvents like water, and PH 6.8 phosphate buffer. Solubility studies were carried out using different solvents saturated solutions were prepared by adding excess amount of drug and solid dispersion to the vehicles and shaking on the shaker for 48 hours at 25±0.5°.during intervals solutions are filtered diluted and analysed by uv spectrophotometer.

## In vitro dissolution study:

Dissolution studies were conducted by using dissolution apparatus (USP Type II )with 900 ml of 6. 8 PH phosphate buffer at 37°C and 50 RPM. Aliquots of 5 ml are collected for every 5 minutes till 1 hr and then after 15 min till 3 hrs. And diluted it to 10ml and analyzed by using UV- Visible spectrophotometer(LAB INDIA UV 3000).

## Extraction of fenugreek mucilage from fenugreek seeds

A batch 100gm of crushed fenugreek seeds was soaked in 500ml of double distilled water and boiled at 80oC using water bath for 4 hours with occasion stirring or till thick mass was obtained. It was kept aside at room temperature for 4 hrs stirred intermittently and then kept aside overnight below 200C. The hydrated mucilage was separated by using muslin cloth. The mucilage was then precipitated with 300 ml of absolute alcohol. The precipitated mucilage was filtered using vacuum filtration. The separated mucilage was then dehydrated with 200ml of acetone. This treatment also removes any extracted oil present in hydrated mucilage. After filtration precipitated mass was air dried for 48 hours. The dried mucilage was then powdered using mortar and pestle and passed through sieve #60. The obtained product(5.6gms) was used as disintegrant in the further formulations.

**FORMULATION OF PIROXICAM FAST DISINTEGRATION TABLETS Table No-3.4**

| SL.NO | INGREDIANTS | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|---|
| 01 | Solid dispersion | 40mg | 40mg | 40mg | 40mg | 40mg |
| 02 | Sodium starch glycollate | 20mg | _ | _ | 10mg | _ |
| 03 | Cross povidone | _ | 20mg | _ | _ | 10mg |
| 04 | Fenugreek gum | _ | _ | 20mg | 10mg | 10mg |
| 05 | Mannitol | 58mg | 58mg | 58mg | 58mg | 58mg |
| 06 | Micro crystalline cellulose | 20mg | 20mg | 20mg | 20mg | 20mg |
| 07 | Talc | 02mg | 02mg | 02mg | 02mg | 02mg |
| 08 | Total | 140mg | 140mg | 140mg | 140mg | 140mg |

## Evaluation Of Piroxicam Fast Disintegration Dosage Form

**EVALUATION PARAMETERS:**

1. Drug- polymer compatibility studies

In the preparation of tablets formulation, drug and polymer may interact with each other, which could lead to the instability of drug. Preformulation studies regarding the drug-polymer interaction are therefore very critical in selecting appropriate polymers. FTIR spectroscopy was employed to know the compatibility between piroxicam and selected polymer.

2.Pre- compression parameters

Angle of repose (θ)

The frictional force in loose powders or granules can be measured by angle of repose. Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane.

In terms of terms of mathematical expression, it is represented as

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

Where as, **θ** is the angle of repose, **H** is the height in cms, **R** is the radius in cms

Different ranges of flowability in terms of angle of repose are given in below **Table No-4.**1

| Angle of repose (θ) | Flow |
|---|---|
| >25 | Excellent |
| 25-30 | Good |
| 30-40 | Passable |
| <40 | Very poor |

**Bulk density**: bulk density was determined by pouring blend in to graduated cylinder via large funnel.

it is mathematically represented as

bulk density= (W)/ (Vb)

where as W is weight of the blend and Vb is bulk volume

**Tapped density**: It is determined by placing a graduated cylinder containing a known mass of blend on mechanical tapping apparatus. tapped density is calculated by using formula :

Tapped density= (W)/(Vt)

where as W is weight of the blend and Vt is tapped volume of the blend.

**%compressibility** : it is calculated by using formula

%compressibility = (ρb- ρt)/ρt*100

In this equation ρb is represented as bulk density and ρt is represented as tapped density

Carr's index(%) as an indication of powder flow properties is represented in the below **Table No-4.2**

| % Compressibility | Flow ability |
|---|---|
| 5 – 12 | Excellent |
| 12 – 16 | Good |
| 18 - 21 | Fair passable |
| 23 – 35 | Poor |
| 33 – 38 | Very poor |
| <40 | Very Very poor |

**Hausner's Ratio**: It is expressed by using following mathematical expression

Hausner's Ratio = ρb/ρt

Where ρb is bulk density and ρt is tapped density

Lower Hausner‟ ratio (<1.25) demonstrates better stream properties and higher Hausner‟ s proportion (>1.25) shows poor stream properties.

3. Post- compression parameters

**Thickness and Diameter:** Tablet thickness and distance across can be estimated utilizing a straightforward system. Five tablets are taken and their thickness is estimated using Vernier calipers. The thickness and width are estimated by setting the tablet between two arms of the Vernier calipers.

**Tablet Hardness :** Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets were determined by using Monsanto hardness tester. it is expressed in Kg/ $cm^2$. three tablets were randomly picked and hardness of the each tablet were determined and took the average hardness value.

**weight variation test:** 20 tablets were selected randomly from a batch and were individually weighed and then the average weight was calculated. The tablets meet the USP specifications if not more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limits.

**Table No-4.3** Average weight of tablets and percentage deviation are as follows

| Average weight of tablet | % deviation |
|---|---|
| 80 mg or less | ±10 |
| More than 80 mg and less than | ±7.5 |
| 250 mg or more | ±5 |

**Tablet friability :** the friability of tablets were determined using roche friabilator. It is expressed in percentage (%). 10 tablets were initially weighed and the weight was noted as W1.and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes or run upto 100 revolutions. the tablets were weighed again and the weight was noted as W2. For conventional tablets the percentage friability should be less than 1% where as friability values of upto 4% are acceptable for fast disintegrating or oral dispersable dosage forms.

The percentage friability is expressed as the loss of weight and is calculated by the formula:

% Friability = [(W1-W2)100]/W1

Where, W1= initial weight of the tablet, W2 = final weight i.e., weight of the tablet after test

The pharmacopoeia furthest reaches of friability test for a tablet isn't over 1%.

**In-Vitro Disintegration time** : disintegration time is the time taken by the tablet to break into smaller particles. The disintegration test is carried out in an apparatus containing a basket rack assembly with six glass tubes which consists of a 10 mesh sieve. the basket is raised and lowered 28-32 times per minute in the medium of 900ml of ph 6.8 phosphate buffer which is maintained at 37±2°C. six tablets were placed in each of the tubes and the time required for complete passage of tablet fragments through the sieve(# 10) was considered as the disintegration time of the tablet. And The time for disintegration of formulations were tabulated.

**Drug content uniformity:** the content uniformity test is used to ensure that every tablet contains the amount of drug substance intendad 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 λmax against ph 6.8 phosphate buffer as a blank reference and reported.

**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.

Method: five circular tissue papers of 10cm 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. The water absorption ratio(R), was determined according to the following eqution:

R=100(Wa-Wb)/Wb

**In- vitro dissolution test:** The test determines the time required for a definite percentage of the drug in a tablet to dissolve under specified conditions.

Dissolution studies were conducted by using dissolution apparatus (USP Type II )with 900 ml of 6. 8 PH phosphate buffer at 37°C and 50 RPM. Aliquots of 5 ml are collected for every 5 minutes till 1 hr and then after 15 min till 3 hrs. And diluted it to 10ml and analyzed by using UV- Visible spectrophotometer(LAB INDIA UV 3000)

## STABILITY TESTING METHODS

Stability testing is a routine procedure performed on drug substances and products and is employed at various stages of the product development. In early stages, accelerated stability testing (at relatively high temperatures and/or humidity) is used in order to determine the type of degradation products which may be found after long-term storage. Testing under less rigorous conditions i.e. those recommended for long-term shelf storage, at slightly elevated temperatures is used to determine a product's shelf life and expiration dates. The major aim of pharmaceutical stability testing is to provide reasonable assurance

that the products will remain at an acceptable level of fitness/quality throughout the period during which they are in market place available for supply to the patients and will be fit for their consumption until the patient uses the last unit of the product (Kommanaboyina et al., 1999). Depending upon the aim and steps followed, stability, testing procedures have been categorized into the following types.

## Real-Time stability testing

Real-time stability testing is normally performed for longer duration of the test period in order to allow significant product degradation under recommended storage conditions. The period of the test depends upon the stability of the product which should be long enough to indicate clearly that no measurable degradation occurs and must permit one to distinguish degradation from inter-assay variation. During the testing, data is collected at an appropriate frequency such that a trend analysis is able to distinguish instability from day-to-day ambiguity. The reliability of data interpretation can be increased by including a single batch of reference material for which stability characteristics have already been established. Stability of the reference material also includes the stability of reagents as well as consistency of the performance of the instrument to be used throughout the period of stability testing. However, system performance and control for drift and discontinuity resulting from changes in both reagents and instrumentation must be monitored

## Accelerated stability testing

In accelerated stability testing, a product is stressed at several high (warmer than ambient) temperatures and the amount of heat input required to cause product failure is determined. This is done to subject the product to a condition that accelerates degradation. This information is then projected to predict shelf life or used to compare the relative stability of alternative formulations. This usually provides an early indication of the product shelf life and thus shortening the development schedule. In addition to temperature, stress conditions applied during accelerated stability testing are moisture, light, agitation, gravity, pH and package. In accelerated stability testing the samples are subjected to stress, refrigerated after stressing, and then assayed simultaneously. Because the duration of the analysis is short, the likelihood of instability in the measurement system is reduced in comparison to the real-time stability testing. Further, in accelerated stability testing, comparison of the unstressed product with stressed material is made within the same assay and the stressed sample recovery is expressed as percent of unstressed sample recovery. For statistical reasons, the treatment in accelerated stability projections is recommended to be conducted at four different stress temperatures.

## Retained sample stability testing

This is a usual practice for every marketed product for which stability data are required. In this study, stability samples, for retained storage for at least one batch a year are selected. If the number of batches marketed exceeds 50, stability samples from two batches are recommended to be taken. At the time of first introduction of the product in the market, the stability samples of every batch may be taken, which may be decreased to only 2% to 5% of marketed batches at a later stage. In this study, the stability samples are tested at predetermined intervals i.e. if a product has shelf life of 5 years, it is conventional to test samples at 3, 6, 9, 12, 18, 24, 36, 48, and 60 months. This conventional method of obtaining stability data on retained storage samples is known as constant interval method. Stability testing by evaluation of market samples is a modified method which involves taking samples already in the market place and evaluating stability attributes. This type of testing is inherently more realistic since it challenges the product not just in the idealized retained sample storage conditions, but also in the actual marketplace

**Storage conditions for Stability studies Table No-4.4**

| Study | Storage conditions | Minimum time period covered by data at submission |
|---|---|---|
| Long term | 25ºC ± 2ºC/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH | 12 months |
| Intermediate | 30ºC ± 2ºC/65% RH ± 5%RH | 6months |
| Accelerated | 40ºC ± 2ºC/75% RH ± 5% RH | 6months |

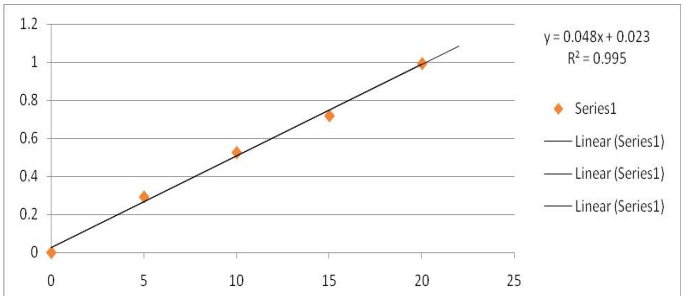
## RESULTS AND CONCLUSION:

Standard Calibration Curve of piroxicam in pH 6.8 phosphate buffer:

Standard plot of piroxicam at 340nm in pH 6.8 phosphate buffer **Table No-4.5**:

| Concentration µgm/ml | Absorbance |
|---|---|
| 0 | 0 |
| 5 | 0.292 |
| 10 | 0.525 |
| 15 | 0.718 |
| 20 | 0.992 |

**Standard calibration curve of piroxicam in 6.8ph phosphate buffer Fig No: 4.1:**




**Discussion:** From standard stock solution different aliquots of calibration standards were prepared by appropriate dilution using 6.8 pH buffer and the absorbance of each solution was measured at 340nm using 6.8 pH buffer as a blank. Beer-Lambert's law was obeyed by maintaining a linear relationship over the concentration range of 2-12 µg/mL at 340nm.

Calibration curve of piroxicam was constructed in 6.8 pH buffer at maximum wavelength of 246 nm and analysed for regression analysis. Regression analysis was selected because it minimize the deviation and correct the variance heterogeneity. The regression line was defined by its slope (m) and its intercept (C) for normal regression analysis was found as 0.0482 and 0.0234, respectively, with regression coefficient of 0.9957 respectively.

## Solubility studies:

**Solubility of drug and solid dispersions using water as solvent Table No-4.6:**

| Formulation | Initial time(0) | 24hours | 48hours |
|---|---|---|---|
| Drug | 1% | 7% | 9% |
| SD(1:1) | 5% | 18% | 22% |
| SD(1:0.5) | 2% | 9% | 10% |
| SD(1:1.5) | 6% | 19% | 23% |

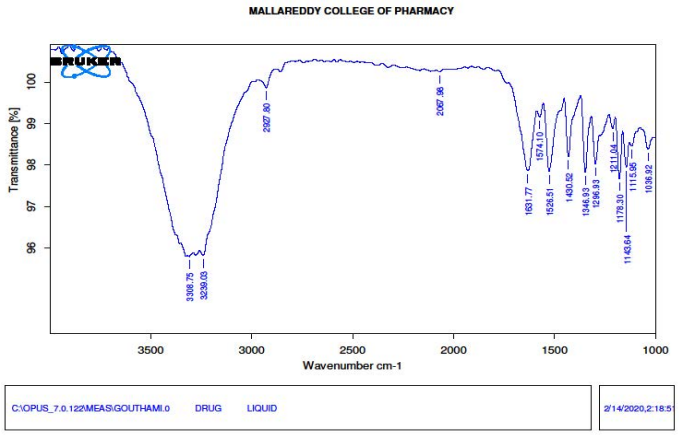
**Solubility of drug and solid dispersions using 6.8ph phosphate buffer as solvent Table No-4.7 :**

| Formulation | Initial time(0) | 24hours | 48hours |
|---|---|---|---|
| Drug | 7% | 20% | 34% |
| SD(1:1) | 19% | 40% | 74% |
| SD(1:0.5) | 10% | 21% | 36% |
| SD(1:1.5) | 20% | 41% | 76% |

**FTIR studies:**

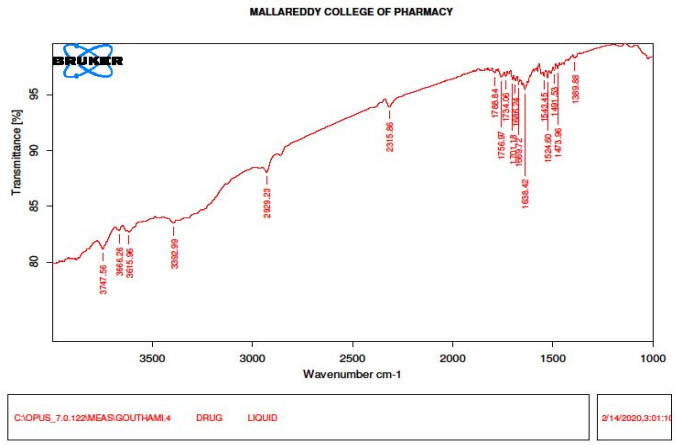
**FT-IR study of piroxicam Fig No: 4.2**

**FTIR study of piroxicam Table No-4.8**



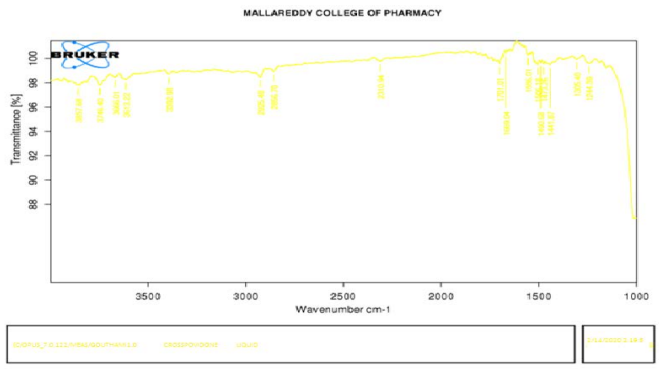

| Functional group | Wave length range | Wave number(nm) |
|---|---|---|
| C-H | 3333-3267 | 3308.75 |
| C= C= C | 2000-1900 | 1631 |
| P-H | 2440-2350 | 2310 |
| C=O | 187-1660 | 1699 |

**FTIR SPECTRUM OF SOLID DISPERSION WITH OTHER EXCIPIENTS Fig No: 4.3:**

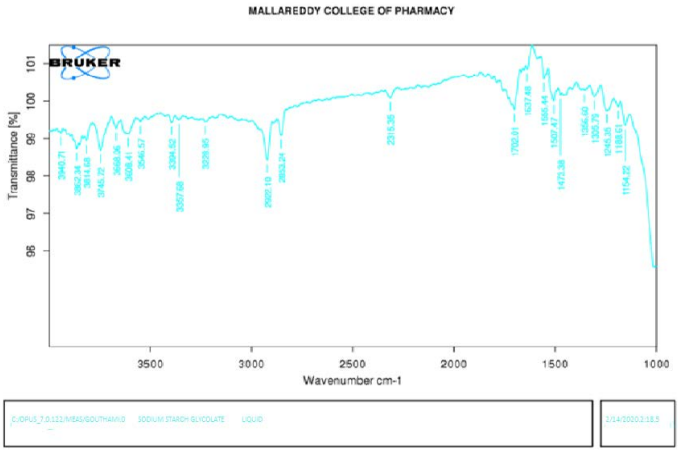



| Functional group | Wave length range | Wave number(nm) |
|---|---|---|
| O-H | 3700-3584 | 3705 |
| N-H | 3350-3310 | 3390 |
| C-H | 3000-2840 | 2829 |
| C=O | 1770-1780 | 1777 |

**FTIR spectrum interpretation of solid dispersion and other excipients Table No-4.9**



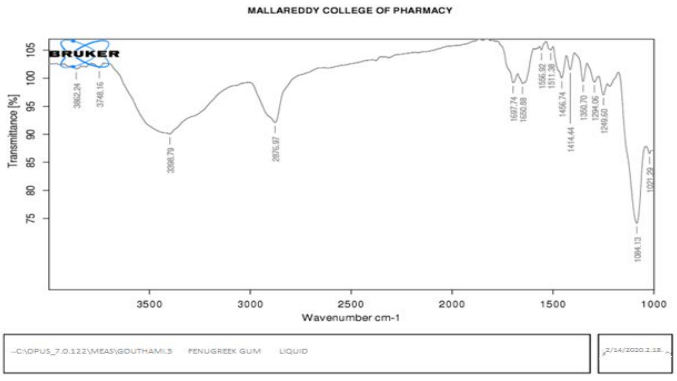

**FTIR SPECTRUM OF CROSS POVIDONE Fig No: 4.4:**




**FT-IR Spectrum interpretation Of crosspovidone Table No-4.10**

| Functional group | Wave length range | Wave number(nm) |
|---|---|---|
| O-H | 3670-3230 | 3613 |
| C-H | 2975-2840 | 2925 |
| P-H | 2440-2350 | 2310 |
| C=O | 187-1660 | 1699 |

**FTIR SPECTRUM OF SODIUM STARCH GLYCOLATE Fig No: 4.5:**




**FT-IR Spectrum interpretation Of sodium starch glycollate Table No-4.11**

| Functional group | Wave length range | Wave number(nm) |
|---|---|---|
| O-H | 3670-3230 | 3548 |
| N-H | 3540-330 | 3394 |
| C-H | 2975-2840 | 2853 |
| C=N | 1690-1630 | 1637 |

**FTIR SPECTRUM OF FENUGREEK MUCILAGE Fig No: 4.6:**

| Functional group | Wave length range | Wave number(nm) |
|---|---|---|
| O-H | 3670-3230 | 3398 |
| C-H | 2975-2840 | 2876 |
| C=C | 1870-1660 | 1697 |
| C=N | 1690-1620 | 1650 |

**FT-IR Spectrum interpretation Of Fenugreek mucilage Table No-4.12**

## EVALUATION OF PIROXICAM FAST DISINTEGRATION TABLETS:

**PRE COMPRESSION PARAMETERS FOR THE POWDER BLEND F1 to F5 Table No-4.13**

| FC | Angle of Repose(θ)±SD | Bulk density(gm/cm) ±SD | Tapped density (gm/cm) ±SD | Hausners ratio(HR) ±SD | Carrsindex(C.I) ±SD |
|---|---|---|---|---|---|
| F1 | 24.62±0.26 | 0.421±0.06 | 0.496±0.16 | 1.18±0.32 | 15.12±0.15 |
| F2 | 25.41±0.43 | 0.416±0.09 | 0.484±0.22 | 1.16±0.21 | 14.05±0.24 |
| F3 | 27.63±0.43 | 0.415±0.03 | 0.501±0.16 | 1.21±0.56 | 17.17±0.63 |
| F4 | 29.84±0.82 | 0.432±0.12 | 0.512±0.06 | 1.19±0.13 | 15.63±0.01 |
| F5 | 25.63±0.51 | 0.417±0.21 | 0.489±0.09 | 1.17±0.64 | 14.72±0.11 |

**Discussion:** Before tabletting, the powder blend of each formulation was evaluated for their flow properties like: Bulk density (BD), Tapped density (TD), Compressibility index (or Carr's index), Hausner's ratio, and angle of repose and the results were mentioned in the above Table. The BD and TD of the formulations F1 to F5 were found in the range between 0.415±0.3 to 0.432±0.12g/cc and 0.484±0.22 to 0.512±0.06g/cc, respectively. In accordance with literature, powders or granules with Carr's index values below 16 % were ideal for producing tablets via direct compression and those with Hausner's ratio values below 1.25 and angle of repose below 35° indicate good flow properties of powders or granules.

**Physical properties of tablet formulation (F-1 to F-5): Table No-4.14**

| FC | Avg. Wt (mg) | Hardness(kg/cm2) | Thickness(mm) | Friability % | Drug Content(%) |
|---|---|---|---|---|---|
| F1 | 140.23±0.26 | 2.4±0.45 | 3.11±0.14 | 0.84±0.12 | 95.2±0.42 |
| F2 | 140.01±0.43 | 2.2±0.34 | 3.08±0.34 | 0.72±0.08 | 98.6±0.12 |
| F3 | 142.56±0.06 | 2.2±0.23 | 3.10±0.24 | 0.68±0.45 | 97.8±0.22 |
| F4 | 141.26±0.29 | 2.3±0.26 | 3.09±0.25 | 0.84±0.60 | 96.8±0.70 |
| F5 | 145.02±0.49 | 2.3±0.44 | 3.08±0.17 | 0.92±0.72 | 100.9±0.65 |

## Discussion

### Physical Parameters (Hardness & Friability)

The punches used to compress the tablets were 7mm, spherical shaped. The shape and size of the tablets were found to be within the limit. The hardness of the tablets was found to be in the range of 2.2 to 2.4 Kg/cm$^2$. It was within the range of monograph specification. The friability of the tablets was found to be less than 1% and it was within the range of standard specification.

### Weight Variation

Weight variation test helps to check whether the tablet contain proper quantity of the drug. From each of the formulations ten tablets were randomly selected and weighed. The average weight of the piroxicam tablets were found to be in the range of 140.01±0.43 to 145.02± 0.49 mg were found to be within the prescribed official limits (IP).

### Percentage of Drug Content

The drug content estimations showed the values in the range of 95 to 100% which reflects good uniformity in drug content among the formulations F1 to F5 and indicates these values were within specified range as per USP (±15% of label claim was acceptable).

## In-vitro drug release studies:

*In-vitro* drug release studies were carried out using USP XXII dissolution apparatus type II (Lab India DS 8000) at 100 rpm. The dissolution medium consisted of900 ml of buffer, maintained37±0.5°C. The drug release at different time intervals was measured using an ultraviolet visible spectrophotometer (PG Instruments). The study was performed in triplicate.

**In-vitro disintegration time,wetting time and water absorption ratio of 5 formulations Table No-4.15**

| Formulation code | In vitro disintegrating Time(min) | Wetting time | Water Absorption ratio |
|---|---|---|---|
| F1 | 1.3±0.18 | 1.5±0.26 | 62.5±0.87 |
| F2 | 1.4±0.16 | 1.7±0.18 | 78.8±0.98 |
| F3 | 3±0.10 | 3.2±0.5 | 88.2±0.24 |
| F4 | 1.2±0.14 | 2±0.14 | 67.2±0.56 |
| F5 | 90 sec±0.23 | 1±0.5 | 72.5±0.35 |

All the formulated tablets (F1—F5) have shown in-vitro disintegration time of less than 3minutes. Among all formulations, tablets which were prepare by using combination of crosspovidone and fenugreek mucilage shows good disintegration time of 1minute.The wetting time of all the formulations (F1-F5) were found to be within 2minutes, which complies with official specification. The water absorption ratio of all the formulated batches was found to be satisfactory in giving effective and better formulations of oral fast disintegrating tablets.

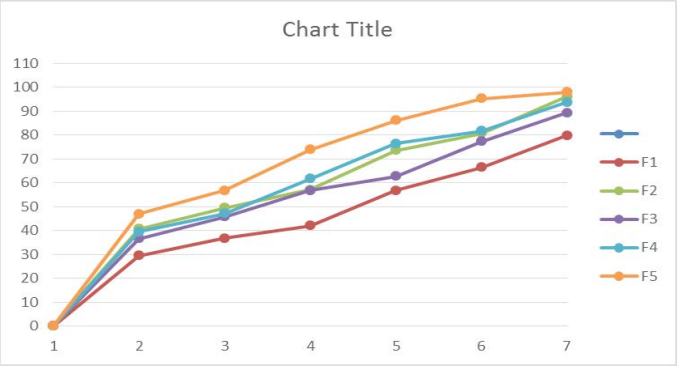
***In-vitro* dissolution study of solid dispersions from SD1 to SD3 Table No-4.16**

| Solid dispersion code | % drug release |
|---|---|
| SD1 | 98.38±0.068 |
| SD2 | 76.66±0.076 |
| SD3 | 98.70±0.026 |

***In-Vitro* Dissolution Study Of Formulation F1 to F5 Table No-4.17**

| Time(mins) | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 29.53 ±0.023 | 40.63±0.065 | 36.59±0.025 | 39.52±0.087 | 46.95±0.084 |
| 10 | 36.79 ±0.034 | 49.51±0.076 | 45.79±0.052 | 47.05±0.076 | 56.75±0.034 |
| 15 | 42.05±0.023 | 57.05±0.043 | 56.75±0.065 | 61.76±0.067 | 73.94±0.098 |
| 20 | 56.76±0.021 | 73.49±0.045 | 62.69±0.082 | 76.45±0.043 | 86.07±0.017 |
| 30 | 66.39±0.041 | 80.69±0.067 | 77.34±0.056 | 81.63±0.048 | 95.34±0.089 |
| 40 | 79.76±0.025 | 96.12±0.048 | 89.36±0.058 | 93.75±0.067 | 98.02±0.024 |

**Dissolution profile of formulations(f1- f5) Fig No:4.7**




Stability studies of optimized formulation

stability studies of optimized formulation (F5) **Table No-4.18**

| S.NO. | Test | 1 month | 3 months |
|---|---|---|---|
| 1 | Thickness (mm) | 3.08±0.22 | 3.06±0.42 |
| 2 | Hardness(kg/cm²) | 2.3±0.49 | 2.2±0.44 |
| 3 | Weight variation | 145.02±0.34 | 144.44±0.30 |
| 4 | % friability | 0.92±0.72 | 0.92±0.25 |
| 5 | Wetting time | 1min±0.18 | 1.2±0.14 |
| 6 | Water absorption ratio | 72.05±0.35 | 73.05±0.85 |
| 7 | Assay | 98±0.30 | 99±0.75 |
| 8 | In-vitro disintegration time. | 90seconds | 1minute |

***In-vitro* dissolution study of optimized formulation(F5) Table No-4.19**

| Time(mins) | percent drug release(%) (1month) | percent drug release(%) (3months) |
|---|---|---|
| 0 | 0 | 0 |
| 5 | 46.95±0.084 | 44.885±0.078 |
| 10 | 56.75±0.034 | 53.60±0.032 |
| 15 | 73.94±0.098 | 71.42±0.032 |
| 20 | 86.07±0.017 | 79.44±0.072 |
| 30 | 95.34±0.089 | 94.42±0.345 |
| 40 | 98.02±0.024 | 97.04±0.035 |

## Discussion

Solubility studies were carried out using 2 different solvents and are analysed by using uv spectrophotometer. The results were shown in the above table. From the obtained results it is proved that SD2 exhibitting low solubility so increased quantity of polymer and developed SD1 and SD2 .after performing solubility test for SD1 and SD3 it is concluded that combinations are exhibiting similar results due to saturation of complexing agent thus SD1 combination was selected and used in the further formulation.

## CONCLUSION

Based on above studies following conclusions can be drawn.

- IR spectroscopy indicated that the drug is compatible with all the excipients used.
- The in-vitro disintegration time of piroxicam solid dispersion tablets prepared by direct compression, method, were found to be within limits, and the results are satisfactory.
- Finally it was proved that the solid dispersion technique is a promising technique to improve the dissolution rate of poorly soluble drugs and the technique used for the preparation of solid dispersions was simple, applicable for scale-up in commercial quantities.

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