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RESEARCH ARTICLE
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PREPARATION AND EVALUATION OF SOLID DISPERSION OF FEBUXOSTAT FOR SOLUBILITY ENHANCEMENT

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ABSTRACT:
This study focused on the pre-formulation and evaluation of solid dispersions of Febuxostat (FEB) to enhance its solubility and dissolution rate. Physical properties of FEB were assessed, showing it to be a white, odourless, tasteless compound. The melting point (211.39°C) and λmax (315 nm) confirmed the purity of the drug, aligning with reported standards. FEB's crystalline structure was confirmed by DSC and SEM, showing long rod-shaped crystals. Both PVPK-25 and l-Arginine were characterized, demonstrating compatibility with FEB through FTIR, DSC, and SEM analyses. Solid dispersions were prepared using solvent evaporation and freeze-drying methods, with results showing that formulations (SE5 and FD5) exhibited increased solubility and dissolution rates compared to pure FEB. XRPD and DSC indicated reduced crystallinity, transitioning FEB into a more amorphous form, further enhancing solubility. SEM analysis of SE5 and FD5 showed rough, irregular morphologies, improving drug wettability. In vitro dissolution studies revealed that FD5 had the highest drug release (86.44%) within 100 minutes, outperforming pure FEB. Stability tests confirmed the formulations' stability over one month at 40°C/75% RH. These findings demonstrate that solid dispersion techniques effectively enhance FEB's solubility, dissolution, and bioavailability.

KEYWORDS: Febuxostat (FEB), Solid dispersions, Solubility enhancement, PVPK-25, l-Arginine, XRPD, Solvent evaporation method.

INTRODUCTION:

Oral drug delivery is the most preferable route of drug administration due to ease of administration, patient compliance, flexibility in formulation, etc. However in case of the oral route there are several challenges such as limited drug absorption resulting in poor bioavailability and poor pharmacological response resulting into inadequate and erratic oral absorption[1]. Oral bioavailability of a drug depends on its solubility and/or dissolution rate, therefore efforts to increase dissolution of drugs with limited water solubility is often needed. Improvement in the dissolution rate of the poorly soluble drugs after oral administration is one of the most crucial challenges in modern pharmaceutics. Many methods are available to improve these characteristics including salt formation, micronization and addition of solvent or surface-active agents[2].

Low aqueous solubility is major problem encountered with formulation development of new chemical entities as well as for the generic development. More than 40% of new chemical entities developed in pharmaceutical industry are lipophilic and fails to reach the market due to their poor water solubility[1]. Improving oral bioavailability of drugs those given as solid dosage forms remains a challenge for the formulation scientists due to solubility problems. Enhancement of solubility, dissolution rate and bioavailability of hydrophobic drugs is one of the major challenges in drug development. Solid dispersion is one of the useful methods for the dispersion of the drug into an inert, hydrophilic polymer matrix. Solid dispersions in water-soluble carriers have attracted considerable interest as a means of improving the dissolution rate, and hence possibly bioavailability of a range of hydrophobic drugs.

Solid dispersions display an enhanced solubility of drug because of the conversion of the drug's crystal lattice into an amorphous form, particle size reduction and increased wettability by the hydrophilic polymer.[3]

Among various approaches, preparing solid dispersions has successfully improved dissolution rates for water insoluble drugs. Solid dispersions were typically prepared by either of two main techniques 1) solvent evaporation and 2) freeze drying method. Considerable difficulties lie in manufacturing this solid dispersion and with physical instability on storage.[4]

Solubility is the property of a solid, liquid, or gaseous chemical substances called solute to dissolve in a solid, liquid, or gaseous solvent to form a homogeneous solution of the maximum quantity of solute in a certain quantity of solvent at specified temperature and pressure[1].

Solubility is a significant physicochemical factor affecting absorption of drug and its therapeutic effectiveness. Formulation development would lead to be failure if drug having poor aqueous solubility. The low dissolution rate and low solubility of drug substances in water in aqueous G.I.T fluid frequently leads to inadequate bioavailability. The venture to improve the solubility and dissolution of hydrophobic drugs remain one of the trickiest tasks in drug development.[5]

Febuxostat is a poorly water-soluble drug used to treat hyperuricemia in gout patients, limiting its bioavailability. Enhancing its solubility is crucial for improving therapeutic outcomes. According to the Biopharmaceutics Classification System (BCS), solubility and permeability play key roles in drug absorption. For BCS Class II and IV drugs, solubility is the rate-limiting factor in drug absorption, necessitating techniques to improve it. Solid dispersion, which involves dispersing the drug in a hydrophilic matrix, is an effective method for enhancing the dissolution rate and bioavailability of poorly soluble drugs. Factors affecting solubility, such as particle size, temperature, polymorphism, and dissolution, must be considered in designing effective formulations. Various methods for solubility enhancement include chemical modifications (e.g., salt formation, co-solvency) and physical techniques (e.g., particle size reduction, solid dispersions). These approaches provide multiple pathways to enhance the solubility and absorption of Febuxostat, making solid dispersion a promising strategy for formulation development.[6]

MATERIAL AND METHODS:

MATERIALS:

The materials used in this study were carefully selected to ensure the accuracy and reliability of the experimental results. Febuxostat, the active pharmaceutical ingredient, was obtained from Ajanta

Pharma Pvt. Ltd., Aurangabad, India, and served as the primary drug for solubility enhancement studies. Various grades of polyvinylpyrrolidone (PVP) – specifically PVPK-25, PVPK-30, and PVPK-90 – were procured from Loba Chemie Pvt. Ltd., Mumbai, India, and were used as polymeric carriers in the formulation of solid dispersions, owing to their known solubility-enhancing properties. L-Arginine, also from Loba Chemie Pvt. Ltd., was employed as a solubility enhancer due to its ability to improve the dissolution rate of poorly water-soluble drugs.

Additionally, Potassium Dihydrogen Phosphate and Disodium Hydrogen Phosphate were sourced from the same supplier and used to prepare buffer solutions for solubility studies, maintaining a controlled pH environment during the dissolution testing. Ethanol and dimethylformamide (DMF), essential for the solvent evaporation process, along with Methanol, were also procured from Loba Chemie Pvt. Ltd. Distilled water, required for various stages of the formulation and evaluation process, was freshly prepared in the laboratory at GCOPK to ensure purity and consistency throughout the experiments. Each chemical and solvent used in the study played a critical role in the formulation development, enabling the investigation of Febuxostat's solubility and dissolution behavior in different conditions.[7,8]

METHODS:

Pre-formulation Study:

The preformulation study focused on evaluating key aspects necessary for formulating solid dispersions of Febuxostat. This included assessing the drug's physical properties, such as solubility and melting point, as well as authenticating the drug and excipients like PVP K25 and L-Arginine to ensure their quality and suitability. A drug-polymer compatibility study was conducted to confirm no adverse interactions between Febuxostat and the polymers. Finally, a phase solubility study was performed to optimize the formulation, determining the ideal excipient concentrations for enhancing the solubility of Febuxostat.[9]

Physical properties of drug:

The drug's physical properties, including solubility and melting point, were assessed.[10]

Authentication of Febuxostat:

1. Melting point determination of drug:

The melting point of Febuxostat was determined using the open capillary tube method. The drug was placed in a capillary tube, submerged in liquid paraffin, and heated. The observed melting point was noted and compared with the standard value.[11]

2. λmax determination of drug:

The purity of Febuxostat was verified by measuring its maximum absorption wavelength (λmax) using a UV-Vis spectrophotometer. A 10 µg/mL solution of the drug was prepared, scanned between 200-400 nm, and the λmax was recorded.[12]

3. Preparation of calibration curve:

Calibration curves were developed in various solvents, including distilled water, methanol-water, DMF, ethanol, and phosphate buffer. Dilutions were prepared from a stock solution of Febuxostat, and their absorbance at λmax was measured to establish the curves.[13]

4. Fourier Transform Infrared Spectroscopy (FTIR) of drug:

FTIR was employed to identify the functional groups and check the purity of Febuxostat. Spectra of the drug and its solid dispersions were recorded, analyzed, and compared to confirm the drug's structure.[14]

5. Differential Scanning Calorimetry (DSC) of drug:
DSC was used to determine the melting point and purity of Febuxostat. The drug and its solid dispersions were analyzed for phase transitions by heating samples under controlled conditions to observe energy changes.[15]

6. X-ray Powder Diffraction (XRPD) of drug:
X-ray diffraction was performed to confirm the crystalline nature of Febuxostat and its solid dispersions. The diffraction patterns were recorded and analyzed to assess the drug's structural properties.[16]

7. Scanning Electron Microscopy (SEM) of drug:
SEM was utilized to study the surface morphology of Febuxostat and its solid dispersions. Samples were coated with gold and examined under various magnifications to capture detailed images of their surface structure.[17]

Authentication of polymer:
The authentication of the polymer was conducted through several analyses. First, the melting point of PVPK-25 was determined to confirm its identity and purity. Next, Fourier Transform Infrared Spectroscopy (FTIR) was performed using a Bruker FTIR spectrometer (IR Affinity 1 model, Japan), providing a spectrum that revealed the functional groups present in the polymer. Lastly, Differential Scanning Calorimetry (DSC) measurements were conducted using a Mettler DSC 823E (Mettler Toledo, Switzerland) to analyze the thermal properties of the polymer, including its melting behavior. These combined results contributed to the comprehensive authentication of the polymer.[18-20]

Authentication of l-Arginine:
The authentication of l-Arginine utilized multiple characterization techniques. The melting point was determined to verify its purity and identity. Fourier Transform Infrared (FTIR) spectroscopy was conducted with a Bruker FTIR spectrometer to analyze its functional groups. Additionally, Differential Scanning Calorimetry (DSC) measurements were performed using a Mettler DSC 823E to assess its thermal properties. Together, these methods confirmed the authenticity of l-Arginine.[21]

Drug Excipients Compatibility Study:
The compatibility study of drug and excipients is an important pre requisite for preparation of formulation. The identification of drug and drug Excipients compatibility study was also done by using Bruker FTIR spectroscopy.[22-24]

Phase solubility study for optimization of batches ratio (phase solubility):
Depending on phase solubility study of drug in the presence or absence of PVPK-25or l-Arginine or both was conducted for the selection of trial batches which was used to determine final optimized botches.[25-27]

Preparation of solid dispersions of Febuxostat:
Solid dispersion of Febuxostat was prepared by two methods namely solvent evaporation and freeze drying technique.[28]

a) Solvent evaporation (SE):
In this method quantity of polymer PVP K-25 and Arginine was dissolved in water and volume was made up to 15 ml as per formulation table 1. Amount of Febuxostat was dissolved in ethanol and volume was adjusted to 25 ml. Both solutions were mixed together then the solvents were evaporated at 80°C under reduced pressure in a rotary evaporator and they were further dried in desiccators over silica gel for 24 hrs to remove all the residual solvents. The dried mass was collected and passed through 60 # and packed in close container.[29-35]

Table 1: Preparation of solid dispersions batches by SE Method

Sr. No.	Drug (mg)	PVP K-25 (mg)	l-Arginine (mg)	Batch code
1	300	60	150	SE1
2	300	180	150	SE2
3	300	300	150	SE3
4	300	60	225	SE4
5	300	180	225	SE5
6	300	300	225	SE6
7	300	60	300	SE7
8	300	180	300	SE8
9	300	300	300	SE9

b) By freeze drying (FD):

Freeze dried powder of FEB was prepared by using delvac mini lyodel freeze dryer**.** Freeze dried powder of FEB was prepared by dissolving drug and hydrophilic polymer (Pvpk-25 and l-Arginine) in respective proportion as flows in table 2**.**

Solid dispersions of Febuxostat were prepared using the freeze-drying method. First, the drug was dissolved in ethanol to form the organic phase, while the polymers were dissolved in distilled water to create the aqueous phase. Both solutions were sonicated for 15 minutes separately. The organic phase was then added to the aqueous phase with continuous stirring. The resulting mixture was frozen in a deep freezer for 24 hours, followed by freeze drying for 48 hours to obtain the solid powder. Each batch was prepared by varying the concentrations of PVP K-25 and Arginine.[36-45]

Table 2: Preparation of solid dispersions batches by FD Method

Sr. No.	Drug (mg)	PVP K-25 (mg)	l-Arginine (mg)	Batch code
1	300	60	225	FD4
2	300	120	225	FD5
3	300	300	225	FD6

Evaluation of Prepared solid dispersion of Febuxostat:

Determination of Percentage practical yield:

The percentage practical yield of the solid dispersion was calculated by comparing the final weight of the solid dispersion after drying with the initial weight of the drug and polymer used. The formula used for this calculation is: [46-48]

% practical yield = (practical weight × 100) / theoretical weight.

Percentage Drug Content:

For percentage drug content determination, a solid dispersion sample equivalent to 10 mg of Febuxostat was dissolved in ethanol/DMF and diluted to 100 µg/mL. The absorbance of the solution was measured at 315 nm using a UV spectrophotometer to calculate the drug content.

Saturation Solubility:

Saturation solubility of pure Febuxostat and its solid dispersions was measured by adding excess solid dispersion (~50 mg) to dissolution media, shaking for 24 hours, filtering, and measuring absorbance at 315 nm.[49-50]

FTIR, DSC, XRD and SEM study of drug, excipients and optimized batches of SD:

FTIR studies were conducted on the drug, excipients, and optimized solid dispersion batches to evaluate chemical interactions. DSC analysis was performed on the drug, excipients, and optimized

solid dispersion batches to study thermal properties and phase transitions. XRD studies were done to analyze the crystalline nature of the drug, excipients, and optimized solid dispersions. SEM analysis was used to observe the surface morphology of the drug and optimized solid dispersion batches.[51-52]

In-vitro dissolution studies

In-vitro dissolution studies were carried out using a USP Type II apparatus in phosphate buffer pH 6.8 at 37 ± 0.5°C, with samples taken at various time intervals to measure Febuxostat dissolution.[53]

Stability study:

The formulation prepared by two method i.e.by using solvent evaporation (SE) and freeze drying (FD) method. The batches SE1 to SE9 and FD5 were subjected for Stability study. The study was done by incubated at 40°C/75% RH for one month, and observed for change in physical properties (color) of formulation and comprised with drug.[54]

RESULT AND DISCUSSION:

Pre-formulation Study:

a) Physical properties:

The physical properties of Febuxostat (FEB) were assessed through organoleptic evaluation. The results indicated that Febuxostat is white in color, odorless, and has no detectable taste.

b) Characterization of Febuxostat:

Melting Point of Febuxostat:

Melting Point of pure Febuxostat was found to be 211.39ºC. (Reported melting point is 205-210°C.) And it matched with standard given in USP. Hence drug was pure and confirmed by DSC. (Figure 1)

λ max determination of Febuxostat:

λ max of Febuxostat in distilled water (D/W) was found to be 315 nm. (Reported λmax is 315 in D/W), it matches with standard given in USP, and hence drug is pure. (Figure 2)

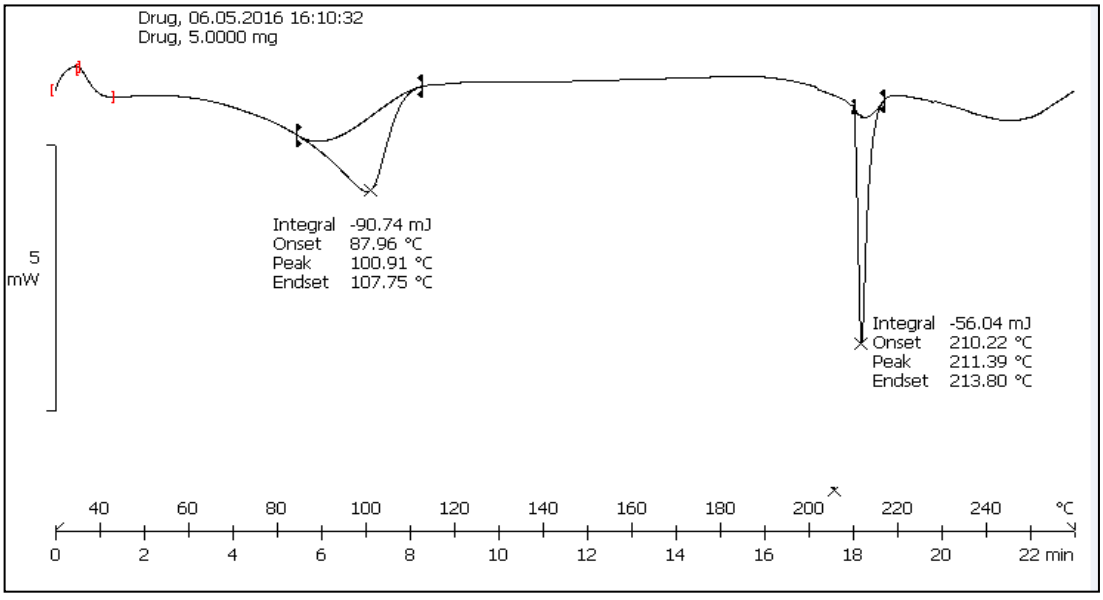

Figure 1: Melting Point of Febuxostat

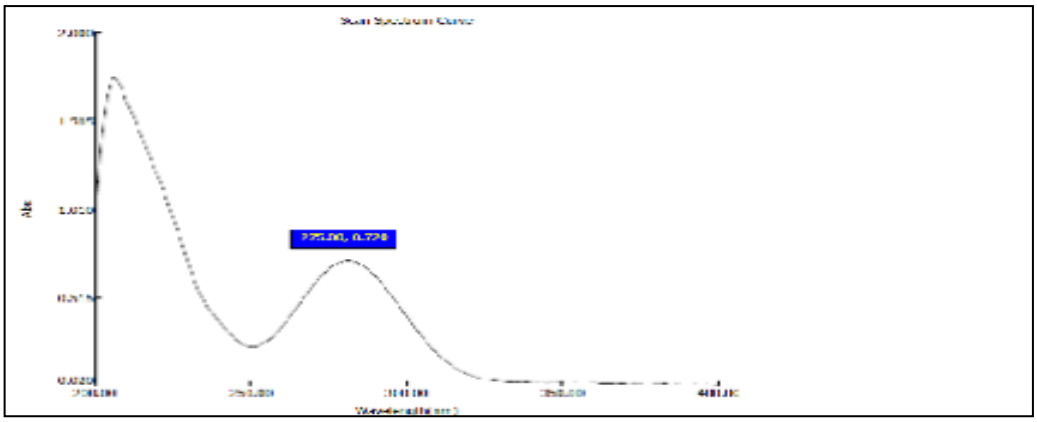

Figure 2: Spectrum of Febuxostat in distilled water

Preparation of calibration curve of Febuxostat in different solvent as follows:

In Distilled Water (D/W)

Absorbance value of Febuxostat was carried over concentration range 2-12 µg/ml in distilled water.

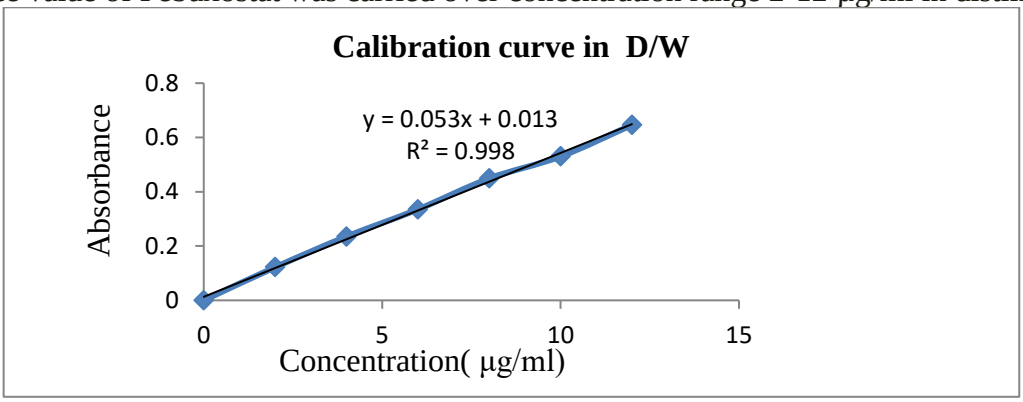

Figure 3: Calibration Curve of Febuxostat in Distilled Water

In water methanol system

Absorbance value of Febuxostat over concentration range 2-12 µg/ml in water methanol system (80:20)

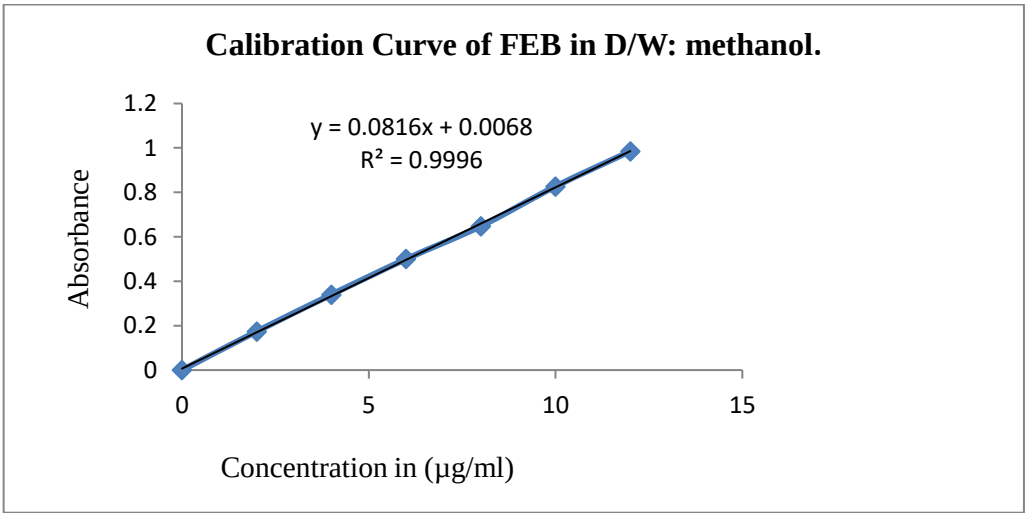

Figure 4: Calibration Curve of Febuxostat in water methanol system

In Phosphate buffer Ph 6.8

Absorbance value of Febuxostat over concentration range 2-14 µg/ml in Phosphate buffer (PB) pH 6.8.

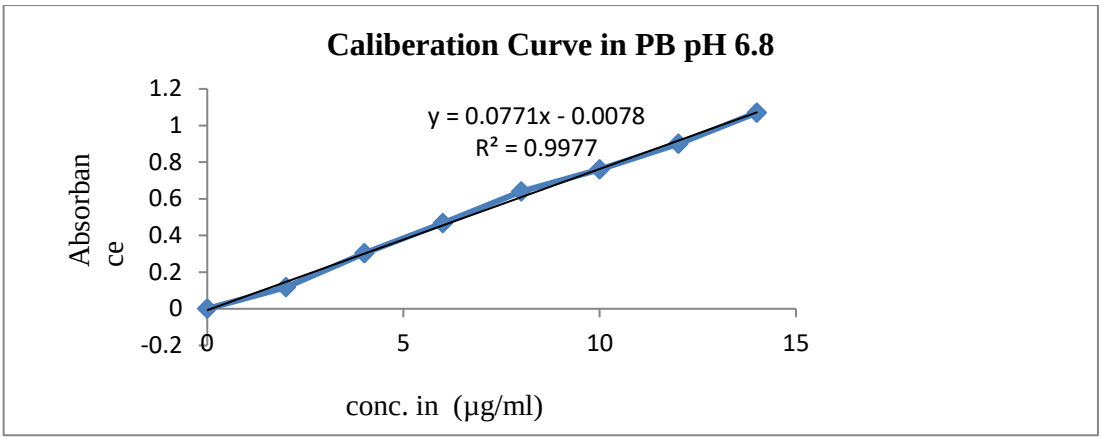

Figure 5: Calibration Curve of Febuxostat in Phosphate buffer

In Dimethylforamide (DMF):

Absorbance value of Febuxostat over concentration range 2-12 µg/ml in Dimethylforamide (DMF)

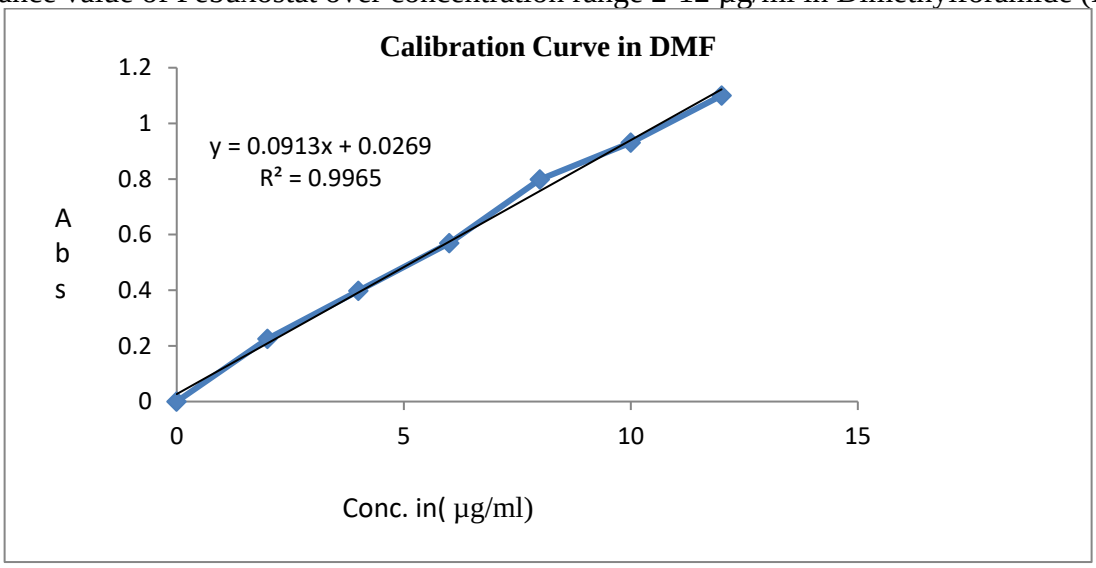

Figure 6: Calibration Curve of Febuxostat in Dimethylforamide

In ethanol:

Absorbance value of Febuxostat over concentration range 2-12 µg/ml in ethanol

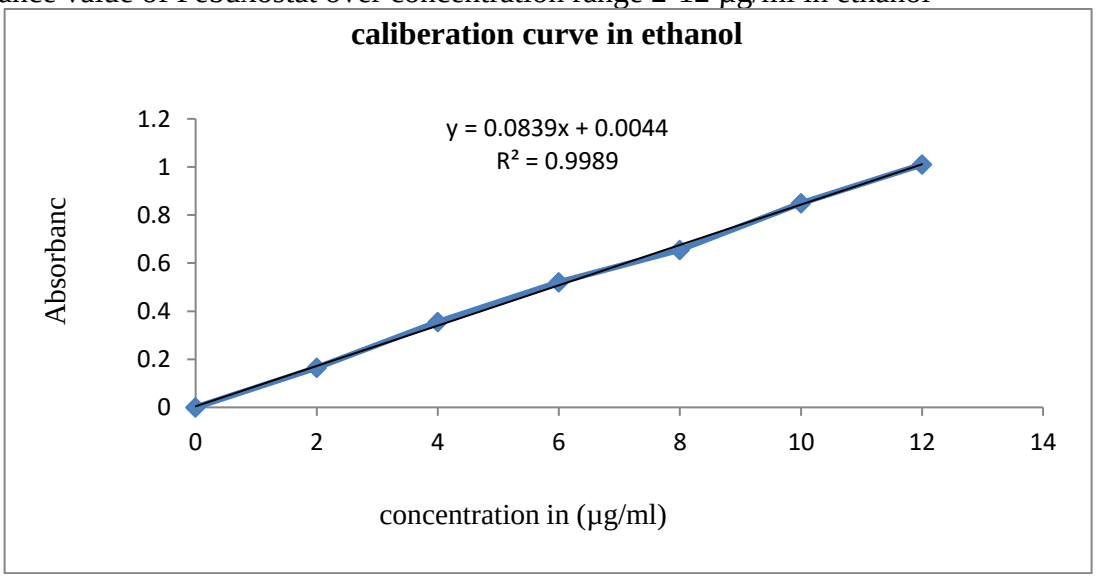

Figure 7: Calibration Curve of Febuxostat in ethanol

Fourier transforms infrared spectroscopy (FTIR) study of drug:

The data obtained from the FTIR it was found that functional group of Febuxostat (FEB) shows peaks at their respective wave number given in the following figure 8 which were consistent in all ternary systems with the polymer.

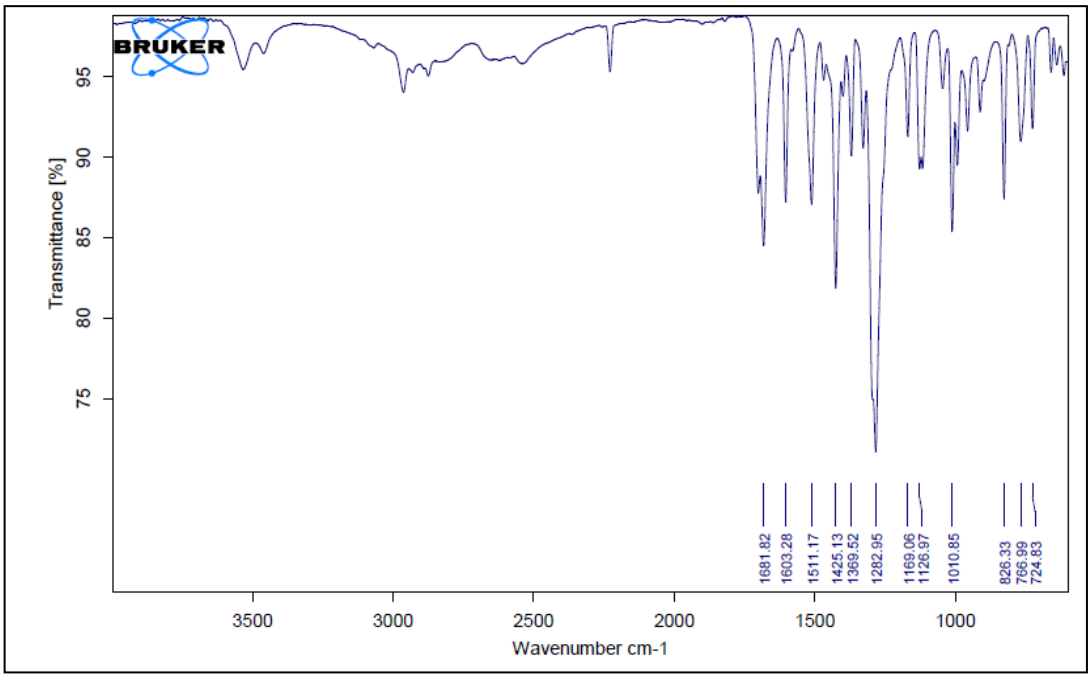

Figure 8: FTIR of Febuxostat

Differential scanning Calorimetry (DSC) of pure drug:

The 4416hermos gram of Febuxostat was studies by using DSC and it shows sharp endothermic peaks at 211.39°C. The Sharp endothermic peak was due to crystalline nature of drug (Reported melting point of Febuxostat 205-210).

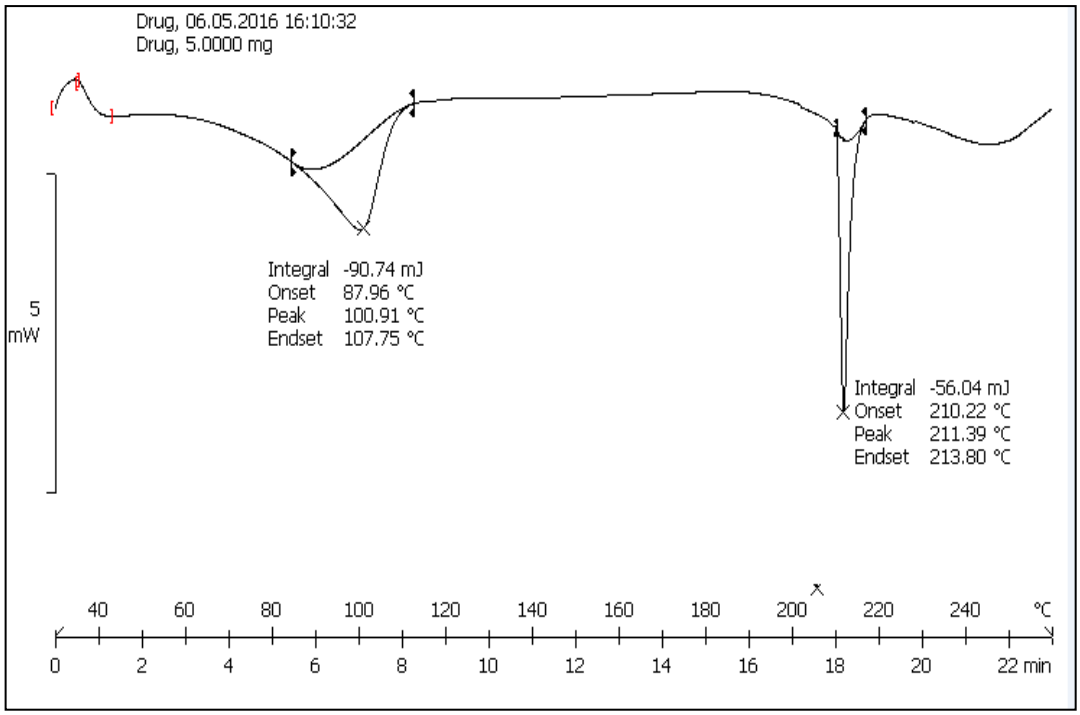

Figure 9: DSC of Febuxostat

X-ray power diffraction (XRPD) of pure drug:

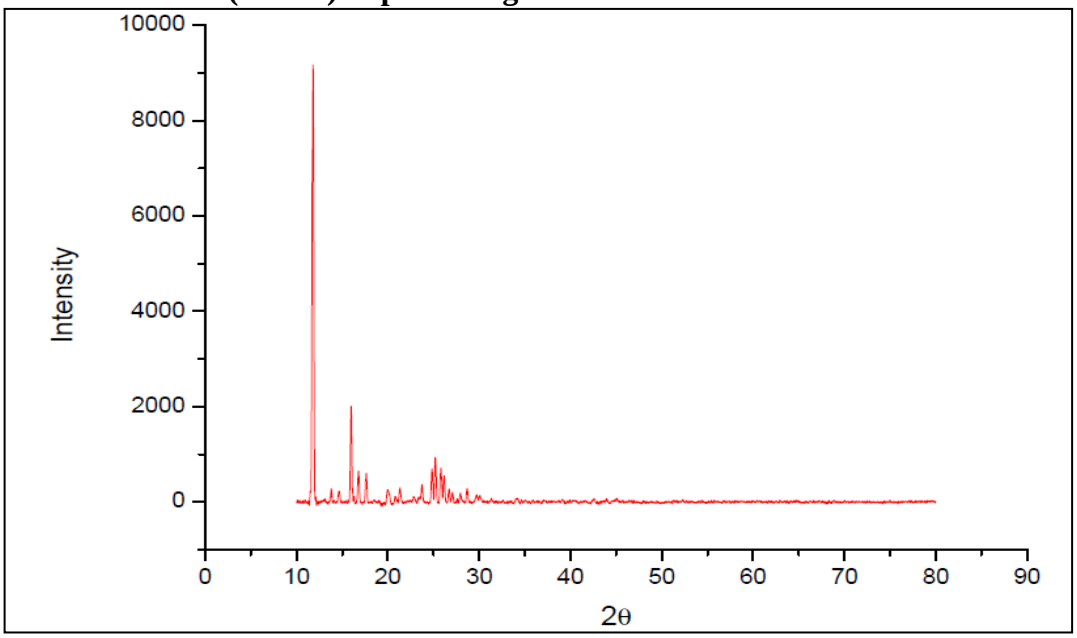

Figure 10: XRPD of Febuxostat

Scanning electron microscopy (SEM) of pure drug:

Scanning electron microscopy was used for the morphology study of drug and formulations. The Febuxostat appeared as long elongated rod shaped crystalline particles which were present in regular structural form. Hence, it might require maximum amount of heat to melt at melting point.

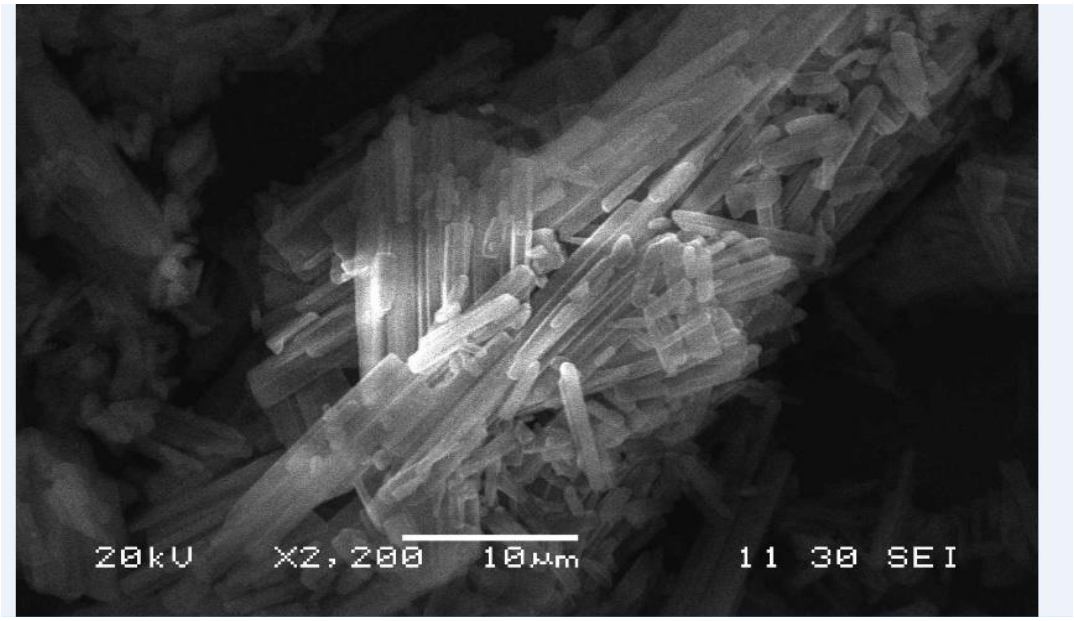

Figure 11: SEM of Febuxostat

c) Characterization of polymer:

FTIR of PVP K-25:

The data obtained from the FTIR it was found that functional group of PVPK-25 shows peaks at their respective wave number cm given in the following figure 12 and which were consistent in all ternary systems with the drug there for pvpk-25 is pure.

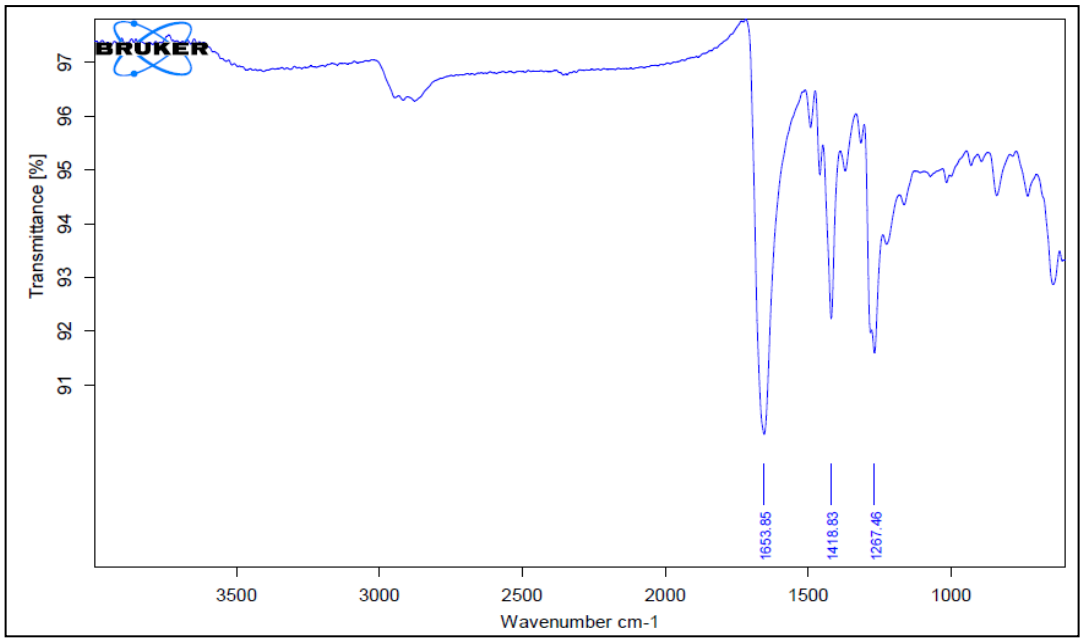

Figure 12: FTIR of polymer

DSC of polymer pvpk-25:

The DSC of PVPK-25 was shows the melting endothermic peak at 178.70°C. This endothermic peak was not a sharp peak which revealed amorphous nature of polymers.

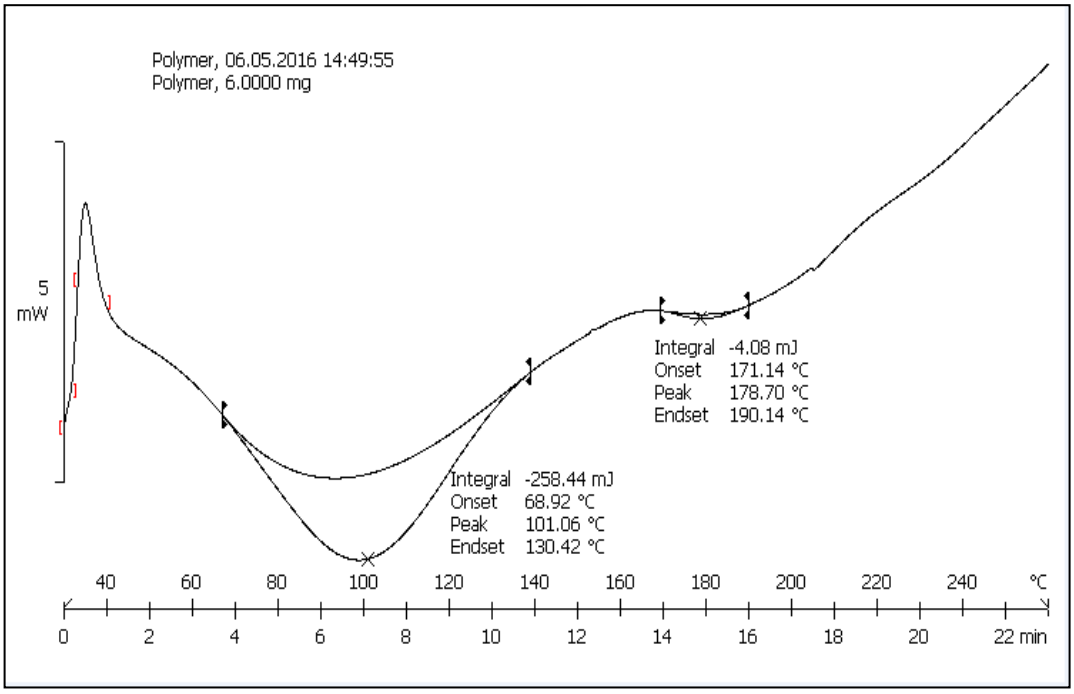

Figure 13: DSC of pvpk-25

d) Characterization of l-Arginine:

FTIR of l-Arginine: The data obtained from the FTIR it was found that functional group of l-Arginine shows peaks at their respective wave number cm given in the following figure 14 and which were consistent in all ternary systems with the drug.

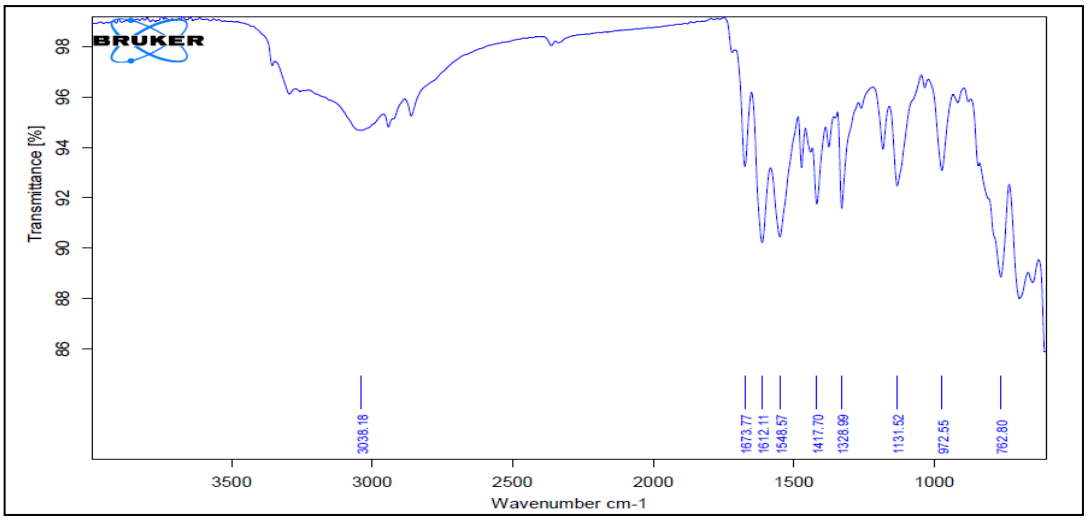

Figure 14: FTIR of l-Arginine

DSC of l-Arginine:

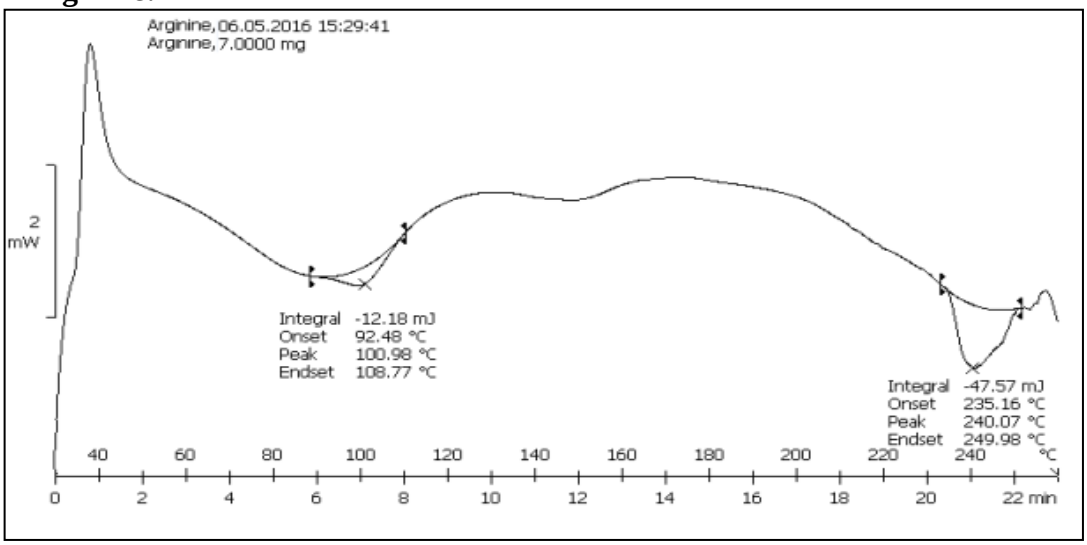

Figure 15: DSC of l-Arginine

e) Compatibility study of Drug and excipients:

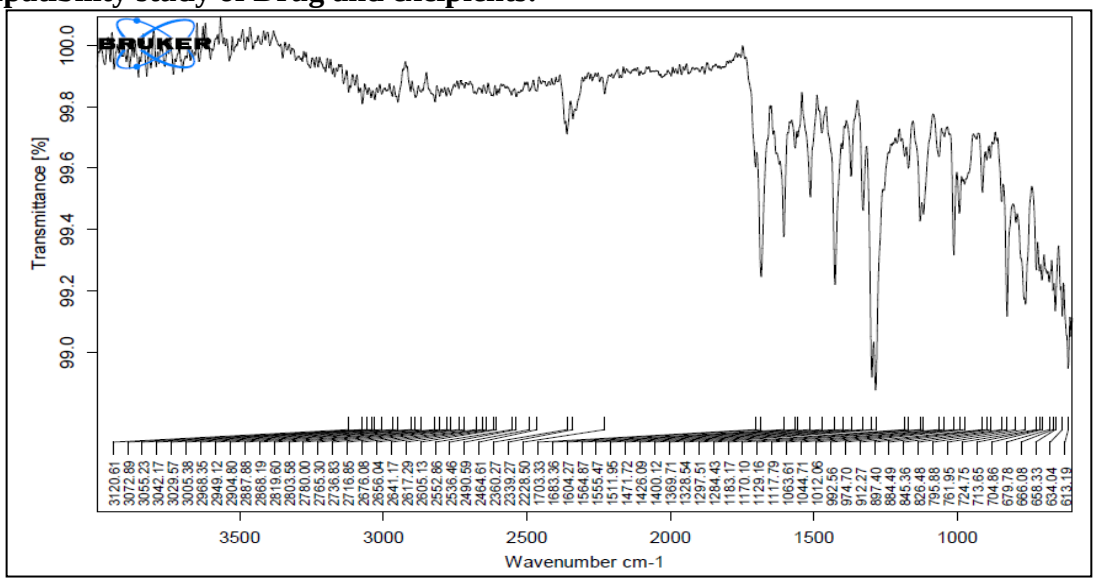

Figure 16: FTIR of drug and polymers Compatibility study

The compatibility study of drug, polymer and l-Arginine were done by preparing physical mixture of Febuxostat (FEB), PVP-25 and l-Arginine. It showed all the peaks present of drug and excipients in physical mixture. Also absence of any extra peak in spectra confirmed compatibility of drug with polymer or excipients. Thus, there was no any interaction between drug and excipients.

Evaluation of formulated batches:

Percentage practical yield:

Percentage practical yield of solid dispersions were calculated and reported in table 3. It was found that as the ratio of drug to excipients increases the practical yield decreases. The highest percentage practical yield was found for SE1 and FD5. There was no any significant difference found in percentage practical yield of solid dispersion prepared by pvp k-25 and l- Arginine by solvent evaporation and freeze drying methods.

Saturation Solubility study:

Saturation Solubility study of solid dispersion was done as per procedure and obtained results was reported in table 3. Maximum solubility was observed for SE5 and FD5. There was no any significant difference found in saturation solubility of solid dispersion prepared with pvp k-25 and l-Arginine by solvent evaporation and freeze drying methods.

Drug content:

Drug content of solid dispersions were calculated and reported in table 3. The highest drug content was found for SE5 and FD5. It was observed that as the ratio of drug to excipients goes on increasing the drug content not goes on increasing. There was no any significant difference found in drug content of solid dispersion prepared by pvp k-25 and l-Arginine by solvent evaporation and freeze drying methods. But % drug contents and saturation solubility was observed maximum for freeze dried formulation (FD5) than solvent evaporation batches.

Table 3: (%) practical yields, Drug Content and Saturation Solubility of SD

Batch code	Percentage (%) practical yield	Drug Content in %	Solubility (µg/ml)
Drug	-	-	0.00300
SE1	**98.36**	74.41	444.5800
SE2	95.23	72.00	6766.00
SE3	97.33	86.12	4402.59
SE4	88.03	88.03	4207.79
SE5	93.02	**95.00**	**6896.10**
SE6	96.96	78.00	3974.02
SE7	90.90	76.09	3363.60
SE8	96.15	70.36	2428.57
SE9	93.33	79.27	3441.50
FD5	**95.02**	**96.01**	**6996.10**

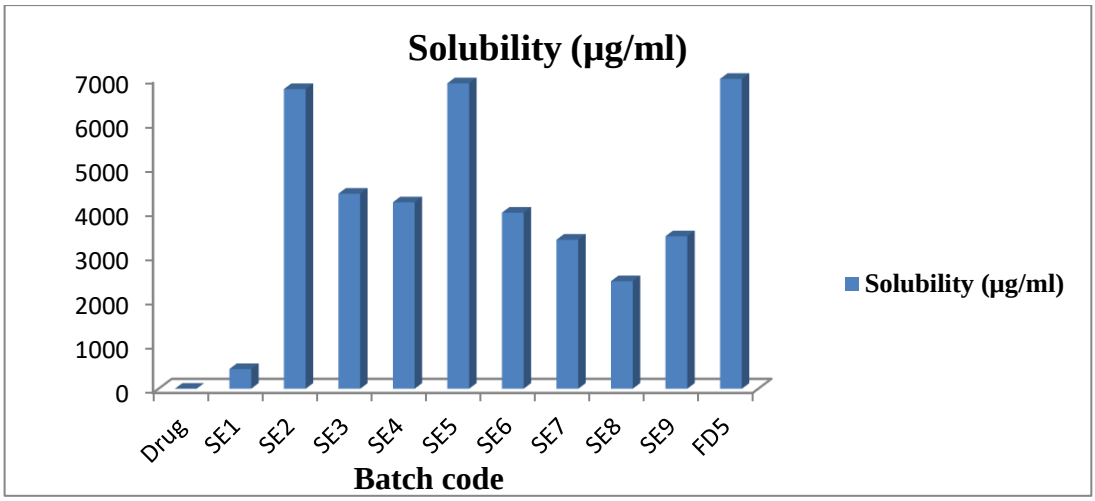

Figure 17: Saturation Solubility of Solid dispersion formulation

FTIR study of optimized batches:

FT-IR spectrum of formulation showed all the characteristic peak of Febuxostat, PVPK-25 and l-Arginine. These peaks at their respective wave number cm were given in the following figures 18-20. Hence, it might confirm that there was no chemical interaction between drugs Febuxostat, PVPK-25 and l-Arginine.

FTIR of drug:

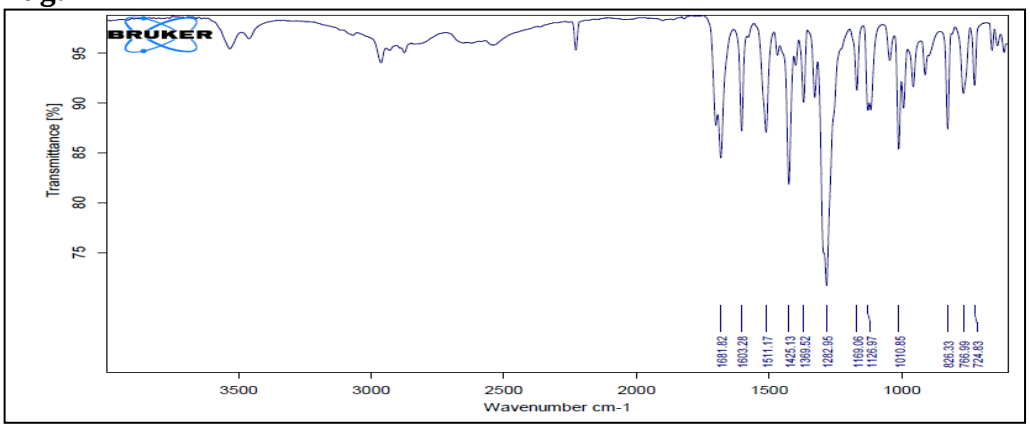

Figure 18: FTIR of drug

FTIR OF SE5:

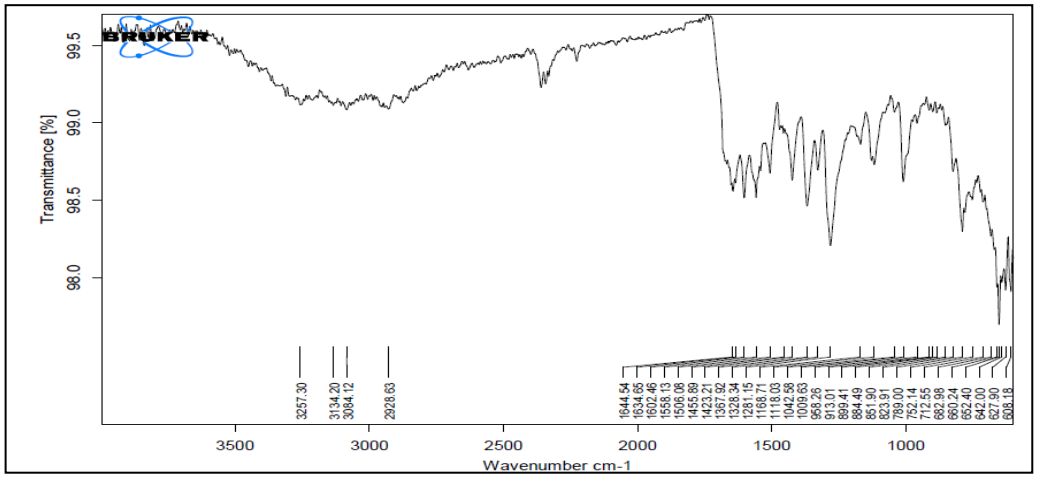

Figure 19: FTIR OF SE5

FTIR OF FD5:

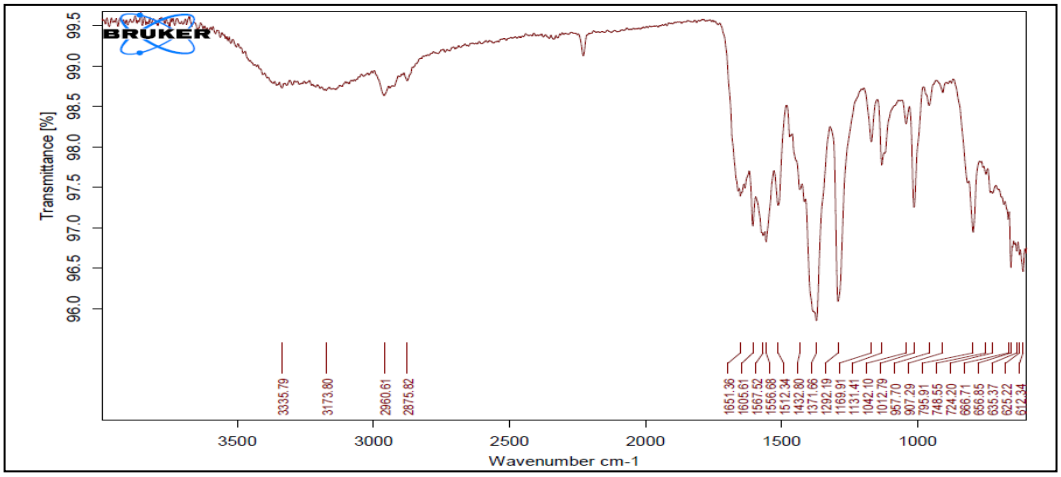

Figure 20: FTIR OF FD5

DSC study of optimized batches

The melting point of Febuxostat (FEB) was determined using DSC, revealing a sharp endothermic peak at 211.39°C, consistent with the reported melting point of 205–210°C, indicating its highly crystalline form. However, in formulations with PVPK-25 and l-Arginine, the DSC showed no peak at this range, and the area of the endothermic peak decreased, suggesting reduced crystallinity. This reduction in crystallinity likely contributed to the increased aqueous solubility of FEB in the formulations compared to the pure drug.

DSC of drug:

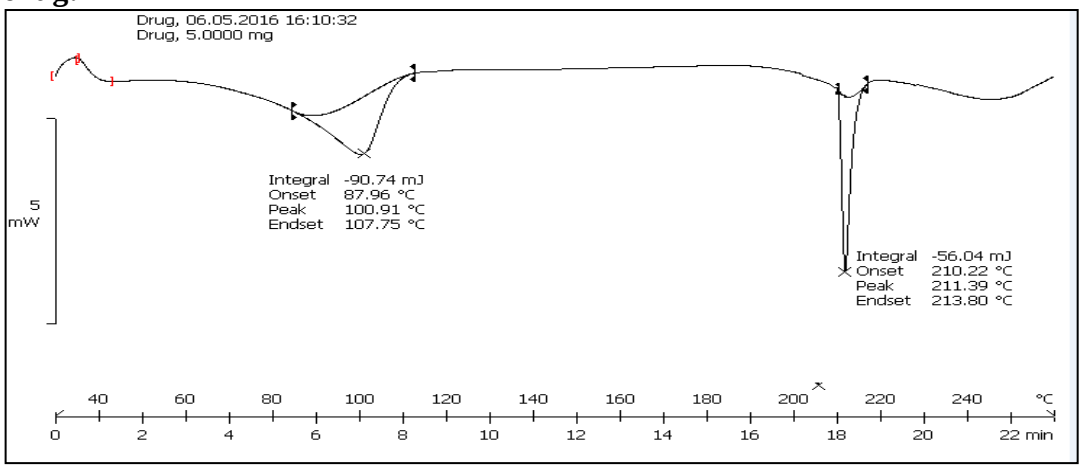

Figure 21: DSC of drug

DSC OF SE5:

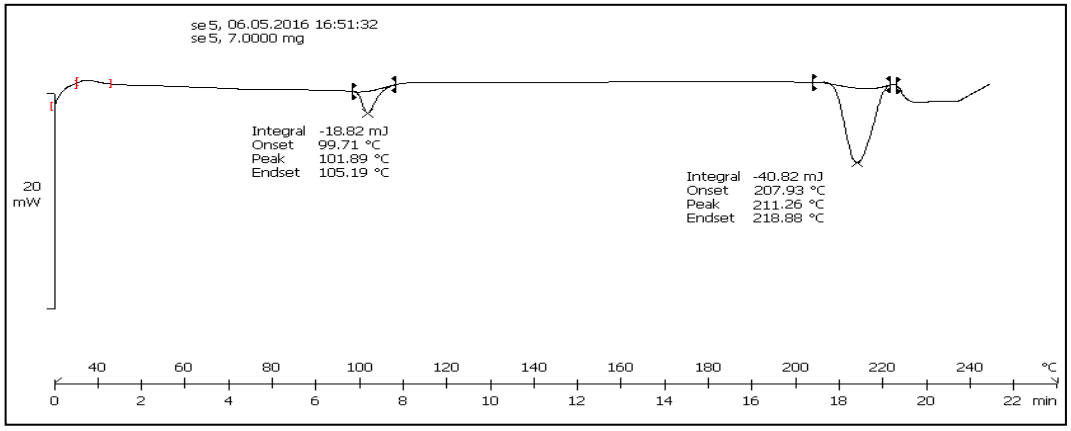

Figure 22: DSC OF SE5

DSC OF FD5:

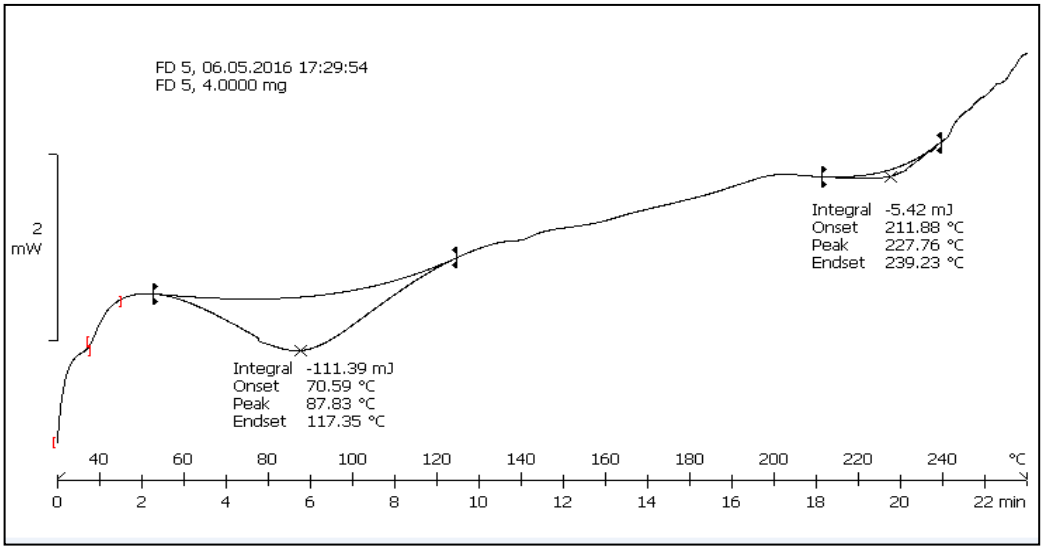

Figure 23: DSC OF FD5

XRPD study of optimized batches: Drug

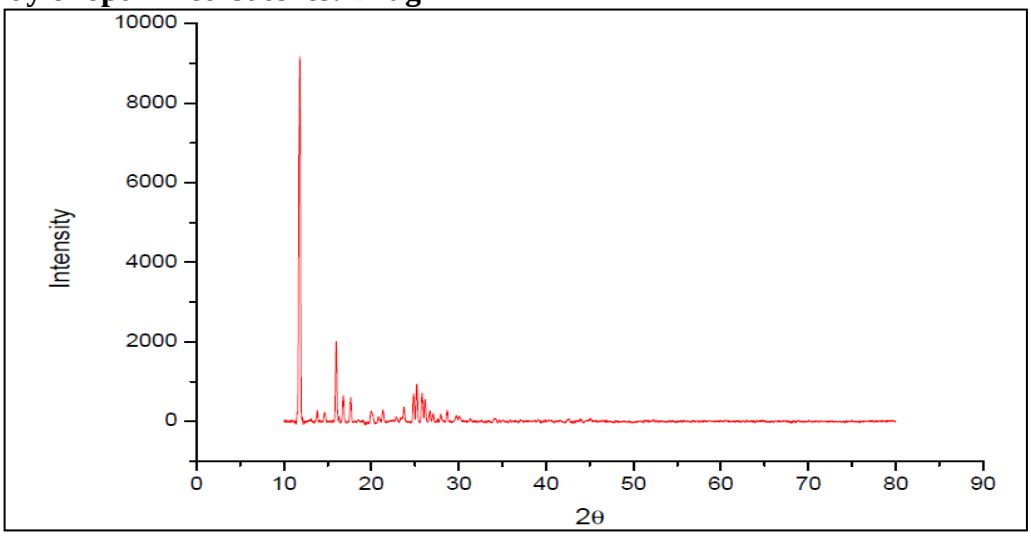

Figure 24: XRPD of drug

XRPD OF SE5:

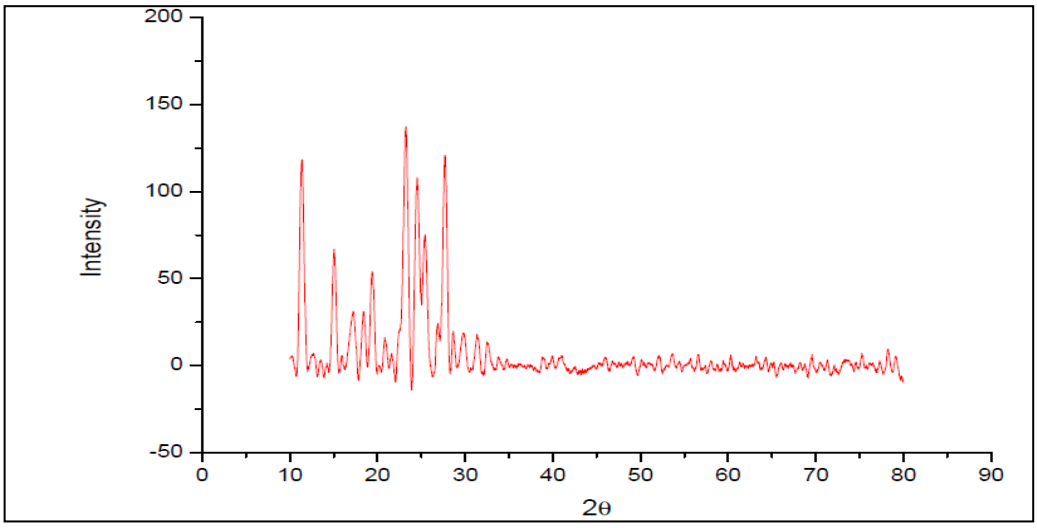

Figure 25: XRPD of SE5

XRPD OF FD5:

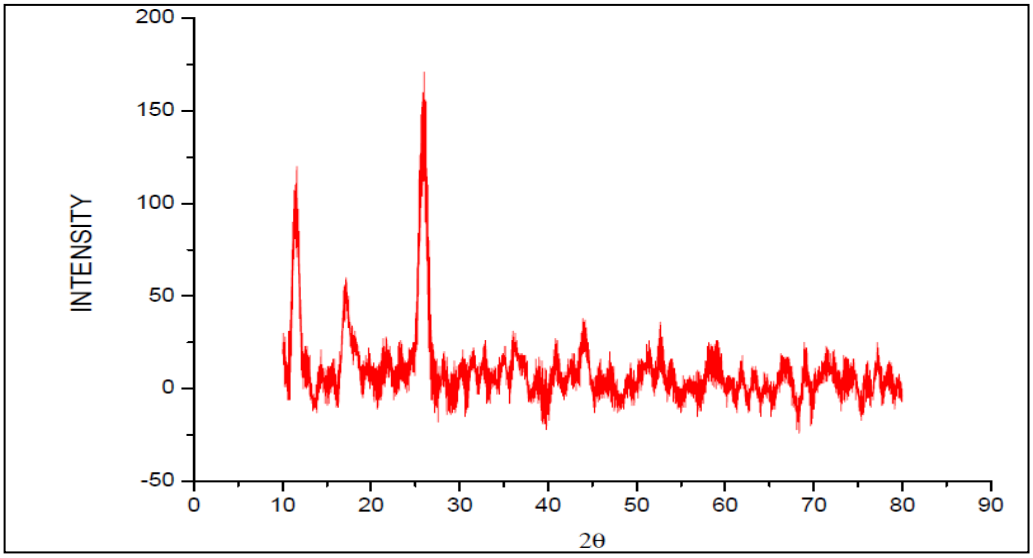

Figure 26: XRPD OF FD5

XRPD pattern of solid dispersions not shows sharp peak intensity at 2θ indicating amorphous nature. Obtained result we can conclude that the FEB present in SE5 and FD5 batches was might be in substantial amorphous form. Amorphous form has high energy & low melting point from due to free energy available for dissolution process and hence dissolution rate was faster than crystalline form. XRPD pattern of solid dispersion was found to be there was reduction in crystallinity because of two reason viz, amorphous hydrophilic polymer and technology dependent transformation. In Freeze drying technique and evaporation of solvent to form uniform particle size leads to reduction crystallinity and Relative Degree of Crystallinity .The smaller the particle size lowers the value of relative degree of crystallinity. Freeze dried and solvent evaporation formulations SE5 and FD5 shows reduced RDC value.

SEM study of optimized batches

DRUG:

Scanning electron microscopy was used for the morphology study of drug and formulations. The Febuxostat appeared as long elongated rod shaped crystalline particles which were present in regular structural form. Hence, it might require maximum amount of heat to melt at melting point.

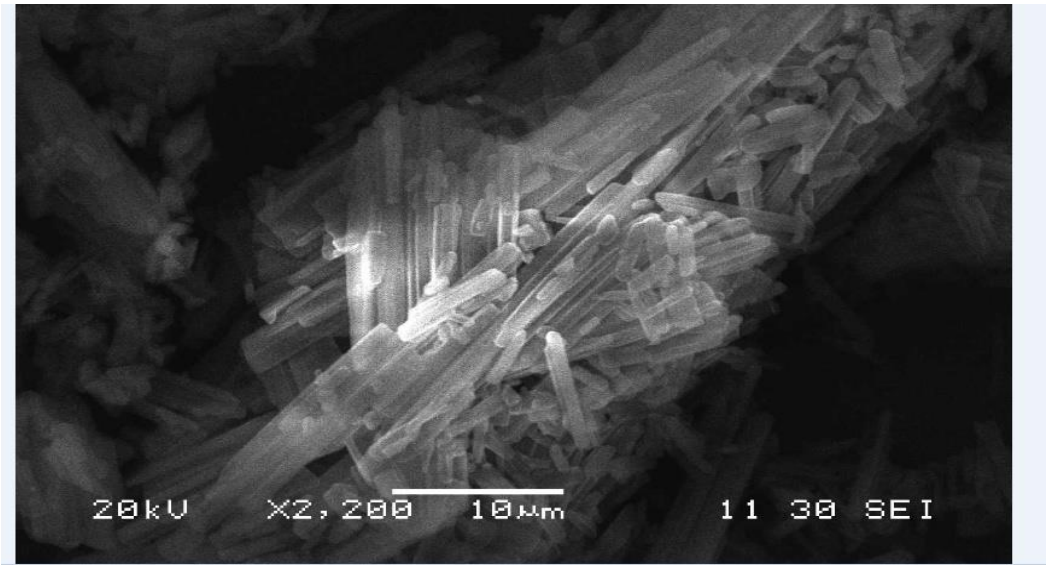

Figure 27: SEM OF DRUG

SEM OF SE5:

Morphological feature of SE5 was examined by Scanning Electron Microscopy. SE5 showed irregular and rough surface morphology. This might be due to entrapment of hydrophilic polymers in/on the drug surface. So, it might responsible to enhance the wettability and dissolution profile of the drug in formulations.

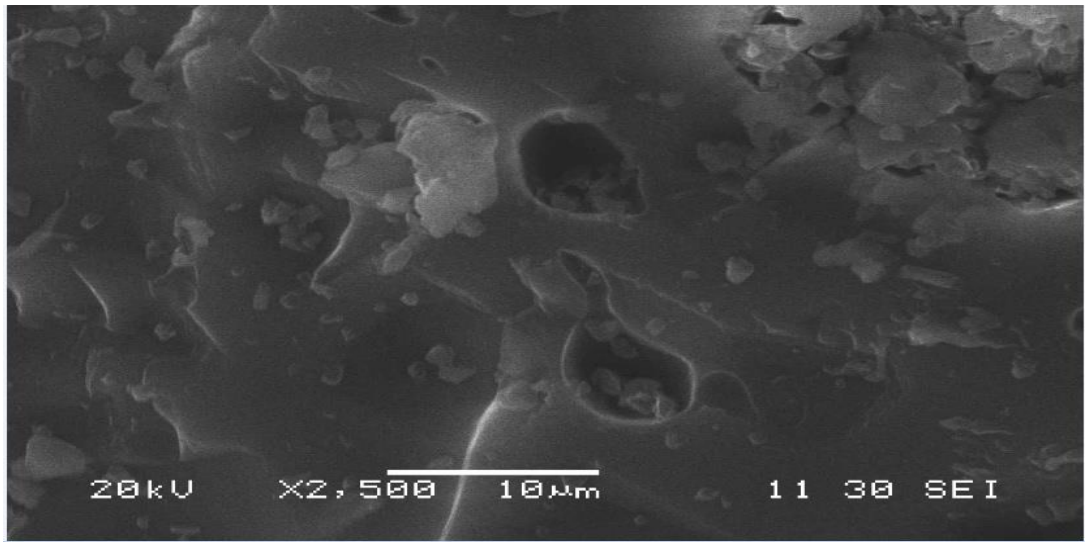

Figure 28: SEM OF SE5

SEM OF FD5:

Morphological feature of FD5 was examined by Scanning Electron Microscopy. FD5 also showed same entrapment of polymers in/on drug. But it showed highly rough and irregular surface than SE5. Hence only, FD5 had present in more amorphous form than SE5 which responsible for enhancing the solubility.

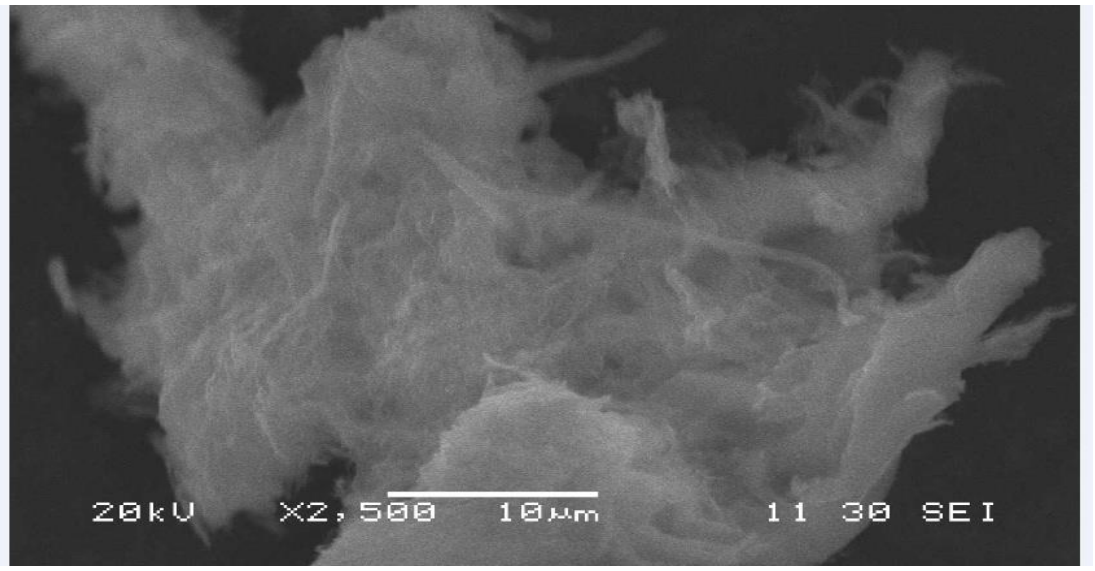

Figure 29: SEM OF FD5

***In-vitro* dissolution study:**

The pure drug at the end of time period 100 min shows 9.28 % of drug release. In case of SE5, drug release was 85.77% and for FD5 drug release was 86.44% of drug release. In short solid dispersion prepared by both freeze drying and solvent evaporation method shows greater drug release as compare pure drug.

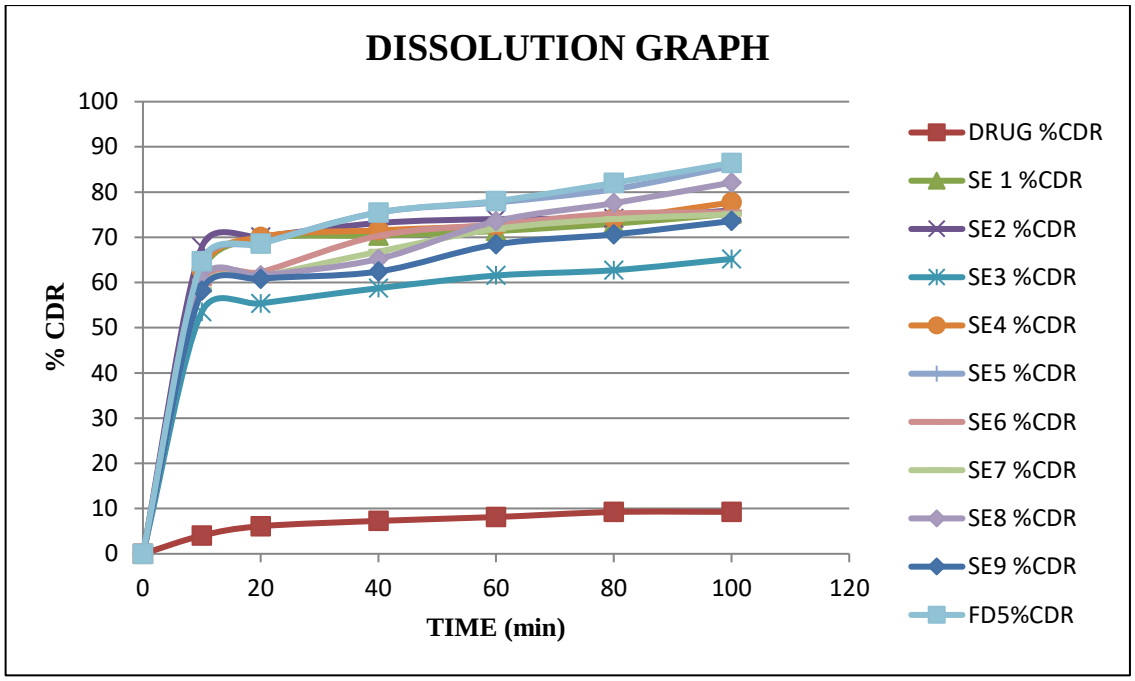

Figure 30: *in-vitro* dissolution study

The solid dispersion prepared by freeze drying and solvent evaporation exhibit a burst release of Febuxostat, that was about >60% of drug release within first 10 min**.** It| might be due to decrease in the crystalline nature of drug and conversion to amorphous form as confirmed by XRPD and DSC studies. This might be due to wettability of drug in the hydrophilic coating of polymeric formulations and increase in surface area was occurred by freeze drying. The particle size and morphology analysis (SEM) again supports improvement in dissolution profile as particle size was reduced and particle surface become smooth which ultimately increased total surface area available for dissolution. The use of water soluble carriers may further enhance drug dissolution because they dissolve rapidly in the dissolution medium and increase the dispersion state of the micronized particles. This showed increased wettability of formulation particles, which enhances dissolution by reducing interfacial tension between the hydrophobic drug and dissolution medium. It is observed that all formulations have significantly improved dissolution rate as compared to pure drug.

Stability study of formulation:

Table 4: Stability study of formulation

Sr. No.	**Batches**	**%Drug present**	
		Time=10 Days	**Time=30 days**
1	**SE1**	96.01	96.00
2	**SE2**	96.02	95.98
3	**SE3**	96.00	95.96
4	**SE4**	**95.98**	**95.94**
5	**SE5**	96.02	96.01
6	**SE6**	96.01	95.96
7	**SE7**	94.95	94.93
8	**SE8**	95.91	95.89
9	**SE9**	95.95	95.90
10	**FD5**	**96.01**	**96.00**

All the formulations were examined for their stability studies in condition 40°C/75%RH for period of 1 month. The formulations were assessed for the drug present in formulations batch. The solid

dispersion was found to be stable during the study period. However, drug shows conversion to its hydrate form due to exposure to moisture during the storage conditions. According to above observation, it was found that drug was not changed in formulations. Hence, it concluded that solid dispersion was stable at normal environmental conditions.

CONCLUSIONS:

This study focused on formulating and characterizing the solid dispersion of a Class II drug to improve its solubility and dissolution rate. The results showed a significant enhancement in both properties when compared to the pure drug. The improvement is attributed to the carrier's effect, drug miscibility, and conversion from crystalline to amorphous form. Using PVP K-25 and l-Arginine as polymers, the freeze-drying and solvent evaporation techniques proved effective. Infrared spectroscopy confirmed no interaction between the drug and carrier, while DSC and XRD studies demonstrated the transition from crystalline to amorphous states. Scanning microscopy revealed a stable amorphous form less prone to recrystallization, with l-Arginine showing superior solubility and dissolution performance compared to PVP K-25. Freeze-drying was identified as a versatile technique for enhancing the dissolution of poorly soluble drugs. Preformulation and evaluation tests met pharmacopeial standards, and the study concludes that solid dispersions of Febuxostat using l-Arginine and PVP K-25 significantly improve oral bioavailability and efficacy.

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Nil

DISCLOSUREOF INTERESTS:

The author declares that they have no conflict of interest

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