Ind. J. Pharm. Edu. Res., 2024; 58(2):446-452.
https://www.ijper.org

Original Article

Development and Evaluation of Fenofibrate Surface Solid Dispersion for Improved Solubility and Dissolution Rate

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ABSTRACT

Objectives: The current work aimed to prepare and characterize Surface-Solid Dispersion (SSD) of Fenofibrate (FNB) in order to improve its solubility and dissolution. **Materials and Methods:** SSD of FNB has been prepared using solvent evaporation techniques through the combination of hydrophilic polymers such as Aerosil 200, Avicel PH 101, Sodium Starch Glycolate (SSG), Crospovidone (CP) and Croscarmellose Sodium (CCS). The produced SSDs were tested for saturation solubility, production yield, Fourier-Transform Infrared Spectroscopy (FTIR), Powder X-ray Diffraction (PXRD), Differential Scanning Calorimetry (DSC), Scanning Electron Microscopy (SEM), and *in vitro* dissolution study. **Results:** PXRD results demonstrated a conversion of the crystalline FNB to an amorphous state when formulated with the carrier, which improved FNB solubility. A decrease in the endothermic peak with respect to FNB in the DSC thermogram of SSD, confirms the loss of crystallinity. Hydrophilic carriers such as Aerosil 200 and CCS at 1:2 (drug: polymer) ratios were found to increase solubility by 3 fold. **Conclusion:** As a result, the creation of SSD using hydrophilic polymers (Aerosil 200 and CCS) by solvent evaporation seemed to be a novel method that enhanced FNB solubility and dissolution.

Keywords: FNB, Surface solid dispersion, Solvent evaporation, Solubility, Dissolution rate.

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Received: 26-08-2023;
Revised: 17-10-2023;
Accepted: 17-01-2024.

INTRODUCTION

Drug delivery through oral administration is the most prevalent. Nevertheless, for many medications, especially those that are not well soluble in water, it is a difficult and ineffective method of delivery. Such medications often have a poor dissolving profile, as well as poorer absorption and bioavailability, due to their limited water solubility. Therefore, increasing drug solubility and subsequent oral bioavailability is still among the most challenging steps in the drug development process, especially for systems that administer drugs orally. There are numerous nanotechnology strategies for addressing inadequate water solubility, or poor bioavailability, of pharmaceuticals. However, these strategies require complex technology and expensive apparatus and are ultimately ineffective. Although many techniques exist and are documented in the literature for improving drug solubility, such as salt formation, co-crystal formation, particle size reduction, and solid dispersion, they have not been widely used.[1]

Solid dispersion, among other methods, has shown promise in increasing the drug's solubility, wettability, rate of drug dissolution, and ultimately its bioavailability.[2] However, there aren't many solid dispersion options on the market.[3,4] Recently, SSDs have gained popularity as a method that can improve on some of the drawbacks of traditional solid dispersions.

It is an effective pharmaceutical strategy for improving the therapeutic efficacy, solubility, and absorption of medicines in formulations. A method for performing and precipitating solid dispersion over an inert carrier surface is SSD. The carrier's hydrophilic characteristics, particle dimension, porosity, and circumference all influence how rapidly a drug is released from it.[5] This method reduces drug agglomeration by increasing the exposed surface area. Smaller amounts of carrier can result in a higher dissolution rate for carriers with greater surface areas, such as silicon dioxide.[6] Aerosil 200, Avicel PH 101, SSG, and CCS were used to improve the solubility of hydrophobic drugs.[7] FNB, the precursor to fenofibric acid, has become among the most commonly used fibrate anti-lipidemic drugs. It is primarily used in the treatment of mixed hyperlipidemia, hypercholesterolemia, and hypertriglyceridemia. Additionally, hyperlipidemia linked to diabetes, hypertension, and other cardiovascular disorders is effectively treated with FNB.[1] The Biopharmaceutics Classification

DOI: 10.5530/ijper.58.2.50

System (BCS) classifies FNB as a BCS class II medication with limited water solubility and high permeability,[2-4] resulting in insufficient dissolution and limited oral bioavailability.[8,9] However, fenofibrate is effectively absorbed from the gastrointestinal tract after it has been dissolved. Therefore, there is a need to improve the solubility and dissolution rate of FNB.

The solvent evaporation method was used in the current investigation to create the SSD of FNB, utilizing five different carriers in four distinct drug carrier ratios. Produced SSDs were evaluated for its drug content and saturation solubility (in water and a 6.8 phosphate buffer medium). FTIR, PXRD, SEM, and DSC were used to characterize the transition from crystalline to amorphous form. The optimized SSD formulations were then assessed for cumulative dissolution studies.

MATERIALS AND METHODS

Materials

Enaltech Pvt. Ltd., Mumbai, India, provided FNB as a complimentary sample. Dichloromethane (DMC), ethanol, SSG (Primogel) were supplied by Loba Chem Ltd., Mumbai, India. CCS and CP were purchased from Yarrow Chemicals, Mumbai, India. Avicel PH 101 (microcrystalline cellulose) was purchased from Signet Pharma, Ahmedabad, India. Aerosil 200 (amorphous colloidal silicon dioxide) was procured from ACME Chemicals, Mumbai, India. Double-distilled water was employed during this research work.

Methods

Preparation of SSD by solvent evaporation technique

The SSDs of FNB were created with hydrophilic carriers (CCS, SSG, CP, Avicel pH 101, and Aerosil 200) in various weight ratios (1:1, 1:2, 1:3, and 1:5) using solvent evaporation techniques (Table 1). Briefly, 0.5g of FNB was dissolved in the required amount of DCM, and then the carrier was suspended in the above drug solution. The aforementioned combination was then put into a rotary evaporator under vaccum at a temperature between 40-45°C to evaporate the solvent. To acquire the final powders, the produced SSD mass was scraped off and passed through sieve no. 80, and the powders were subsequently dried at 40°C in a tray dryer until a consistent mass was obtained. These powders were then placed in desiccators for further investigation.[10,11]

Evaluation of SSD

Production yield

For assessing the efficiency of any procedure, the percentage of production yield was taken into consideration. As a result, it aids in the selection of a suitable manufacturing technique. The produced SSDs were taken apart and accurately weighed in order to compute the production yield using the formula.[12]

$$\% \text{ Production yield} = \frac{\text{Weight of SSD}}{\text{Weight of drug and polymer}} \text{ X } 100$$

Saturation solubility studies

To investigate the aqueous solubility of FNB and SSDs, a saturation solubility study was conducted. An excess amounts of the plain FNB and SSDs in separate glass-stoppered flasks holding both 5 mL of distilled water and 5 mL of 6.8 phosphate buffer solution separately. The samples were placed in a mechanical shaker for 72 hr at 37°C and 100 rpm (Lab Hosp Instruments Mfg. Co., Mumbai, India). Whatman No. 41 filter paper was used to filter the supernatant. The filtrate was adequately diluted and spectrophotometrically analyzed at 286 nm.[13,14] The production yield and saturation solubility values were used to optimize the batches, which were then characterized for FTIR, PXRD, DSC, SEM, content and *in vitro* dissolution studies.

FTIR

An FTIR spectrophotometer (Bruker Alpha II) with diffuse reflectance principle was used to detect the drug excipient compatibility. OPUS software was used to scan the 5 to 10 mg of solid samples over the frequency range of 4000-400 cm^{-1}.

PXRD

Diffractograms of pure FNB and SSDs were produced using a powder X-ray diffractometer (AXS D8 Advances, Broker Ltd., Germany). Copper is used as the X-ray target, with a tube anode Cr spanning the range of 10-70°/2 θ and a 1.54 wavelength.[15]

DSC

Mettler Toledo DSC 821 was used to record the DSC thermogram. Utilizing indium as a reference, the DSC instrument was calibrated. To keep the atmosphere inert, at a speed of 30 mL/min, nitrogen gas was expelled. The samples were heated at a steady rate of 10°C/min in a hermetically sealed aluminum pan throughout a temperature range of 30 to 300°C.

SEM

The surface morphology of SSD was examined using a scanning electron microscope (JEOL JSM-6360, Japan). The sample was placed on a piece of gold-sputtered double-sided adhesive tape, and photomicrographs were taken at various magnifications using an accelerating voltage of 15 kV.[16]

Drug content

In a 10 mL volumetric flask, SSD equivalent to 10 mg of FNB was put, and then methanol was added to form the final volume. The resulting solution was suitably diluted and filtered, and the absorbance of the subsequent solution was measured at 286 nm using a UV spectrophotometer (UV-1800, Shimadzu).[12]

Table 1: Composition of different SSD formulations.

Batch Code	FNB: Carrier (w:w ratio)	FNB (gm)	Aerosil 200 (gm)	Avicel PH101 (gm)	CCS (gm)	CP (gm)	SSG (gm)
F1	1:1	0.5	0.5	-	-	-	-
F2			-	0.5	-	-	-
F3			-	-	0.5	-	-
F4			-	-	-	0.5	-
F5			-	-	-	-	0.5
F6	1:2	0.5	1	-	-	-	-
F7			-	1	-	-	-
F8			-	-	1	-	-
F9			-	-	-	1	-
F10			-	-	-	-	1
F11	1:3	0.5	1.5	-	-	-	-
F12			-	1.5	-	-	-
F13			-	-	1.5	-	-
F14			-	-	-	1.5	-
F15			-	-	-	-	1.5
F16	1:5	0.5	2.5	-	-	-	-
F17			-	2.5	-	-	-
F18			-	-	2.5	-	-
F19			-	-	-	2.5	-
F20			-	-	-	-	2.5

In vitro dissolution study

The *in vitro* dissolution investigations of both pure FNB and optimized SSDs were carried out using a USP Type II dissolution test apparatus. The SSD equivalent to 500 mg of FNB was placed in 900 mL of phosphate buffer pH 6.8 with 1% sodium lauryl sulphate as a dissolving media, maintained at 37°C±0.5°C, and stirred at a constant speed of 100 rpm. The analyte samples (5 mL each) were removed and refilled with an equivalent volume of new medium after each time interval. The obtained samples were filtered, and the amount of FNB in the solution was quantified using a UV spectrophotometer (UV-1800, Shimadzu) at 286 nm. The cumulative release from the SSD formulations was tested in triplicate.[6,17]

RESULTS AND DISCUSSION

Production yield

The production yield of all batches of SSDs was in the range of 79.99% to 92.88%. As the concentration of hydrophilic carriers (Aerosil 200 and CCS) was raised, the manufacturing yield increased (up to a 1:2 ratio), which can be attributed to the drug's better dispersion within the polymer matrix. Aerosil 200 and CCS were found to be more effective in creating SSDs from solvent evaporation than other polymers, as evidenced by the fact that these polymers' production yield and saturation solubility findings were noticeably higher than those of the other polymers shown in Table 2. As a result, SSDF6 and SSDF8 were chosen as the optimized batches, and samples from these batches were chosen for additional characterization and assessment.[12]

Saturation solubility

A drug's water solubility is a major factor in its rate of dissolution and absorption. FNB has poor aqueous solubility. The use of hydrophilic polymers greatly enhanced FNB's solubility. As polymer concentration increases, FNB solubility increases up to a 1:2 drug-to-carrier ratio; however, a further rise in carrier concentration results in a drop in solubility. The solubility of FNB with Aerosil 200 was observed to be 96.62 mg/mL and 99.44 mg/mL in water and phosphate buffer pH 6.8, respectively. The solubility of FNB SSD with CCS was observed to be 97.21 mg/mL and 99.98 mg/mL in water and phosphate buffer pH 6.8, respectively (Table 2). The prepared SSD shows increased solubility by threefold with Aerosil 200 and CCS at 1:2 ratios. The apparent solubility of SSD formulations was significantly higher compared to pure FNB.[18]

According to the findings of the solubility investigations, solubility increases as carrier concentration increases. The drug's partial amorphization in the dispersed state compared to its pure crystalline form, improved wettability, porosity, and increased

Table 2: Solubility and production yield of fabricated SSD.

Batch code	Saturation solubility in water (µg/mL)	Saturation solubility in phosphate buffer pH 6.8 (µg/mL)	% Yield
Pure FNB	35.55	51.85	-
F1	54.00	54.55	90.00
F2	55.66	55.99	88.98
F3	55.00	55.61	89.98
F4	49.66	49.98	87.76
F5	63.66	63.99	90.15
F6	96.62	99.44	91.57
F7	50.00	50.22	89.99
F8	97.21	99.98	92.88
F9	49.33	49.45	89.09
F10	80.55	80.89	80.55
F11	60.11	60.67	89.09
F12	45.44	45.99	87.00
F13	74.88	74.55	89.89
F14	49.88	50.00	88.89
F15	69.44	69.99	90.09
F16	50.33	50.99	90.02
F17	58.66	59.22	79.99
F18	70.00	72.00	89.77
F19	54.00	55.00	88.98
F20	70.22	71.22	89.98

surface area through dispersion could all be significant factors for solubility.[12] The hydrophilic properties of Aerosil 200 and CCS may be responsible for the improved solubility and dissolving rate of FNB in SSD.

FTIR

To investigate the potential interaction between FNB and polymers, FTIR spectroscopy was employed. The FTIR spectra of FNB, physical combinations, and SSD do not significantly differ from one another (Figure 1). Wavenumbers 3061cm^{-1}, 2979 cm^{-1}, 1721 cm^{-1}, 1644 cm^{-1}, 1589, 1413 cm^{-1}, 1380 cm^{-1}, 1243 cm^{-1}, 1010 cm^{-1}, 972 cm^{-1}, 923 cm^{-1}, 850 cm^{-1}, 818 cm^{-1}, 761 cm^{-1}, 683 cm^{-1}, and 650 cm^{-1} all have strong FNB peaks (Table 3). The CCS polymer showed spectral peaks at 3244 cm^{-1}, 2878 cm^{-1}, 1726 cm^{-1}, 1585 cm^{-1}, 1411 cm^{-1}, 1317 cm^{-1}, 1015 cm^{-1}, and 896 cm^{-1}, while the Aerosil 200 polymer showed spectral peaks at 1085 cm^{-1} and 807 cm^{-1}. These peaks were all preserved in the physical mixtures and the optimized SSD batches SSDF6 and SSDF8, demonstrating clearly that there is no interaction between pure FNB and the polymers used in the preparation of SSD.[12]

Table 3: Peak absorbance values of FTIR spectra of FNB.

Functional group	Standard wave number (cm^{-1})	Observed wave number (cm^{-1})
CH (Aromatic)	3100-3000	3061
C-H (Alkane)	3000-2850	2979
C=O Stretch (Ester carbonyl)	1750-1700	1721
-C(=O)- (Ketone Carbonyl)	1725-1705	1721
C=C (Benzene ring)	1650-1520	1644, 1589
-CH3 (Alkane)	1450-1375	1413, 1380
C-O-C (Ether carbonyl)	1300-1000	1243, 1010
C-X (Cl) stretch	800-600	761, 683, 650

PXRD

Using PXRD, the physical nature of prepared SSDs and pure FNB was investigated. The diffraction peaks show the crystalline nature of Pure FNB and retain their diffraction peaks at 11.02°,

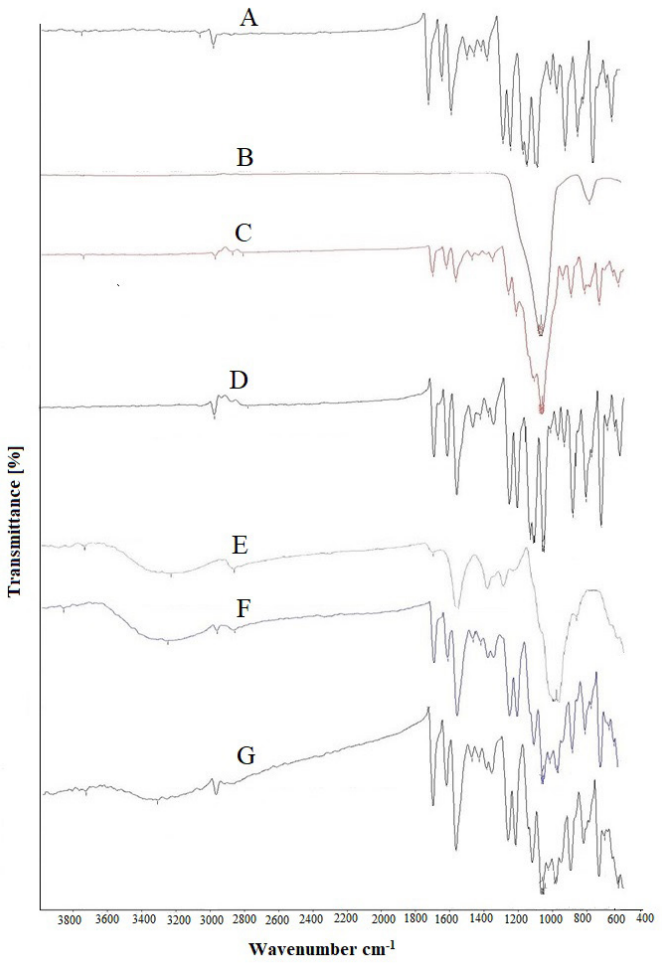

Figure 1: FTIR spectra of Pure drug (FNB) (A), Aerosil 200 polymer (B), physical mixture FNB: Aerosil 200 (C), and Optimized SSD formulation with Aerosil 200 (SSDF6) (D), CCS polymer (E), physical mixture FNB: CCS (F), Optimized SSD formulation with CCS (SSDF8) (G).

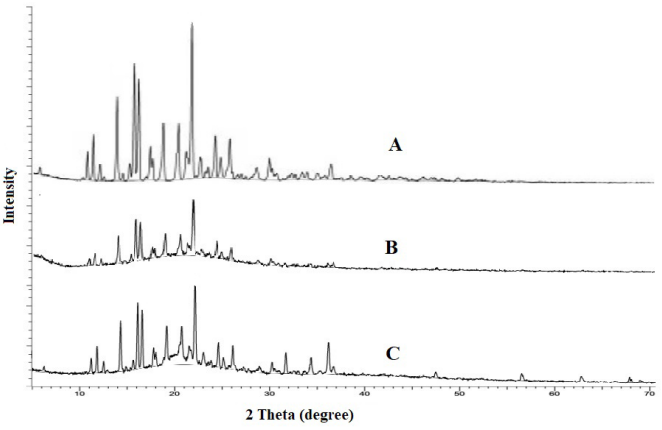

Figure 2: PXRD pattern of FNB (A), SSD formulation SSDF6 (B), SSD formulation SSDF8 (C).

14.09°C, 16.06°C, 22.05°C, 25.12°C and 27.02°C at 2θ (Figure 2). On the other hand, it was noticed that in the optimized batches SSDF6 and SSDF8, sharp, distinctive peaks vanished and were replaced with characteristic diffraction peaks that appeared in the same location but had lower intensities (Figure 2). These findings point to a reduction in crystallinity and a modification of orientation during the crystal development phase. A significant amount of FNB in SSDs is likely to have undergone an amorphous transformation. Similar outcomes were reported in the previous literature.[6]

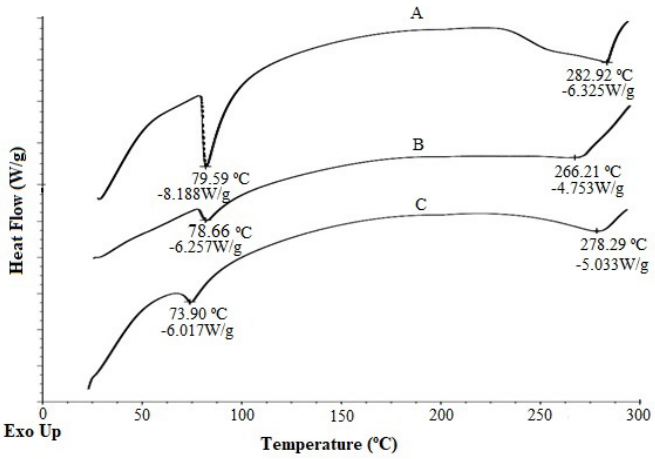

Figure 3: DSC of pure FNB (A), Optimized SSD formulation SSDF6 (B), Optimized SSD formulation SSDF8 (C).

DSC

Figure 3 depicts the DSC thermogram of pure FNB, which reveals a prominent endothermic peak at 79.59°C, which corresponds to the melting temperature of crystalline FNB. SSDF6 and SSDF8 DSC thermogram demonstrate a decrease in the endothermic peak of FNB at 78.66°C and 73.90°C, respectively (Figure 3). The reduction in intensity of the endothermic peaks and meting at lower temperatures indicates that the FNB was converted into an amorphous or molecular state in SSD.[19] Previous literature reported the same outcomes.[8]

SEM

SEM micrographs of pure FNB and optimized batches of SSDs were shown in Figure 4. From the SEM micrograph, it was clear that FNB particle size was significantly reduced after being solvent evaporated using Aerosil 200 (SSDF6) 1:2 and CCS (SSDF8) 1:2. Large crystalline blocks were visible in the SEM micrographs of pure FNB; however, the SSD was determined to have a smooth surface. The needle-shaped crystalline substance has a rough exterior. Particle size and surface roughness is reduced by using Aerosil 200 (SSDF6) 1:2 and CCS (SSDF8) 1:2 in surface solid dispersion. The particles produced by this method are spherical and have a smooth surface with pores.[10]

Drug content

The FNB content in the optimized SSD formulations SSDF6 and SSDF8 were 96.74% and 97.14%, and were found to be within the acceptable limit.[20]

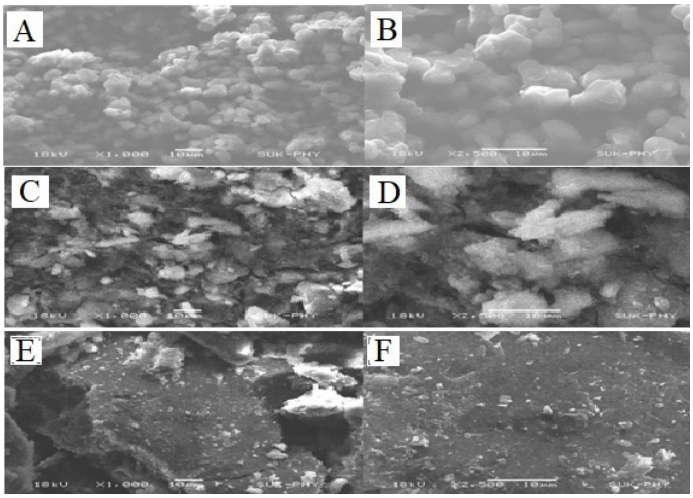

Figure 4: SEM micrographs of pure FNB (A) at 1000 x, (B) at 2500 x; SEM micrographs of SSD formulation with Aerosil 200 (SSDF6) (C) at 1000 x, (D) at 2500 x; SEM micrographs of SSD formulation with CCS (SSDF8) (E) at 1000 x, (F) at 2500 x.

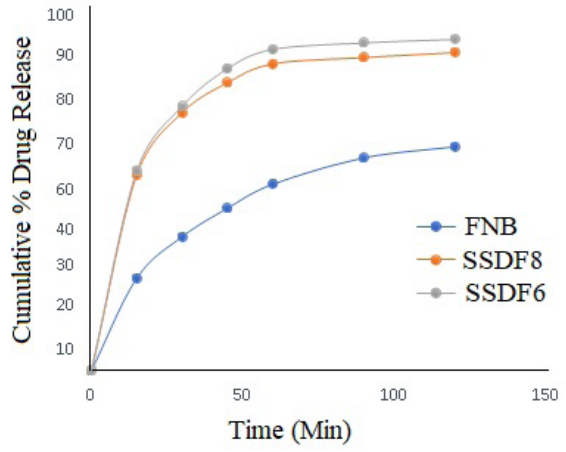

Figure 5: *In vitro* dissolution profile of pure FNB, and SSDF6 and SSDF8.

In vitro dissolution study

The dissolution characteristics of a pure FNB and optimized SSDs (SSDF6, SSDF8) are shown in Figure 5. At 30 min, pure FNB, SSDF6, and SSDF8 showed 37.52%, 74.05%, and 72.26% of drug release, respectively. After 120 min, the drug release of FNB from SSDF6 and SSDF8 was found to be 92.75 % and 89.06%, respectively. This improved dissolution rate of SSD may be explained by wettability due to the presence of hydrophilic carries in addition to the amorphization of FNB. The release profile data reveals that the *in vitro* dissolution of FNB was improved by the SSD.[17]

CONCLUSION

In the current study, SSDs of FNB were prepared for improved solubility and dissolution rate. SSD is largely dependent on the quantity and type of carriers present. SSD improved the saturation solubility of FNB in water and in pH 6.8 buffer solutions (>96 mg/mL). The XRD, SEM, and DSC analyses further confirmed that the drug was in a molecularly dispersed state and that it underwent a change from crystalline to amorphous form. The FTIR study confirms that there is no incompatibility between the FNB and the carriers used in the formulation of SSD. From the results of the *in vitro* dissolution study, it was revealed that the SSD had a noticeably higher level of dissolution (>89%) within 120 min. As a result, the creation of SSD using hydrophilic carriers (Aerosil 200 and CCS) by solvent evaporation seemed to be a novel method that enhanced FNB solubility and dissolution.

ACKNOWLEDGEMENT

The authors are thankful to the Principal of Government College of Pharmacy, Karad, Maharashtra, India for providing the facility to complete this research.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

SSD: Surface-solid dispersion; **FNB:** Fenofibrate; **FTIR:** Fourier-transform infrared spectroscopy; **PXRD:** Powder X-ray diffraction; **DSC:** Differential scanning calorimetry; **SEM:** Scanning electron microscopy; **SSG:** Sodium Starch Glycolate; **CP:** Crospovidone; **CCS:** Croscarmellose Sodium; **DMC:** Dichloromethane.

SUMMARY

SSDs of FNB were prepared using solvent evaporation technique for improved solubility and dissolution rate. SSD is largely dependent on the quantity and type of carriers present. SSD of batches SSDF6 and SSDF8 result in a noticeably higher saturation solubility (in water and in pH 6.8 buffer solutions) and percentage yield. In the *in vitro* dissolution study, it was revealed that SSD had a noticeably higher level of dissolution than pure FNB. As a result, the creation of SSD using hydrophilic carriers (Aerosil 200 and CCS) by solvent evaporation seemed to be a novel method that enhanced FNB solubility and dissolution.

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Cite this article: Hosmani AH, Patil ND, Pawar AA, Honmane SM, Thorat YS. Development and Evaluation of Fenofibrate Surface Solid Dispersion for Improved Solubility and Dissolution Rate. Indian J of Pharmaceutical Education and Research. 2024;58(2):446-52.