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# FORMULATION AND IN VITRO EVALUATION OF IMMEDIATE RELEASETABLETS CONTAINING FEBUXOSTAT

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**Abstract:**

*The present study focuses on the Formulation and inVitro Evaluation of Immediate Release tablets Containing Febuxostat, a xanthine oxidase inhibitor used in the treatment of hyperuricemia and gout. The primary objective was to enhance the dissolution rate and ensure rapid onset of action by incorporating various superdisintegrants. Immediate release tablets were formulated using different polymers including Sodium Starch Glycolate, Polyplasdone XL10, and Ac-Di-Sol in varying concentrations. A total of nine formulations (F1–F9) were prepared by direct compression method. Pre-compression and post- compression parameters such as angle of repose, bulk density, hardness, friability, disintegration time, and drug content were evaluated and found to be within acceptable limits as per IP specifications. Among all the formulations, F5, containing Polyplasdone XL10, exhibited the best performance with a drug release of 99.75% within 30 minutes, making it the optimized formulation. The study concludes that Polyplasdone XL10 is an effective superdisintegrant for the development of immediate release Febuxostat tablets, offering rapid disintegration and enhanced drug release profile.*

**Keywords:** *Febuxostat, Immediate Release Tablets*

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## INTRODUCTION:

The Oral route is one of the most sought after route for the systemic effect due to its ease of ingestion, simple, safest, convenient, non-invasive, versatility and most importantly, patient compliance. Solid oral delivery systems are cheaply manufactured because they don't require sterile conditions [1]. Although, increased focus and interest generated in the area of controlled release and targeted drug delivery system in recent years, tablet dosage forms that are intended to be swallowed whole, disintegrate, and release their medicaments fast and furiously in the gastrointestinal tract [2] An ideal dosage regimen of drug therapy is the one, which immediately nab the desired therapeutic concentration of drug in plasma (or at the site of action) and maintains it constantly for the entire duration treatment [3]. Of late, the scientists have focused their attention on the formulation immediately released tablet. The effort of developing a rapidly disintegrating tablet is accomplished by using suitable diluents and super disintegrants [4]

**Definition: Immediate Release Tablets:**

Immediate release tablets are invented to disintegrate and release their dosage form with no special rate controlling features, such as special coatings and other techniques. Immediate release tablets are those which disintegrate swiftly and get dissolved to release the medicaments. [5] The oral bioavailability of drug dependent on disintegration, dissolution and various physiological factors. [6] An immediate release dosage form helps a manufacturer to diversify market and simultaneously offering patients a convenient dosage form or dosage regimen. [7] The development of enhanced oral protein delivery technology by immediate release tablets which may release the drugs at an enhanced rate are very promising for the delivery of poorly soluble drugs high molecular weight protein and peptide. The oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy, manufacturing and ease of administration lead to high levels of patient compliance, [8]. Many patients require quick onset of action in particular therapeutic condition and consequently immediate release of medicament is required. It is estimated that 50% of the population is affected by this problem, which results in a high incidence of ineffective therapy.

**Advantages of Immediate Release Drug Delivery System [9]:**

- Improved compliance / added convenience, solubility, stability, bioavailability.
- Allows high drug loading, cost-effective.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Adaptable and amenable to existing processing and packaging machinery.
- Decreased dissolution and disintegration times for immediate release oral dosage forms.[9]

**Disadvantage:**

- Frequent dosing is necessary for a drug with a short half-life.
- Drug release at a time may produce high plasma concentration which may produce toxicity.
- Patient may suffer from tremors therefore they have difficulty to take tablet, powder and liquids. In dysphasia physical obstacles and adherence to an esophagus may cause gastrointestinal ulceration.
- Swallowing of solid dosage forms like tablet and capsules and produce difficulty for young adult of incomplete development of muscular and nervous system and elderly patients suffer from dysphasia.

**Criteria for immediate release drug delivery system [10]:**

Immediate release dosage form should In the case of solid dosage it should dissolve or disintegrate in the stomach within a short period.

- In the case of liquid dosage form it should be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasing mouth feel.
- It should not leave minimal or no residue in the mouth after oral administration.
- Exhibit low sensivity to environmental condition as humidity and temperature.
- Be manufactured using conventional processing and packaging equipment at low cost.
- Rapid dissolution and absorption of drug, which may produce rapid onset of action.

**Conventional Techniques Used for Preparation of Immediate Release Tablets [13-14]:**

Several technologies are available to manufacture immediate-release tablets. The most common preparation methods are molding, lyophilization or freeze drying, direct compression, spray drying and sublimation**.**

**Tablet Molding Technique:**

In this technology, water-soluble ingredients are incorporated to disintegrate and dissolve the tablet more swiftly. The hydroalcoholic solvents are used to moistened powder blend and then apply compression

pressure that is lower than the conventional tablets compression to mold the tablet. The solvent is then removed by air-drying. Dissolution is enhanced by a porous structure of molded tablets .

**Direct Compression**:
In which tablets formulations are directly compressed from a powder blend of suitable excipients and API is called a direct compression method. Pre-treatment of blended powder by dry or wet granulation procedure is not necessary. Its provide merits mostly in terms of speedy production, as it requires less machinery, reduced number of personnel, fewer unit operations and significantly less processing time along with improved product stability.

**Granulation Technique**:
It is a process of size enlargement in which small particles convert into larger agglomerates and make it physically stronger. It is beneficial to avoid segregation of the product's constituent, refine powder flow and handling and minimize the dustiness.

## METHODOLOGY:

**Buffer Preparation:**

**Preparation of 0.2M Potassium dihydrogen orthophosphate solution:**
Accurately weighed 27.218 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000 mL of distilled water and mixed.

**Preparation of 0.2M sodium hydroxide solution:**
Accurately weighed 8 gm sodium hydroxide pellets were dissolved 1000 ml of distilled water and mixed.

**Preparation of pH 6.8 Phosphate buffer:** Accurately measured 250ml of 0.2M potassium Dihydrogen orthophosphate and 112.5 ml 0.2M NaOH was taken into the 1000ml volumetric flask. Volume was made up to 1000 ml with distilled water.

**Pre formulation Studies**

Pre formulation involves the application of biopharmaceutical principles to the physicochemical parameters of drug substance are characterized with the goal of designing optimum drug delivery system.

**Analytical method development for febuxostat:**

**a) Determination of absorption maxima**

A spectrum of the working standards was obtained by scanning from 200-400 nm against the reagent blank to fix absorption maxima. The $\lambda_{max}$ was found to be 317 nm. Hence all further investigation was carried out at the same wavelength.

**b) Preparation of Standard graph in pH 6.8 phosphate buffer**

100 mg of Febuxostat was dissolved in 100 mL of pH 6.8 phosphate buffer to give a concentration in 1mg/mL (1000µg/mL) 1 ml was taken and diluted to 100 ml with pH 6.8 phosphate buffer to give a concentration of 0.01 mg/ml (10µg/ml). From this stock solution aliquots of 1.0 ml, 2.0 ml, 3.0 ml, 4.0 ml, 5.0 ml, were pipette out in 10 ml volumetric flask and volume was made up to the mark with pH 6.8 phosphate buffer to produce concentration of 10, 20, 30, 40 and 50µg/ml respectively. The absorbance of each concentration was measured at respective (λmax) i.e., 317nm.

**Formulation Development:**

- Drug and different concentrations for super Disintegrates and required ingredients were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass mortar for 15 minutes.
- The obtained blend was lubricated with Magnesium stearate and glidant (Talc) was added and mixing was continued for further 5 minutes.
- The resultant mixture was directly compressed into tablets by using puch of rotary tablet compression machine. Compression force was kept constant for all formulations.

**Table no: 1 Formulation of Immediate Release tablets**

| INGREDIENTS (MG) | FORMULATIONS | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
| Febuxostat | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Sodium starch Glycolate | 20 | 40 | 60 | - | - | - | - | - | - |
| Polyplasdone XL10 | - | - | - | 20 | 40 | 60 | - | - | - |
| Ac- Di- Sol | - | - | - | - | - | - | 20 | 40 | 60 |
| Talc | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Mg.Stearate | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| Mannitol | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 |
| Lactose | QS | QS | QS | QS | QS | QS | QS | QS | QS |
| Total weight (mg) | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

Total weight of tablets = 200mg

**Evaluation parameters:**

**Pre compression parameters:**

Measurement of Micromeritic Properties of Powders

**1. Angle of repose**

The angle of repose of API powder is determined by the funnel method. The accurately weight powder blend are taken in the funnel. The height of the funnel is adjusted in way that, the tip of the funnel just touched the apex of the powder blend. The powder blend is allowed to flow through the funnel freely on the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation.

$\tan \theta = h/r$

Where, h = are the height

r = radius of the powder cone.

**2. Bulk density**

The powder sample under test is screened through sieve No.18 and the sample equivalent to 25 gm is weighed and filled in a 100 ml graduated cylinder and the power is leveled and the unsettled volume, $V_o$ is noted. The bulk density is calculated in $g/cm^3$ by the formula.

Bulk density = $M/V_0$

M= Powder mass

$V_0$= apparent unstirred volume

**3. Tapped density**

The powder sample under test is screened through sieve No.18 and the weight of the sample equivalent to 25 gm filled in 100 ml granulated cylinder. The mechanical tapping of cylinder is carried out using tapped density tester at a nominal rate for 500 times initially and the tapped volume $V_0$ is noted. Tappings are proceeded further for an additional tapping 750 times and tapped volume, $V_b$ is noted. The difference between two tapping volume is less than 2%, $V_b$ is considered as a tapped volume $V_f$ . the tapped density is calculated in $g/cm^3$ by the formula.

Tapped density=$M/V_f$

M= weight of sample power taken

$V_f$= Tapped volume

**4. Compressibility Index**

The Compressibility Index of the power blend is determined by Carr's compressibility index to know the flow character of a powder. The formula for Carr's Index is an below:

Carr's Index (%)=[(TD-BD) / TD]x100

**5. Hauser's ratio**

The Hauser's ratio is a number that is correlated to the flowability of a powder or granular material. The ratio of tapped density to bulk density of the powders is called the Hauser's ratio. It is calculated by the following equation.

$H=\rho T / \rho B$

Where $\rho T$= tapped density, $\rho B$ = bulk density

**Post compression parameters:**

**a) Thickness**

The thickness of tablets was determined by using Digital micrometer. Ten individual tablets from each batch were used and the results averaged.

**b) Weight variation**

Twenty tablets randomly selected from each batch and individually weighed. The average weight and standard deviation three batches were calculated. It passes the test weight variation test if not more than two of the individual tablets weights deviate from the average weight by more than the allowed percentage deviation and more deviate by more than twice the percentage shown. It was calculated on an electronic weighing balance.

**c) Friability**

The friability values of the tablets were determined using a Roche-type friabilator. Accurately weighed six tablets were placed in Roche friabilator and rotated at 25rpm for 4 min.

Percentage friability was calculated using the following equation.

Friability = $([w_0-w] / w_0) \times 100$

**d) Assay**

The content of drug was carried out by five randomly selected tablets of each formulation. The five tablets were grinded in mortar to get powder; this powder was dissolved in pH 6.8 phosphate buffer by sonication for 30 min and filtered through filter paper. The drug content was analyzed spectrophotometrically at 317nm using UV spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

**e) Disintegration test**

Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 minutes and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

**f) Dissolution test of Febuxostat tablets**

Drug release from Febuxostat tablets was determined by using dissolution test United States Pharmacopoeia (USP) 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8 Phosphate Buffer as the dissolution medium of quantity 500ml. the whole study is being carried out at a temperature of 37°C and at speed of 50 rpm.

5 ml aliquots of dissolution media were withdrawn each time at suitable time intervals (5, 10, 15, 20, 25 and 30 minutes) and replaced with fresh medium. After withdrawing, samples were filtered and analyzed after appropriate dilution by UV Spectrophotometer. The

concentration was calculated using standard calibration curve.

**Drug-Excipients compatibility studies:**

Drug Excipients compatibility studies were carried out by mixing the drug with various excipients in different proportions (In 1:1 ratio were prepared to have maximum likelihood interaction between them) was placed in a vial, and closed with rubber stopper and sealed properly.

## RESULTS AND DISCUSSION:

**Determination of $\lambda_{max}$ :**

The prepared stock solution was scanned between 200-400 nm to determine the absorption maxima . It was found to be 317 nm.

**Calibration curve of Febuxostat:**

The standard curve of Febuxostat was obtained and good correlation was obtained with $R^2$ value of 0.998, the medium selected was pH 6.8 phosphate buffer.

**Table no: 2 Standard graph values of Febuxostat at 317nm in pH 6.8 phosphate buffer**

| Concentration (µg/ml) | Absorbance |
|---|---|
| 0 | 0 |
| 10 | 0.148 |
| 20 | 0.281 |
| 30 | 0.418 |
| 40 | 0.549 |
| 50 | 0.682 |

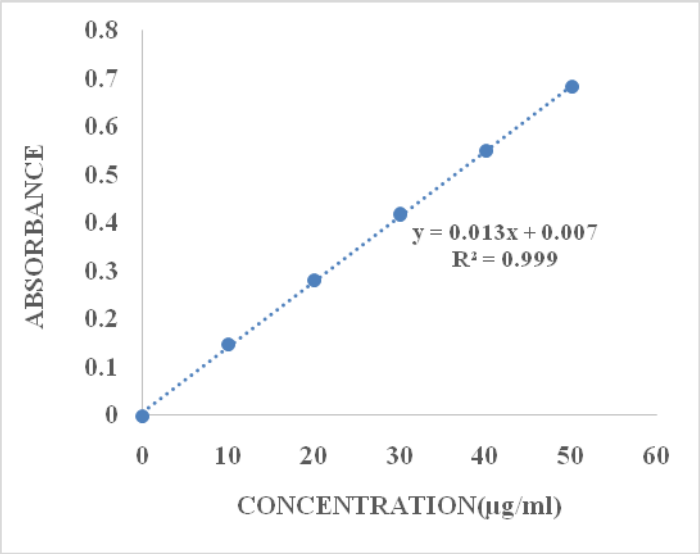


**Figure no:1 Standard curve of Febuxostat**

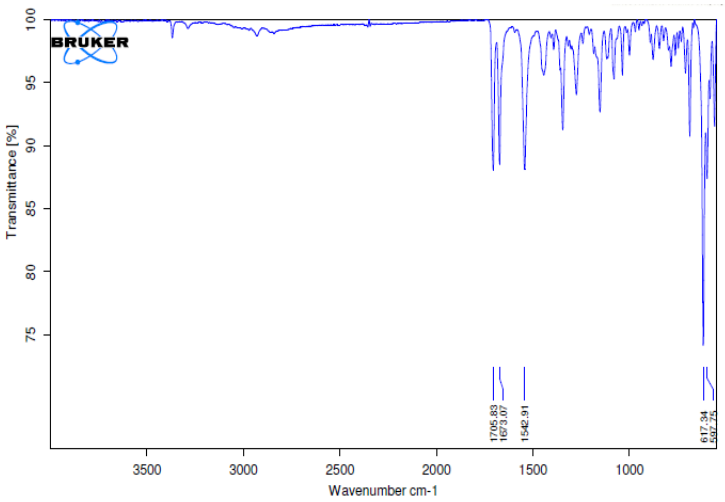


**Figure no:2 Drug-Excipient compatibility studies by FTIR studies:**

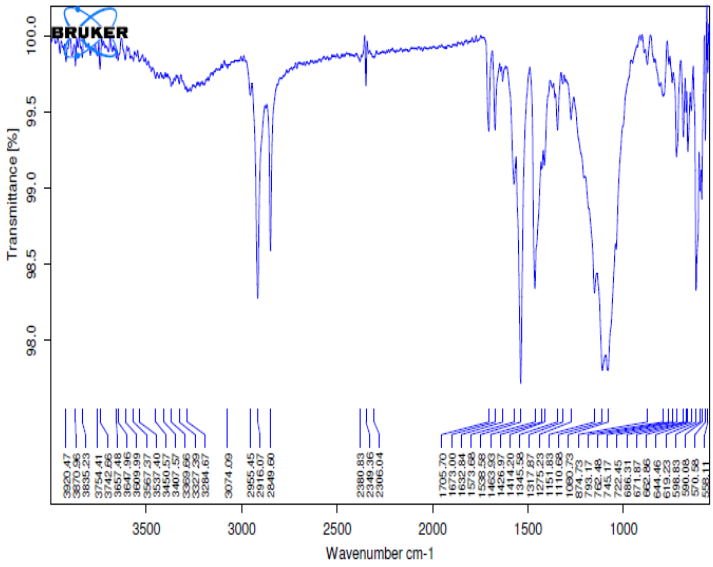


**Figure no:3 FTIR spectra of optimized formulation**

no color change at the end of two months , providing no drug –excipient interactions.

**Evaluation of Immediate Release tablets:**

**Characterization of precompression blend :**

The precompression blend of Febuxostat were characterized with respect to angle of repose , bulk density , tapped density, Carr's index and Hausner's ratio.

Angle of repose was less than 28 ˚, Carr's index values were less than 11 for the precompression blend of all the batches indicating good to fair flowability and compressibility . Hausner's ratio was less than 1.25 for all batches indicating good flow properties.

**Table :3 Physical properties of precompression blend**

| Formulation code | Angle of repose (Ɵ) | Bulk density (gm/cm$^3$ | Tapped density(gm/cm$^3$) | Carr's index (%) | Hausner's ratio |
|---|---|---|---|---|---|
| F1 | 30.48±0.02 | 0.515±1.47 | 0.610±0.01 | 15.57±1.4 | 1.18±0.01 |
| F2 | 31.24±0.04 | 0.523±0.45 | 0.612±0.01 | 14.95±0.66 | 1.17±0.02 |
| F3 | 30.86±0.03 | 0.518±0.25 | 0.613±0.02 | 15.35±0.3 | 1.18±0.01 |
| F4 | 33.28±0.01 | 0.517±1.05 | 0.617±0.03 | 15.66±0.10 | 1.185±0.15 |
| F5 | 32.19±0.02 | 0.525±0.99 | 0.611±0.01 | 14.91±0.33 | 1.175±0.03 |
| F6 | 31.10±0.02 | 0.522±0.36 | 0.623±0.02 | 14.56±0.20 | 1.170±0.01 |
| F7 | 39.23±0.01 | 0.527±0.45 | 0.618±0.01 | 16.53±1.6 | 1.198±0.21 |
| F8 | 32.21±0.01 | 0.516±0.24 | 0.622±0.05 | 14.96±0.15 | 1.186±0.03 |
| F9 | 33.54±0.04 | 0.522±0.25 | 0.615±0.04 | 15.64±0.26 | 1.175±0.02 |

All the values represent n=3

**Evaluation of tablets:**

**Physical evaluation of Febuxostat Immediate release tablets:** The results of the weight variation , hardness , thickness , friability , and drug content of tablets are given in table . All the tablets of different batches complied with the official requirement of weight variation as their weight variation passes the limit . The hardness of the tablets ranged from 2.28±86 - 2.96±68 kg/cm$^2$ and the friability values were < than 0.39±66 % indicating that the tablets were compact and hard . The thickness of the tablets ranged from 2.01±22 -2.08±57. All the formulations satisfied the content of the drug as they contained 98-100% of Febuxostat and good uniformity in drug content was observed . Thus all physical attributes of the prepared tablets were found to be practically within control limits.

**Table :4 Evaluation of Febuxostat Immediate release tablets**

| Formulation code | Average Weight (mg) | Thickness (cm) | Hardness (Kg/cm$^2$) | Friability (%) | Content uniformity (%) | *In Vitro* Disintegration time (Minutes) |
|---|---|---|---|---|---|---|
| F1 | 198.18 | 2.02±98 | 2.65±25 | 0.42±95 | 99.18 | 4.3 |
| F2 | 196.68 | 2.05±84 | 2.84±96 | 0.56±64 | 97.27 | 4.4 |
| F3 | 199.25 | 2.01±22 | 2.82±88 | 0.38±84 | 100.68 | 4.6 |
| F4 | 197.37 | 2.06±31 | 2.90±76 | 0.51±72 | 101.85 | 4.8 |
| F5 | 200.99 | 2.08.14 | 2.55±22 | 0.63±38 | 96.39 | 2.8 |
| F6 | 201.76 | 2.02±96 | 2.28±86 | 0.54±99 | 99.47 | 3.3 |
| F7 | 199.55 | 2.01±65 | 2.47± 65 | 0.48±57 | 98.25 | 4.1 |
| F8 | 198.68 | 2.06±77 | 2.96±68 | 0.56±75 | 96.44 | 3.6 |
| F9 | 199.91 | 2.08±57 | 2.87±46 | 0.39±66 | 98.19 | 3.1 |

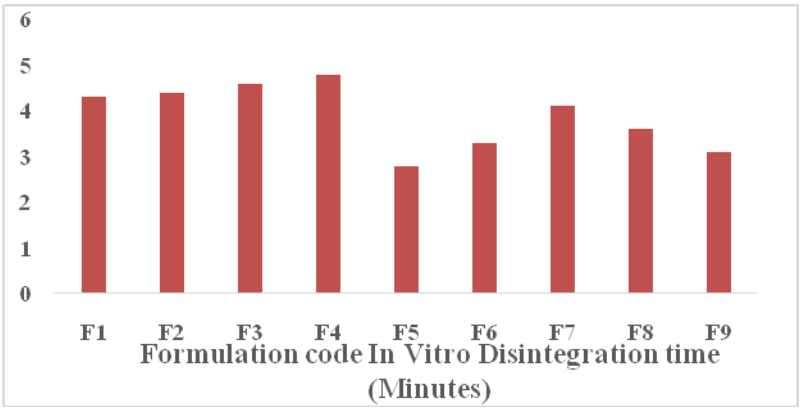


**Figure no :4 *In vitro* disintegration time Graph**

***In vitro* Dissolution:** The drug release rate from tablets was studied using the USP type II dissolution test apparatus . The dissolution medium was 500 ml of pH 6.8 phosphate buffer at 50 rpm at a temperature of 37±0.5 ˚C . Samples of 5 ml were collected at different time intervals up to 1 hr and has analyzed after appropriate dilution by using UV spectrophotometer at 317nm.

**Table :5 *In vitro* data for formulation F1- F9**

| TIME (Minutes) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 17.82 | 15.62 | 18.33 | 19.21 | 28.51 | 24.82 | 21.84 | 24.17 | 34.73 |
| 10 | 41.24 | 37.83 | 27.75 | 37.38 | 44.39 | 54.51 | 29.36 | 33.49 | 46.93 |
| 15 | 48.51 | 59.99 | 55.63 | 49.72 | 57.96 | 55.33 | 36.28 | 43.73 | 55.74 |
| 20 | 67.57 | 67.26 | 79.57 | 62.58 | 72.62 | 74.88 | 54.49 | 58.45 | 62.96 |
| 25 | 74.44 | 89.57 | 88.33 | 76.88 | 84.88 | 82.47 | 66.22 | 73.33 | 89.66 |
| 30 | 82.22 | 95.13 | 93.81 | 88.34 | 99.75 | 97.36 | 78.99 | 88.72 | 94.45 |

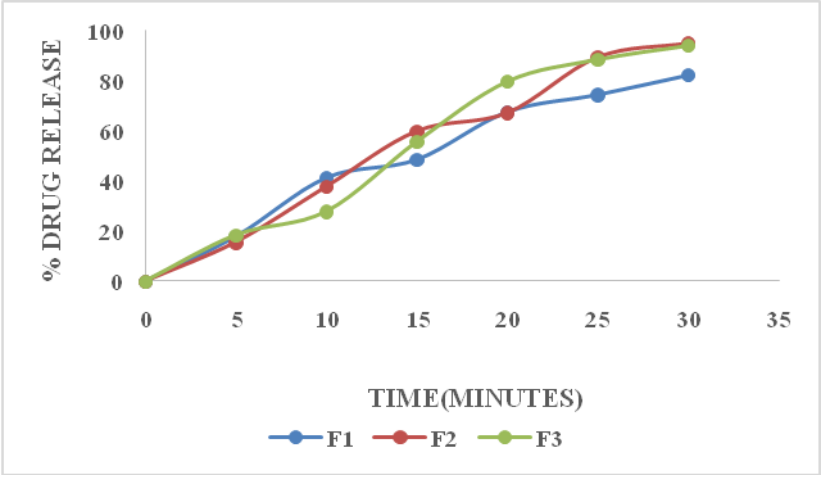


**Figure no:5 *In vitro* dissolution data for formulation F1 - F3**

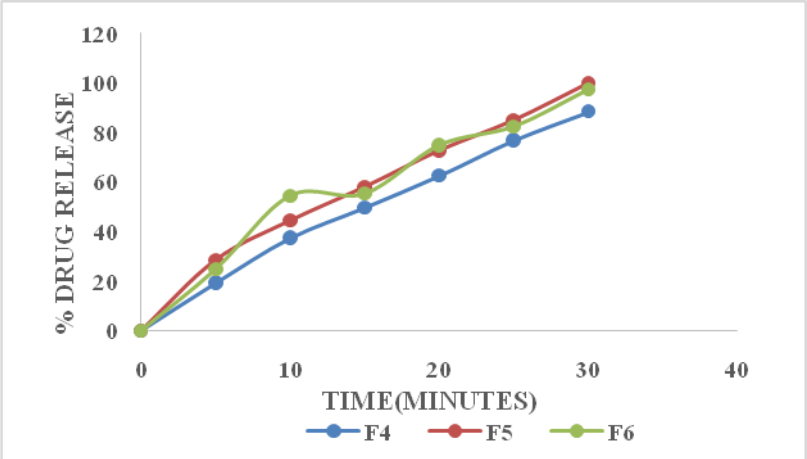


**Figure no :6 *In vitro* dissolution data for formulations F4 - F6**

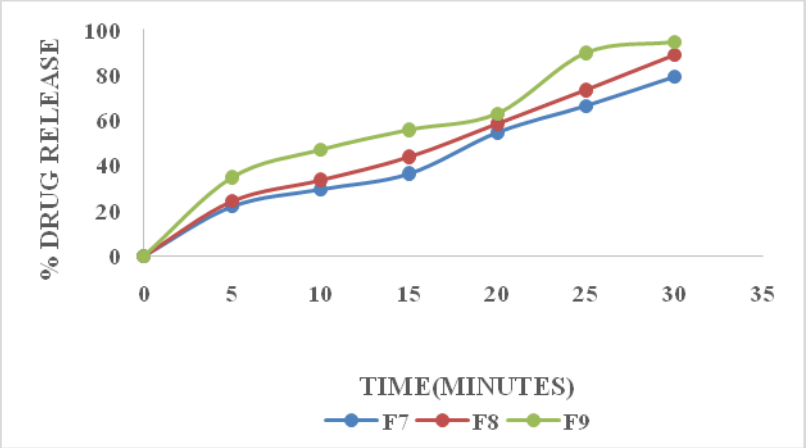


**Figure no :7 *In vitro* dissolution data for formulations F7 - F9**

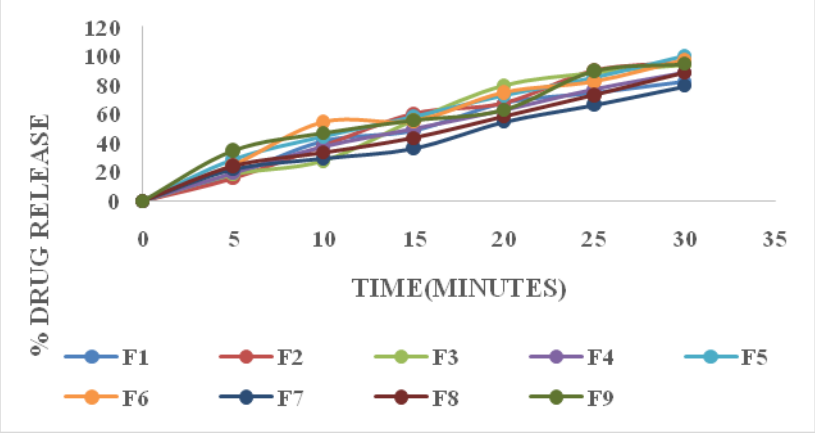


**Figure no:8 *In Vitro* dissolution data for formulations F1 - F9**

Among all the formulations F5 formulation containing drug and Polyplasdone XL10 showed good result that is 99.75% in 30 minutes, at the concentration of 40mg and F5 Formulation showed Less Disintegration time (2.8Minutes). Hence from all the formulations it is evident that F5 formulation is the better formulation.

## CONCLUSION:

The present study successfully demonstrated the formulation and in vitro evaluation of immediate

release tablets containing Febuxostat using various super disintegrants and excipients. All the pre-compression and post-compression parameters were found to be within the acceptable limits as per IP standards, indicating good flow properties and mechanical strength of the tablets. Among the different formulations, the optimized batch exhibited rapid disintegration time, superior drug release profile more than 98% within 30 minutess, and satisfactory physical characteristics.

This suggests that the developed immediate release formulation of Febuxostat can significantly enhance the onset of action, potentially improving therapeutic efficacy in the management of hyperuricemia and gout.

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