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FORMULATION AND INVITRO EVALUATION OF IMMEDIATE RELEASE TABLETS CONTAINING FEBUXOSTAT

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ABSTRACT

In the present research work Febuxostat Immediate Release Tablet were prepared by direct compression method using varying concentrations of Lycoat, Crospovidone & Croscarmellose sodium as disintegrants. The formulations prepared were evaluated for precompression& post compression parameters. Form the drug excipient compatibility studies we observe that there are no interactions between the pure drug (Febuxostat) and optimized formulation (Febuxostat+ excipients) which indicates there are no physical changes. Post compression parameters was found to be within the limits. Among the formulation prepared the tablet containing 12mg of CCS shows 98.13% of the drug release within 45 min & follows first order kinetics. The precompression parameters like bulk density, tapped density, Carr's index and angle of repose were determined. All the formulations showed acceptable flow properties. The postcompression parameters like the hardness, thickness, friability and weight variation, disintegration time, disintegration time in oral cavity and Invitro release were carried out and the values were found to be within IP limits.

KEYWORDS: Febuxostat, CCS, Lycoat, Crospovidone.

INTRODUCTION

In the present study and research novel drug delivery systems are developed for expanding markets/indications, extending product life cycles and generating opportunities. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly patient compliance. In these solid formulations do not require sterile conditions and are therefore, less expensive to manufacture**.** Patient compliance, high-precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice. Excipients and equipments choices will be significantly affected should solid dosage form technologies change in response to the unprecedented shifts in the drug discovery such as genomics. 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. Many patients require quick onset of action in particular therapeutic condition and consequently immediate release of medicament is required. It is estimated that50% of the population is affected by this problem, which results in a high incidence of ineffective therapy.

Evaluation of powder blend

The prepared blend is evaluated by following tests.

1. Angle of repose
2. Bulk density
3. Tapped density
4. Hauser’s ratio
5. Carr’s index

EVALUATION OF TABLETS

These tests are as following:-

1. Appearance
2. Thickness
3. Hardness
4. Weight variation
5. Friability

6. Disintegration
7. Uniformity of dispersion
8. Drug content
9. *In vitro* Dissolution

METHODOLOGY

Table 1: Materials Used.

S. No	Materials	Company
1.	Febuxostat	Spectrum labs
2.	Lycoat	Signet Chemical Corp., Mumbai
3.	Crospovidone	Signet Chemical Corp., Mumbai
4.	Croscarmellose sodium	Signet Chemical Corp., Mumbai
5.	Microcrystalline cellulose	Aurbindo Pharma Ltd., Hyd.
6.	Talc	S.D. Fine Chem. Ltd.
7.	Magnesium stearate	S.D. Fine Chem. Ltd.

PREFORMULATION STUDIES[1-5]

It is one of the important prerequisite in development of any drug delivery system. Preformulation studies were performed on the drug, which included melting point determination, solubility and compatibility studies.

Determination of UV spectrum of Febuxostat

10mg of Febuxostat was dissolved in 2-3ml of methanol then makeupto10ml with 6.8pH buffer so as to get a stock solution of 1000 µg/ml concentration. From the above stock solution pipette out 1ml of the solution and makeup the volume to 10ml using 6.8pH buffer to get the concentration of 100µg/ml concentration. From this stock solution pipette out 1ml of the solution and makeup the volume to 10ml using 6.8pH buffer to get the concentration of 10µg/ml concentration, this solution was scanned under UV Spectroscopy using 200-400nm.

Preparation of Standard Calibration Curve of Febuxostat in pH 6.8 phosphate buffer

10mg of Febuxostat was accurately weighed and transferred into 10ml volumetric flask. It was dissolved and diluted to volume with pH 6.8 phosphate buffer to give stock solution containing 1000µg/ml. The standard stock solution was then serially diluted with pH 6.8 phosphate buffer to get 2 to 12µg/ml of Febuxostat. The absorbance of the solution were measured against pH 6.8 phosphate buffer as blank at 315nm using UV visible spectrophotometer. The absorbance values were plotted against concentration (µg/ml) to obtain the standard calibration curve.

Solubility

Solubility of Febuxostat was determined in Methanol, Ethanol, pH 1.2, pH 6.8 and pH 7.4 phosphate buffers. Solubility studies were performed by taking excess amount of Febuxostat in different beakers containing the solvents. The mixtures were shaken for 24 hrs at regular intervals. The solutions were filtered by using whattmann's filter paper grade no. 41. The filtered solutions were analyzed spectrophotometrically at 315 nm.

Compatibility Studies

FTIR analysis

The drug-polymer interactions were studied by FTIR spectrometer, Shimadzu 8400 S. 2% (w/w) of the sample, with respect to a potassium bromide (KBr; SD Fine Chem. Ltd., Mumbai, India) was mixed with dry KBr. The mixture was ground into a fine powder using mortar and then compressed into a KBr discs in a hydraulic press at a pressure of 10000 PSI. Each KBr disc was scanned 10 times at a resolution of 2 cm–1 using Happ-Genzel apodization. The characteristic peaks were recorded.

Formulation of Immediate release Tablets of Febuxostat[6-15]

The inner core tablets were prepared by using direct compression method as per the developed formulation table which was shown below. Accurately weighed amounts of Febuxostat, MCC, Crospovidone, CCS, Lycoat and Talc were dry blended for about 15min followed by addition of magnesium stearate. The mixture was then further blended for 10 min. Now the resultant powder blend was manually compressed using punching machine and finally the core tablet was obtained.

Table 2: Formulation Table of Febuxostat IR Tablets.

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Febuxostat	40	40	40	40	40	40	40	40	40
Lycoat	4	8	12	--	--	--	--	--	--
Crosspovidone	--	--	--	4	8	12	--	--	--
CCS	--	--	--	--	--	--	4	8	12
MCC	103	99	95	103	99	95	103	99	95
Mg.sterate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Total	150	150	150	150	150	150	150	150	150

Evaluation of IR Tablet[16-23]

Tablets were subjected to evaluation of properties including drug content uniformity, weight variation, tablet hardness, friability, and thickness, and in-vitro drug release with different

media.

1. Weight variation

The weight of the tablet being made was routinely determined to ensure that a tablet contains the proper amount of drug. The USP weight variation test is done by weighing 20 tablets individually, calculating the average weight and comparing the individual weights to the average. The tablets met the USP specification that not more than 2 tablets are outside the percentage limits and no tablet differs by more than 2 times the percentage limit. USP official limits of percentage deviation of tablet are presented in the below table.

Table 3: Weight variation limits.

Sr. No.	Average weight of tablet (mg)	Maximum % difference allowed
1	130 or less	10
2	130-324	7.5
3	324<	5

2. Tablet hardness

The resistance of tablets to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of each batch of tablet was checked by using Monsanto hardness tester. The hardness was measured in terms of kg/cm.[2] 3 tablets were chosen randomly and tested for hardness. The average hardness of 3 determinations was recorded.

3. Friability

Friability generally refers to loss in weight of tablets in the containers due to removal of fines from the tablet surface. Friability generally reflects poor cohesion of tablet ingredients.

Method

20 tablets were weighed and the initial weight of these tablets was recorded and placed in Roche friabilator and rotated at the speed of 25 rpm for 100 revolutions. Then tablets were removed from the friabilator, dusted off the fines and again weighed and the weight was recorded. Percentage of friability of the tablets of a badge can be find by the following

Formula

$$\text{Percentage Friability} = W1 - W2/W1 \times 100$$

Where,

W1 = weight of tablets before testing

W2 = weight of tablets after testing.

4. TABLET THICKNESS

Thickness of the tablet is important for uniformity of tablet size. Thickness was measured using Vernier Calipers. It was determined by checking the thickness of ten tablets of each formulation.

5. Content Uniformity

The tablets were tested for their drug content uniformity. At random 20 tablets were weighed and powdered. The powder equivalent to 25 mg was weighed accurately and dissolved in 100ml of buffer used. The solution was shaken thoroughly. The un dissolved matter was removed by filtration through Whattman's filter paper No.41. The absorbance of the diluted solutions was measured at 315 nm. The concentration of the drug was computed from the standard curve of the Febuxostat in 6.8 phosphate buffer.

6. Disintegration time

Tablet disintegration is an important step in drug absorption. The test for disintegration was carried out in Electrolab USP disintegration test apparatus. It consists of 6 glass tubes which are 3 inches long, open at the top, and held against a 10 mesh screen, at the bottom end of the basket rack assembly. To test the disintegration time of tablets, one tablet was placed in each tube and the basket rack was positioned in a 1 litre beaker containing distilled water at 37°C ± 1°C such that the tablet remains 2.5 cm below the surface of the liquid. The time taken for the complete disintegration of the tablets was noted.

7. Invitro Dissolution time

In-vitro dissolution study of core and coated tablets of Febuxostat was carried out using Lab India DS8000 USP dissolution test apparatus. The details are given as below:

RESULTS

PREFORMULATION STUDIES

Solubility: It was determined as per standard procedure. The results are given Table 4.

Table 4: Solubility studies of Febuxostat in various solvents.

Solvent	Solubility (µg/mL)
Ethanol	1.264
Methanol	1.764
0.1 N HCL	0.557
6.8pH buffer	0.874
7.4pH buffer	0.917

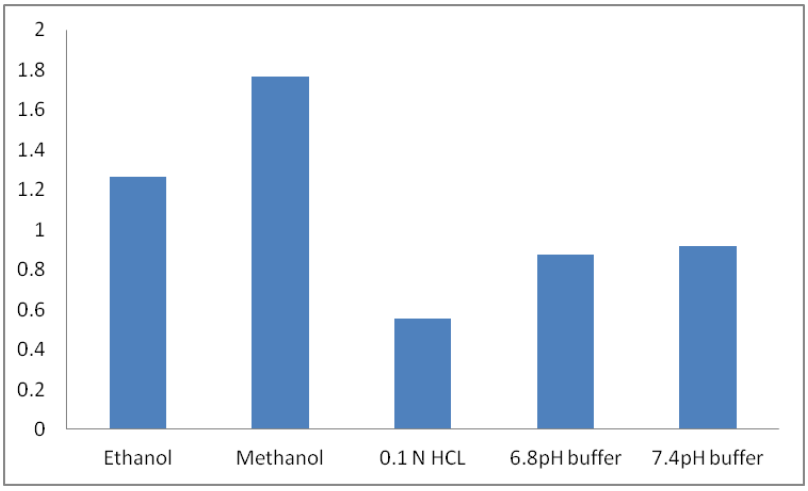

Fig. 1: Solubility studies of Febuxostat in various solvents.

From the spectra of Febuxostat, combination of Febuxostat with polymers, it was observed that all characteristic peaks of Febuxostat were not altered and present without alteration in the combination spectrum, thus indicating compatibility of the drug and polymers. FTIR spectra of Febuxostat, and Optimized formulation are shown in Figure 7.2 and 7.3 respectively.

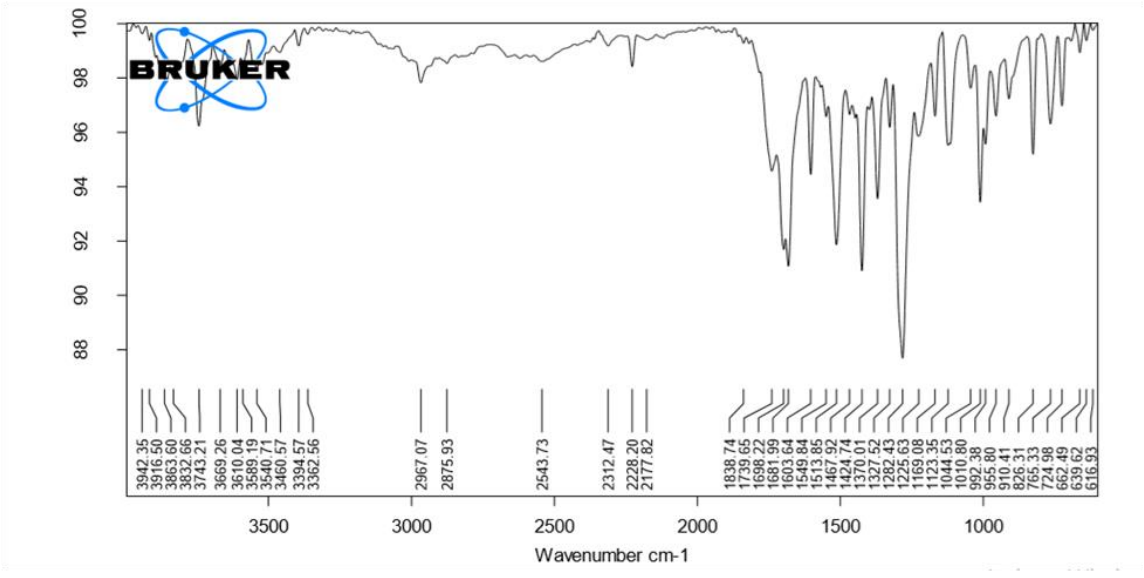

Figure 2: FTIR spectrum of Febuxostat.

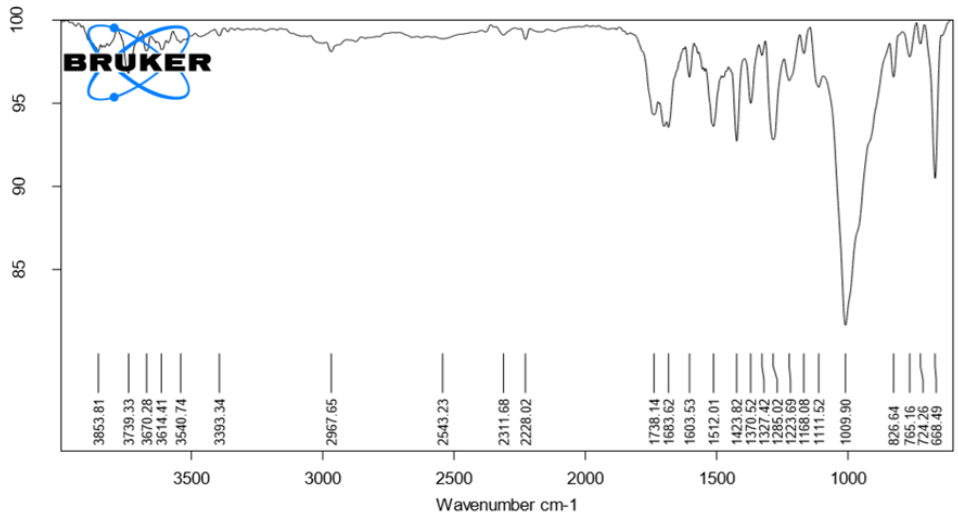

Figure 3: FTIR Spectrum of optimised formulation.

DISCUSSION

- Chemical interaction between drug and the polymeric material was studied by using FTIR. There was no difference between the IR patterns of Febuxostat, physical mixture of Febuxostat and Febuxostat optimized formulation.

λ_{max} Determination of Febuxostat

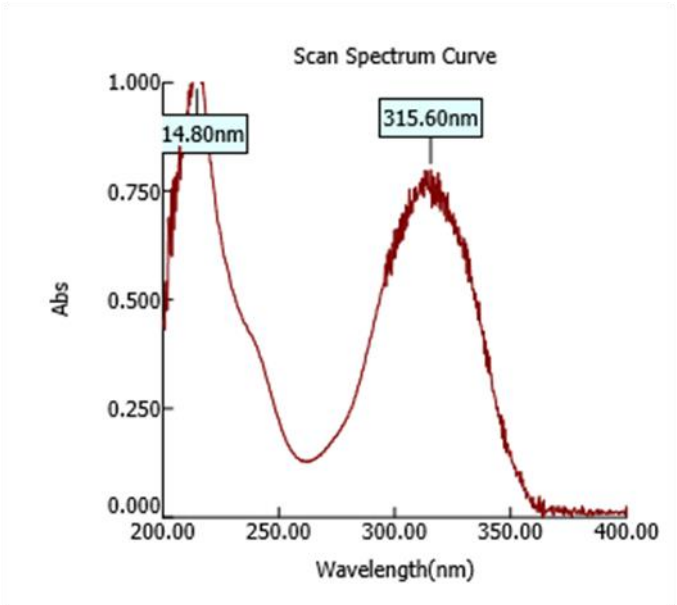

Fig. 4: λ_{max} Determination of Febuxostat.

Standard Calibration Curve

The standard calibration curve of Febuxostat was developed in pH 6.8 phosphate buffer. Two buffers were selected in order to mimic the in-vivo conditions of the GIT.

a. Standard Calibration Curve in 6.8 pH

Standard graph of Febuxostat showed linearity at the concentration range of 2-12µg with correlation coefficient of 0.999. Table 7.2 gives the data of the standard graph and Figure 7.5 shows the standard graph in pH 6.8.

Table 5: Data for calibration curve of Febuxostat in pH 6.8.

Concentration (µg/ml)	Absorbance
0	0
2	0.156
4	0.324
6	0.472
8	0.631
10	0.776
12	0.946

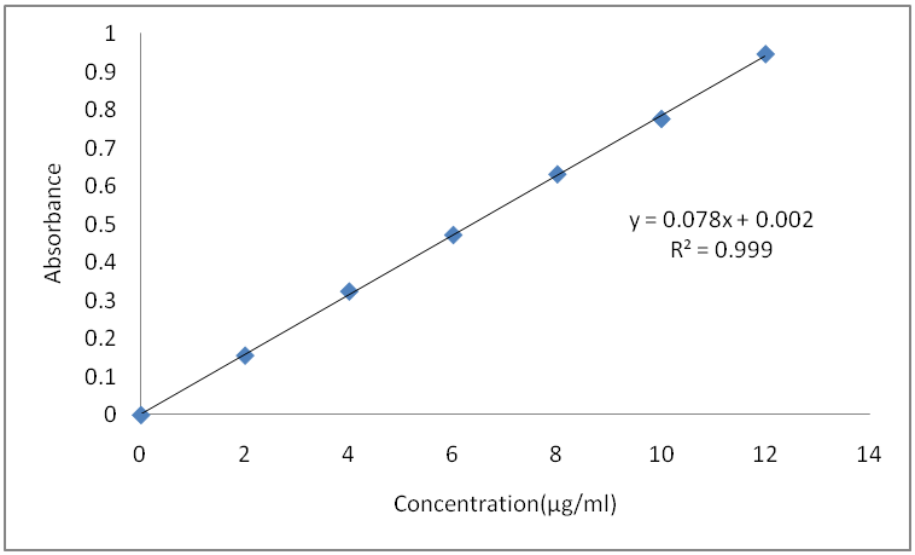

Figure 6: Standard Calibration Curve of Febuxostat in pH 6.8 at 315 nm.

Table 6: Flow properties of powder blend.

Formulation Code	Angle of Repose±SD	Bulk Density (g/ml)±SD	Tapped Density (g/ml)±SD	Carr's Index. (%)±SD	Hausner's ratio±SD
F1	28.64±0.16	0.375±0.15	0.461±0.86	15.82±0.02	1.19±0.62
F2	27.49±0.24	0.377±0.23	0.465±0.24	17.53±0.52	1.20±0.59
F3	29.84±0.85	0.395±0.64	0.457±0.15	16.42±0.98	1.22±0.18
F4	26.59±0.63	0.371±0.78	0.471±0.39	18.53±0.36	1.18±0.63
F5	27.12±0.21	0.387±0.26	0.475±0.50	15.75±0.42	1.23±0.42
F6	29.46±0.14	0.389±0.94	0.469±0.16	17.88±0.15	1.21±0.15

CONCLUSION

The postcompression parameters like the hardness, thickness, friability and weight variation, disintegration time, disintegration time in oral cavity and Invitro release were carried out and the values were found to be within IP limits. The percentage drug content of all the tablets was found to be between 72.66 – 98.79 % of Febuxostat, which was within the acceptable limits.Among all the formulations F6 shows 98.34% drug release at the end of 45min. F6 contains CCS (12mg), it shows better % drug release when compared to other formulations. So F6 was considered as the optimized formulation. The drug release kinetics shows that the optimized formulation F6 follows First order drug release.

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