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Formulation and In-vitro Evaluation of Immediate Release Tablets Containing Febuxostat

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A B S T R A C T
The aim of the present study is to develop and evaluate the immediate release tablet of Febuxostat by direct compression method. The Super disintegrant Primojel, Ac-Di-Sol and Polyplasdone XL10 were used for immediate release of drug from tablet. The prepared tablets were evaluated for all pre-compression parameters and post-compression parameters. The drug excipients interaction was investigated by FTIR. All formulation showed compliances with Pharmacopoeial standards. The study reveals that formulations prepared by direct compression F3 exhibit highest dissolution using primojel showed faster drug release 98.01% over the period of 45min while disintegration time of the tablet was showed 25sec comparison to other formulations of Febuxostat.

Keywords: Febuxostat, superdisintegrant, Immediate release tablet, primojel

A R T I C L E I N F O

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CONTENTS

1. Introduction

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.

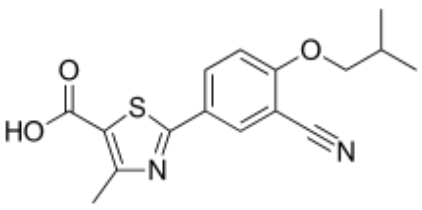

Fig.1: Febuxosta

Drug category: xanthine oxidase inhibitor
Chemical name/ Nomenclature / IUPAC Name: 2-(3-cyano-4-isobutoxyphenyl)-4-methyl-1,3-thiazole-5-carboxylic acid.
Molecular Formula : $C_{16}H_{16}N_2O_3S$
Molecular Weight : 316.38 gm/mole.
Physicochemical properties:
Description (Physical State): solid
Solubility: lightly soluble in methanol, freely soluble in N, N-dimethylformamide and sparingly soluble in ethanol.
Storage Conditions: room temperature, between 68 F to 77 F (20 C to 25 C).
Dosage: tablet
Melting point: 207.0 to 211.0 °C

pKa(strongest acidic): 3.3

Pharmacokinetic properties:

Bioavailability : ≥84% absorbed.

Half-life : 5–8 hrs

Absorption : After oral administration, about 85% of febuxostat is absorbed rapidly. Tmax ranges from 1 to 1.5 hours. Following once-daily oral administration, Cmax was approximately 1.6±0.6mcg/mL at dose of 40 mg febuxostat and 2.6±1.7mcg/mL at a dose of 80 mg febuxosta.

Volume of Distribution : 29 to 75 L

Protein binding : 99.2 %

Primojel

Primojel Sodium starch glycolate is a superdisintegrant suitable for a variety of tablet and capsule formulations. In higher concentrations, Primojel can act as a dissolution enhancing agent. Primojel is highly effective when used intragranular and/or extragranular in granular formulations.

Functional Category: Disintegrant.

Applications:

Primojel is widely used in oral pharmaceuticals as a disintegrant in capsule and tablet formulations. It is commonly used in tablets prepared by either direct-compression or wet-granulation processes. The usual concentration employed in a formulation is between 2% and 8%, with the optimum concentration about 4%, although in many cases 2% is sufficient. Disintegration occurs by rapid uptake of water followed by rapid and enormous swelling. Although the effectiveness of many disintegrants is affected by the presence of hydrophobic excipients such as lubricants, the disintegrant efficiency of sodium starch glycolate is unimpaired. Increasing the tablet compression pressure also appears to have no effect on disintegration time. Sodium starch glycolate has also been investigated for use as a suspending vehicle.

Functional Category: Tablet and capsule disintegrant.

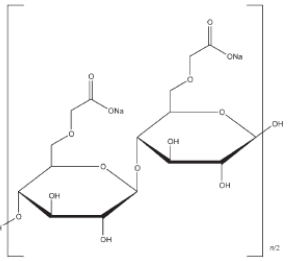

Fig.2: Primojel

2. Methodology

Characterization of Febuxostat

Organoleptic properties:

Take a small quantity of sample and spread it on the white paper and examine it visually for color, odour and texture.

Determination of Febuxostat Melting point

The melting point of Febuxostat was determined by capillary tube method according to the USP. A sufficient quantity of Febuxostat powder was introduced into the capillary tube to give a compact column of 4-6 mm in height. The tube was introduced in electrical melting point apparatus and the temperature was raised. The melting point was recorded, which is the temperature at which the last solid particle of Febuxostat in the tube passed into liquid phase**.**

Buffer Preparation:

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

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

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

Analytical method development for Febuxostat:

a) Determination of absorption maxima

A spectrum of the working standards was obtained by scanning from 200-400nm against the reagent blank to fix absorption maxima. The λ_{max} was found to be 315 nm. Hence all further investigation was carried out at the same wavelength.

P Standard graph in pH 6.8 phosphate buffer

100 mg of Febuxostat was dissolved in 100ml of Phosphate buffer of pH 6.8., form primary stock 10ml was transferred to another volumetric flask made up to 100ml with Phosphate buffer of pH 6.8, from this secondary stock was taken separately and made up to 10 ml with Phosphate buffer of pH 6.8, to produce 2, 4, 6, 8 and 10µg/ml respectively. The absorbance was measured at 315 nm by using a UV spectrophotometer.

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 punch of rotary tablet compression machine.

Pre formulation Studies

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.

$$\tan \theta = h/r \quad \text{……..(1)}$$

Where, h and r are the height and redius 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 …… (2)

M= Powder mass

V_0= apparent unstrirred 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. Tapings are preceded 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 ……. (3)

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 …….(4)

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=ρT / ρB ……(5)

Where ρT= tapped density, ρB = 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) x 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 spectrophotometrically315nm 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 900ml. the whole study is being carried out at a temperature of 37^0C and at speed of 75 rpm. 5 ml aliquots of dissolution media were withdrawn each time at suitable time intervals (5, 10, 15, 20, 25, 30 and 45minutes) 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.

Application of Release Rate Kinetics to Dissolution Data:

Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Zero order release rate kinetics:

To study the zero–order release kinetics the release rate data ar e fitted to the following equation.

$F = K_o t$

Where, 'F' is the drug release at time't', and 'K_o' is the zero order release rate constant. The plot of % drug release versus time is linear.

First order release rate kinetics: The release rate data are fitted to the following equation

Log (100-F) = kt

A plot of log cumulative percent of drug remaining to be released vs. time is plotted then it gives first order release.

Higuchi release model: To study the Higuchi release kinetics, the release rate data were fitted to the following equation.

$F = k\ t1/2$

Where, 'k' is the Higuchi constant.

In higuchi model, a plot of % drug release versus square root of time is linear.

Korsmeyer and Peppas release model:

The mechanism of drug release was evaluated by plotting the log percentage of drug released versus log time according to Korsmeyer- Peppas equation. The exponent 'n' indicates the mechanism of drug release calculated through the slope of the straight Line.

$M_t/ M_\infty = K\ t^n$

Where, M_t/ M_∞ is fraction of drug released at time 't', k represents a constant, and 'n' is the diffusional exponent, which characterizes the type of release mechanism during the dissolution process. For non-Fickian release, the value of n falls between 0.5 and 1.0; while in case of Fickian

diffusion, n = 0.5; for zero-order release (case I I transport), n=1; and for supercase II transport, n>1. In this model, a plot of log (M_t/ M_∞) versus log (time) is linear.

Hixson-Crowell release model:$(100-Q_t)^{1/3} = 100^{1/3} – K_{HC}.t$

Where, k is the Hixson-Crowell rate constant.

Hixson-Crowell model describes the release of drugs from an insoluble matrix through mainly erosion. (Where there is a change in surface area and diameter of particles or tablets).

Table.1: Formulation table

Ingredients	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Febuxostat	100	100	100	100	100	100	100	100	100
Primojel	40	80	120	-	-	-	-	-	-
Ac-Di-Sol	-	-	-	40	80	120	-	-	-
Polyplasdone XL10	-	-	-	-	-	-	40	80	120
Beta-Cyclodextrin	10	20	30	10	20	30	10	20	30
MCC	122	72	22	122	72	22	122	72	22
Aspartame	15	15	15	15	15	15	15	15	15
Mg stearate	7	7	7	7	7	7	7	7	7
Talc	6	6	6	6	6	6	6	6	6
Total Weight of Tablet (mg)	300	300	300	300	300	300	300	300	300

3. Results and Discussion

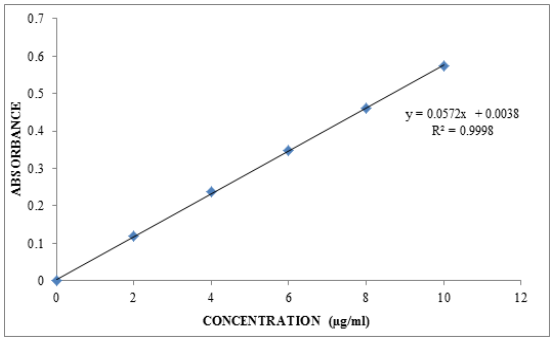

Fig.3: Standard curve of Febuxostat

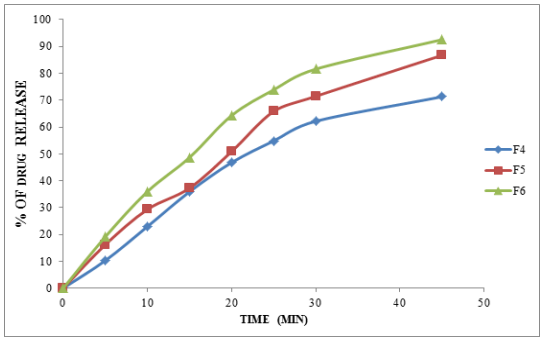

Fig.6: In vitro dissolution data for formulations F4-F6

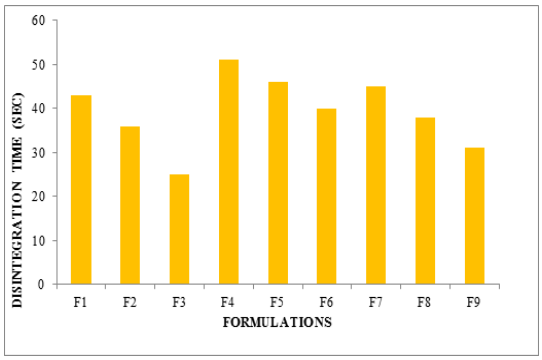

Fig.4: Disintegration Test (Sec)

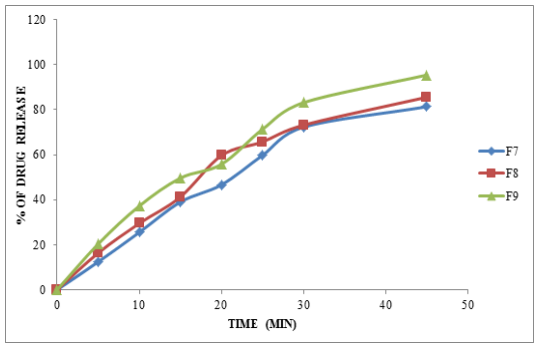

Fig.7: In vitro dissolution data for formulations F7-F9

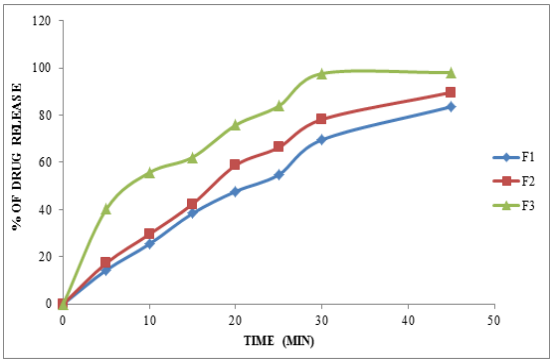

Fig.5: In vitro dissolution data for formulation F1-F3

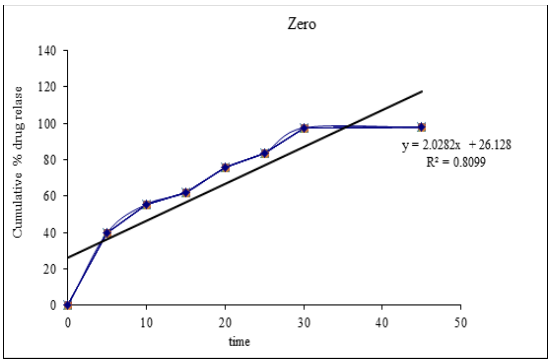

Fig.8: Zero order release kinetics graph

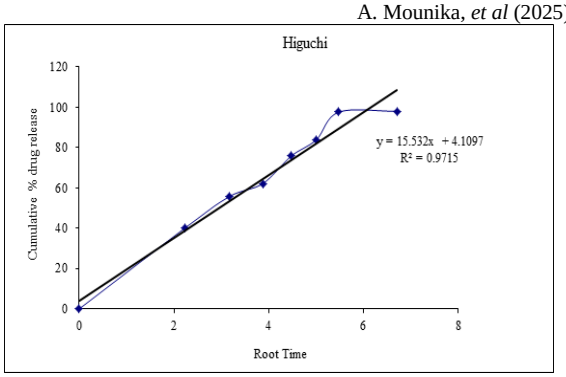

Fig.9: Higuchi release kinetics graph

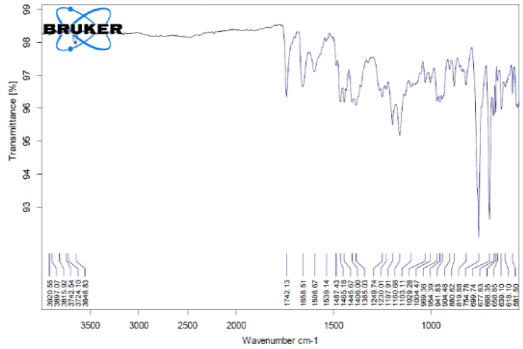

Fig.12: FTIR spectra of pure drug

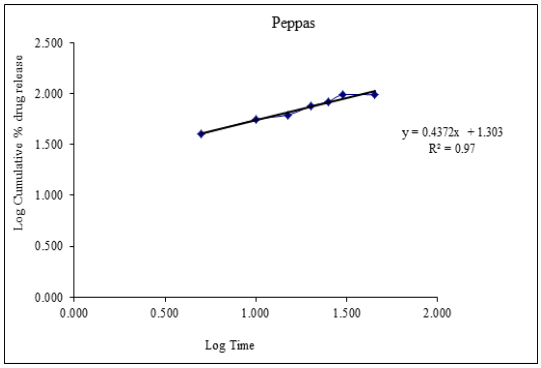

Fig.10: Peppas release kinetics graph

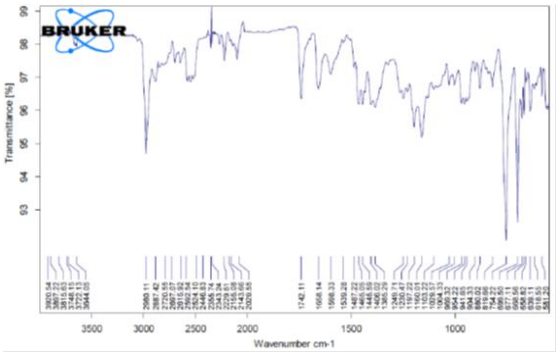

Fig.13: FT-IR spectra of optimized formulation

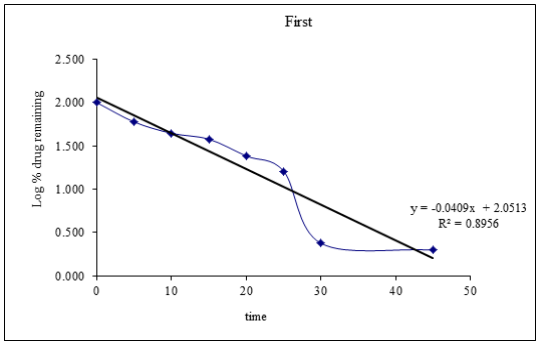

Fig.11: First order release kinetics graph

Discussion

From the above studies it was found that there was no shifting in the major peaks which indicated that there were no significant interactions occurred between the Febuxostat and excipients used in the preparation of different Febuxostat Immediate Release formulations. Therefore the drug and excipients are compatible to form stable. Formulations under study, The FTIR spectra of Febuxostat and physical mixture used for optimized formulation were obtained and these are depicted in above figures. From the FTIR data it was evident that the drug and excipients does not have any interactions. Hence they were compatible.

Table.2: Peaks characterization for Optimized formulation Febuxostat

Functional group	Reference wave number (cm−1)	Obtained wave number (cm−1)
C=O (carbonyl)	1656-1715	1658.14-1742.11
-C=C-Aromatic	1450-1650	1406-02-1598.22
Amide	3675.36	3644.05

Table.3: Peaks characterization for pure Febuxostat

Functional group	Reference wave number (cm−1)	Obtained wave number (cm−1)
C=O (carbonyl)	1656-1715	1658.51
-C=C-Aromatic	1450-1650	1406.00-1598.67
Amide	3675.36	3646.83

Table.4: Standard graph values of Febuxostat at 315 nm in pH 6.8 phosphate buffer

Concentrations (µg/ml)	Absorbance
0	0
2	0.119
4	0.238
6	0.347
8	0.461
10	0.574

Table.5: Physical properties of Pre compression blend

Formulation code	Angle of repose (Ɵ)	Bulk density (gm/cm^3)	Tapped density(gm/cm^3)	Carr's index (%)	Hausner's ratio
F1	35.13±0.032	0.4236±0.0026	0.4854±0.0018	12.73±0.0494	1.14±0.0014
F2	35.15±0.041	0.4230±0.0020	0.4766±0.0033	11.23±0.1272	1.12±0.0035
F3	29.24±0.008	0.4127±0.0180	0.4821±0.0029	14.36±0.7566	1.16±0.0000
F4	27.47±0.027	0.4227±0.0038	0.5231±0.0253	19.19±0.0565	1.23±0.0071
F5	35.12±0.019	0.3823±0.0032	0.4852±0.0044	20.01±0.0848	1.26±0.0000
F6	34.99±0.003	0.3910±0.0014	0.4650±0.0036	15.90±0.3040	1.16±0.0070
F7	33.86±0.002	0.2896±0.0014	0.3449±0.0013	16.04±0.3676	1.18±0.0424
F8	35.23±0.001	0.3100±0.0035	0.3655±0.0031	15.19±0.2969	1.17±0.0070
F9	32.61±0.001	0.3925±0.0026	0.4614±0.0028	14.93±0.9545	1.16±0.0070

Table.6: *In-vitro* dissolution data for formulation F1-F9

Time (Min)	% of Drug Release								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0	0	0	0	0	0	0	0	0	0
5	14.37	17.33	40.18	10.27	16.18	19.13	12.36	16.34	20.35
10	25.39	29.57	55.68	22.95	29.32	35.95	25.48	29.47	37.22
15	38.37	42.36	62.15	35.89	37.25	48.66	38.99	41.23	49.63
20	47.69	58.75	75.78	46.77	50.87	64.29	46.62	59.65	55.77
25	54.76	66.33	83.84	54.83	65.83	73.85	59.75	65.74	71.32
30	69.54	78.18	97.62	62.16	71.45	81.58	72.31	73.18	83.17
45	83.58	89.65	98.01	71.28	86.73	92.56	81.36	85.62	95.48

Table.7: Physical evaluation of Febuxostat

Formulation code	Weight variation (mg)	Thickness (cm)	Hardness (Kg/cm^2)	Friability (%)	Content Uniformity (%)	Disintegration Time (Sec)
F1	296.21	3.69	4.2	0.36	98.16	43
F2	298.80	3.48	4.9	0.24	97.62	36
F3	295.16	3.15	4.6	0.59	99.35	25
F4	299.60	3.75	4.1	0.37	96.28	51
F5	296.21	3.61	4.7	0.49	97.19	46
F6	298.52	3.95	4.3	0.36	99.25	40
F7	296.79	3.47	4.2	0.61	99.61	45
F8	298.31	3.64	4.0	0.48	98.18	38
F9	297.10	3.18	4.8	0.57	97.29	31

Table.8: Organoleptic properties

S NO.	Properties	Reported results	Observed results
1	State	Solid	Solid
2	Colour	White	White
3	Odour	Odourless	Odourless
4	Melting point	129.2-129.8	129.5

Table.9: Release Kinetics

Cumulative (%) Release Q	TIME (T)	ROOT (T)	LOG (%) Release	LOG (T)	LOG (%) Remain	RELEASE RATE (Cumulative % Release / t)	1/Cum% Release	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
40.18	5	2.236	1.604	0.699	1.777	8.036	0.0249	-0.396	59.82	4.642	3.911	0.731
55.68	10	3.162	1.746	1.000	1.647	5.568	0.0180	-0.254	44.32	4.642	3.539	1.103
62.15	15	3.873	1.793	1.176	1.578	4.143	0.0161	-0.207	37.85	4.642	3.358	1.284
75.78	20	4.472	1.880	1.301	1.384	3.789	0.0132	-0.120	24.22	4.642	2.893	1.748
83.84	25	5.000	1.923	1.398	1.208	3.354	0.0119	-0.077	16.16	4.642	2.528	2.113
97.62	30	5.477	1.990	1.477	0.377	3.254	0.0102	-0.010	2.38	4.642	1.335	3.306
98.01	45	6.708	1.991	1.653	0.299	2.178	0.0102	-0.009	1.99	4.642	1.258	3.384

4. **Conclusion**

Pre formulation studies of Febuxostat were performed; the FT-IR analysis revealed that the superdisintegrants and excipients used were compatible with Febuxostat. Immediate release tablets of Febuxostat are to be prepared by direct compression technique using Super disintegrants, namely Primojel, Ac-Di-Sol, Polyplasdone XL10. Amongst all the formulations, formulation containing Primojel as super disintgrants is fulfilling all the parameters satisfactorily. It has shown excellent *in-vitro* disintegration compared to other Superdisintegrants. Combines multiple mechanisms to achieve disintegration at low levels without forming gel i.e. require slow dissolution, disintegration and provides rapid disintegration in direct compression tablet as well increases tablet breaking force and reduces friability; enhances the dissolution of poorly soluble drugs. Apart from all the formulations,F3 formulation showed maximum drug release (98.01) at the end of 45 min. F3 was followed Higuchi release kinetic mechanisam.

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