



## Dissolution Enhancement of Flurbiprofen by Solid Dispersion Adsorbate Technique

Sohansinh S. Vaghela\*, Samkit M. Shah, Sanjesh G. Rathi, Shrenik K. Shah

Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar.

\*Corresponding author's E-mail: [Sohansinh@gmail.com](mailto:Sohansinh@gmail.com)

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### ABSTRACT

Flurbiprofen solid dispersion Adsorbate (SDA) has been prepared using PEG 4000 and Poloxamer 188 as carrier and Neusilin as adsorbent material. The SDA of Flurbiprofen was prepared by using Fusion method in various drugs to carrier ratios. The phase solubility study concludes that both polymers have ability to improve the aqueous solubility of flurbiprofen. Pure API Flurbiprofen and final formulation samples of SDA are characterized by FTIR, DSC and X-ray diffraction spectroscopy. X-ray powder diffraction and DSC study indicated that the drug was present in amorphous form. FTIR study revealed that the characteristic peaks in spectra of pure Flurbiprofen are also present in spectra of SDA's. Drug found compatible with the excipients. The highest improvement in solubility and in-vitro drug release were observed in solid dispersion prepared with Poloxamer 188 (F14) by fusion method. The increased dissolution rate of drug from solid dispersion adsorbates may be due to surface tension lowering effect of polymer to the medium and increased wettability and dispersibility of drug. Hence, F14 Solid dispersion adsorbates with the Poloxamer carrier in 1:2 ratio considered as most satisfactory among all solid dispersion adsorbates.

**Keywords:** Flurbiprofen, Solid Dispersion Adsorbate, dissolution.

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### INTRODUCTION

Introduction of Solid Dispersion Adsorbate: Solid Dispersion term is defined as the dispersion of one or more Active Pharmaceutical Ingredient (Drug Substance) into the carrier matrix solid form by using various methods like solvent evaporation, or fusion (melting) method.<sup>1</sup> Now a days, Solubility enhancement can be done by using various methods and it's significantly improves the bioavailability of drug as per published literature review. Among this, the Solid dispersion is the most useful and well-known technique for the enhancement of the solubility. Many literatures are available which stated that the solid dispersion is the best technique for the improvement of solubility for BCS Class II and IV drugs. It is the more convenient and effective method as compared to the physical method likes particle size distribution.<sup>1</sup> Various methods are available for solid dispersion<sup>2,3</sup> like Melting method, Solvent method, Melting solvent method (melt evaporation), Melt extrusion method, Lyophilization Technique, Melt Agglomeration Process, The use of surfactant, Electrospinning, Super Critical Fluid (SCF) Technology, Direct capsule filling, Dropping solution method, Co-precipitation method.

### Solid Dispersion Adsorbate<sup>5</sup>

Solid Dispersion Adsorbates method is same as Solid Dispersion, but the only different is that the use Adsorbent materials like Neusilin US2 (selected adsorbent). In this method, the solid dispersion is prepared using the carrier material and drug molecule. After that the prepared solid dispersion is adsorbed on the adsorbent material using melting or fusion method. It is helpful for the preparation of the free-flowing granules of solid dispersion. As per the literature, the solubility of the SDA is more as compared to the SD of drugs. Flurbiprofen is a Nonsteroidal anti-inflammatory agent (NSAID's) with antipyretic and analgesic activity. Flurbiprofen belongs to BCS Class II drug which have low water solubility and high permeability. Flurbiprofen has a poor oral bioavailability due to limited aqueous solubility and Hepatic first-pass effect. Solubility and dissolution are the key parameters for the therapeutic effect of a drug and to achieve desired concentration of drug in systemic circulation for pharmacological response. Aqueous solubility of a drug can be a critical limitation to its oral absorption. For the enhancement of oral bioavailability of poorly soluble drugs remains one of the most challenging aspects of drug development. The drugs with poor aqueous solubility generally show dissolution rate limited absorption. The low solubility of Flurbiprofen limits its absorption from the gastrointestinal tract and reduces its oral bioavailability due to poor dissolution. In case of poorly water-soluble drugs (Flurbiprofen) dissolution is rate limiting step in process of drug absorption. The solid dispersion adsorbate approach has been widely and successfully applied to improve their dissolution rate. By preparing solid dispersion adsorbate of Flurbiprofen, it enhances absorption from GI tract which



goes in systemic circulation and give quick response to conditions. Hence, the focus of present work is to prepare solid dispersion adsorbate of Flurbiprofen.

### Material

Flurbiprofen received as gift sample from Torrent Pharma, Ahmedabad, Neusilin US2 received from Gangwal Chemicals, Mumbai and PEG 4000, Poloxamer 188, Avicel pH 102, Talc and Magnesium Stearate are laboratory reagents purchased from local market.

### Methodology

#### Preformulation Study

Preformulation study is the primary step of Formulation development. Various physicochemical parameters can be check and reported before starting the development work.

Physical Appearance of Drug: First check the physical appearance of the Drug by visually and report its colour and physical form.

Melting point of Drug: Melting point of the drug was checked using capillary method in melting point apparatus. Record the observed results.

Identification of drug using FTIR: The initial identification of drug was done using FTIR spectroscopy. The drug sample was scanned under FTIR and the obtained peaks of pure API graph checked with the reported values. The full scan of drug was done in the IR range between  $400\text{cm}^{-1}$  to  $4000\text{cm}^{-1}$ .

Identification of drug using DSC: To check the purity of drug and identify the same, differential scanning calorimetry (DSC) method was used. The full scan of drug was done in differential scanning calorimeter. The obtained DSC thermogram was recorded and the melting point was checked with the reported value.

Identification of drug using XRD: The pure drug sample was checked in XRD meter and the obtained scanned was checked with the reported value. The  $2\theta$  values are compared with the reported values of drug.

Flow properties of Drug: Flow properties of Drug are important factor in formulation development. Initially the Bulk Density and Tapped Density are checked and then based on its further parameters were checked like Hausner ratio and Carr's Index. Angle of Repose also checked.

#### Solubility Study

Solubility of drug was checked in different solvents. Some non-aqueous solvents also used to check the solubility of drug in non-aqueous solvent. The physiological pH range buffers also considered for solubility study. The known quantity of drug was added into the solvent slowly and stops further addition of drug when saturation of solvent achieved. Calculate the solubility of drug in mg/ml.

### Preparation of Standard Calibration Curve

Standard Calibration curve of Flurbiprofen prepared using UV Visible Spectrophotometer. Standard stock solution was prepared by taking 10 mg of drug into 100 ml volumetric flask and make up the volume using 0.1 N HCl (pH 1.2). This stock solution is 100  $\mu\text{g}/\text{ml}$ . Further, take 1 ml of stock solution and dilute by 100 ml of 0.1 N HCl and prepared 1  $\mu\text{g}/\text{ml}$  solution. Similarly prepare 2,4,6,8 and 10  $\mu\text{g}/\text{ml}$  solution and scanned in 200-400 nm range of UV Spectroscopy.

### Phase Solubility Study

The Phase Solubility study of Flurbiprofen was carried out by considering two carriers which is Poloxamer 188 and PEG 4000. The carriers were taken separately and dissolve the same in the water to prepare the different concentration solution of 2,4,6,8 and 10 %w/v solution. An excess quantity of drug was added in to 20 ml carrier (polymer) solution. The prepared solutions were shaken on shaker at  $37^\circ\text{C}$  for 24 hours. Finally, the solubility of drug was determined and reported.

### Preparation of Solid Dispersion Adsorbates of Flurbiprofen

The Solid Dispersion of Flurbiprofen was prepared by Fusion method. Different ratio of Drug to Carrier was selected (1:0.5, 1:1 and 1:1.5). Carrier material was melting in the porcelain dish on water bath. The drug was dispersed in to the molten mass with continuous stirring. The melted mass was then cooled at room temperature. The prepared Solid Dispersion of drug and carrier was then adsorbed on the Neusilin Surface which is previously melted. These solid dispersion adsorbates was cooled at room temperature and sieved. Different ratio of carriers and amount was given below in formulation table 1.

### Characterization of Solid Dispersion Adsorbate of Flurbiprofen

#### Drug content

Solid dispersion adsorbate equivalent to 10 mg of drug were weighed accurately and transferred to 100 ml volumetric flask. The volume of mark up with the 0.1 N HCl and sonicated for 10 min. The drug content was checked using UV spectrometer at specific wavelength.

#### In vitro dissolution studies

*In vitro* drug release of Flurbiprofen was performed using USP dissolution apparatus type-II paddle. The dissolution medium was selected 0.1N HCl, 900 ml and performed at  $37^\circ\text{C} \pm 0.5^\circ\text{C}$  and stirred at 50 rpm. Exactly 5 ml aliquots were withdrawn at predetermined intervals. Sink condition was maintained by replacing the volume equivalent to the quantity removed with fresh dissolution medium. The solutions were diluted with 0.1N HCl and analyzed by UV spectrophotometer.



**Table 1:** Formulation table of Solid Dispersion Adsorbates

Formulation Code	Drug (mg)	PEG 4000 (mg)	Poloxamer 188 (mg)	Neusilin (mg)
F1	10	5	-	10
F2	10	10	-	10
F3	10	15	-	10
F4	10	5	-	20
F5	10	10	-	20
F6	10	15	-	20
F7	10	5	-	30
F8	10	10	-	30
F9	10	15	-	30
F10	10	-	5	10
F11	10	-	10	10
F12	10	-	15	10
F13	10	-	5	20
<b>F14</b>	<b>10</b>	<b>-</b>	<b>10</b>	<b>20</b>
F15	10	-	15	20
F16	10	-	5	30
F17	10	-	10	30
F18	10	-	15	30

### Formulation of SDA Tablets

Prepared Solid dispersion Adsorbate (SDA) powder used for preparation of tablets. Two different tablets were prepared. One is using optimized batch of SDA and second with plain Drug. The excipients were weighed accurately and pass through 40# sieve except magnesium stearate and talc which are passed from 60#. Then SDA powder/API was mixed with the diluent manually in polybag. Add talc and mix for 2 min further. At last add magnesium stearate and mix for further 2 min and compress the blend on tablet punching machine.

**Table 2:** Formulation table of SDA tablets and plain tablets

Ingredients (mg)	Pure Drug Tablet	SDA Tablet
Flurbiprofen	10.0	--
SDA of Flurbiprofen Eq. to 10 mg drug	--	40.0
MCC (Avicel 102)	84.0	54.0
Talc	2.0	2.0
Magnesium Stearate	4.0	4.0
Total	<b>100.0</b>	<b>100.0</b>

## RESULTS AND DISCUSSION

### Preformulation study

#### Physical Appearance of Drug

Flurbiprofen is white colored crystalline solid powder.

### Melting point of Drug

The melting point of the drug was found 118°C which is matching with the reported values of Flurbiprofen melting point.

### Flow properties of Drug

The flow properties of the Flurbiprofen API were calculated using bulk density and tapped density data. The obtained results were given below table 3;

**Table 3:** Flow properties of Flurbiprofen API

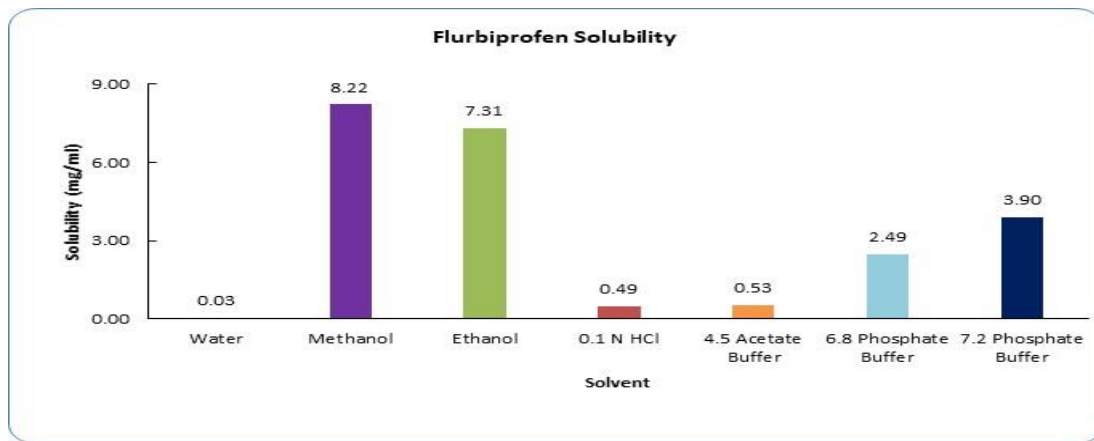
Parameters	Results
Bulk Density (g/ml)	0.235 g/ml
Tapped Density (g/ml)	0.501 g/ml
Compressibility Index	53.09
Hausner Ratio	2.132
Angle of Repose	58.9 °
Inference	Very very poor

Flow properties of the Powder material confirms by compressibility Index and Hausner Ratio. Compressibility Index and Hausner Ratio of API calculated by using the bulk density and tapped density of API. The results revealed that the flurbiprofen API having a very very poor flow. Angle of repose found 58.9 °C which was also indicate the poor flow.

### Solubility study of Drug

The solubility of flurbiprofen in aqueous media as a function of pH was measured and is presented in below table. The aqueous solubility of flurbiprofen is low (~0.03 mg/ml) and increase across the physiological pH range.





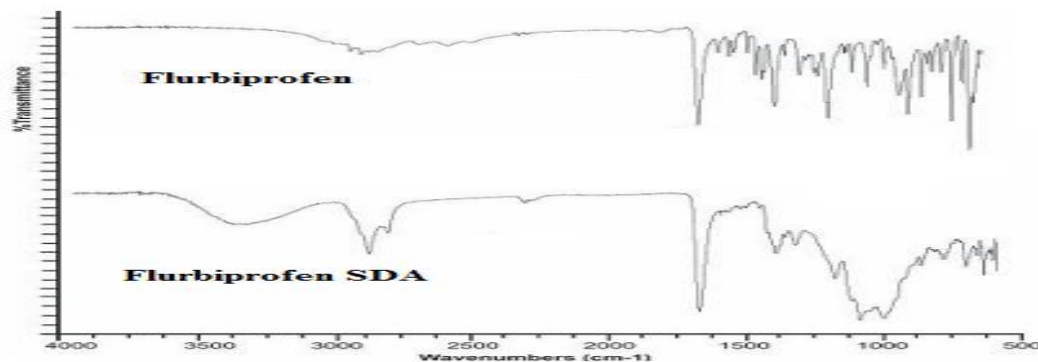
**Figure 1:** Flurbiprofen Solubility data

### Phase Solubility Study

The solubility of drug was found 0.0249 mg/ml in water. The solubility of drug was checked in the polymeric solution and reported as a phase solubility study. Flurbiprofen was found more soluble in polymeric solution of both carriers. It was found that the drug have more solubility in Poloxamer as compared to PEG 4000.

### Characterization of SDA

#### Characterization of SDA by FTIR

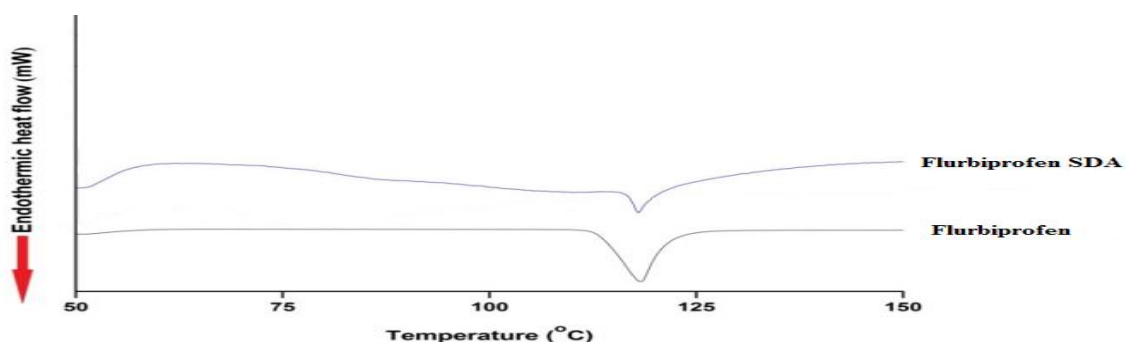


**Figure 2:** FTIR Spectra of Flurbiprofen and Flurbiprofen SDA

### Characterization of SDA by DSC

The DSC thermogram of pure API flurbiprofen and Flurbiprofen SDA was figured below. The DSC thermogram of Pure Flurbiprofen shows the sharp endothermic peak at 118°C which confirms the

crystalline nature of drug. However, the DSC thermogram of Flurbiprofen SDA shows the similar peak at the same point but the intensity of the peak is low as compared to the pure Flurbiprofen. It indicates the slightly conversion of crystalline form to amorphous form.

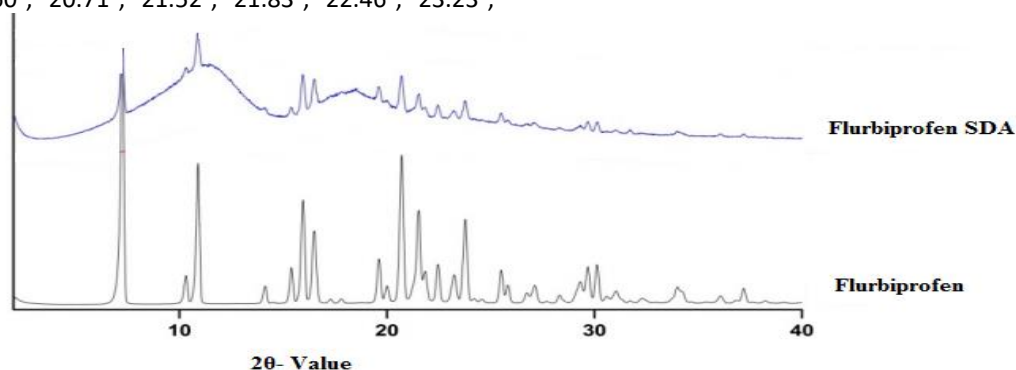


**Figure 3:** DSC Thermogram of Flurbiprofen and Flurbiprofen SDA

### Characterization of SDA by XRD

Below figure shows the XRD pattern of pure flurbiprofen API and SDA of Flurbiprofen. The Diffraction pattern of Flurbiprofen pure API showed sharp characteristic peaks at  $2\theta$  equal to  $7.25^\circ$ ,  $10.30^\circ$ ,  $10.89^\circ$ ,  $14.11^\circ$ ,  $15.40^\circ$ ,  $15.94^\circ$ ,  $16.49^\circ$ ,  $19.60^\circ$ ,  $20.71^\circ$ ,  $21.52^\circ$ ,  $21.83^\circ$ ,  $22.46^\circ$ ,  $23.23^\circ$ ,

$23.78^\circ$ ,  $25.51^\circ$ ,  $25.82^\circ$ ,  $26.75^\circ$ ,  $27.12^\circ$ ,  $29.32^\circ$ ,  $29.69^\circ$ ,  $30.12^\circ$ ,  $34.01^\circ$  and  $37.21^\circ$  confirming the crystalline nature of the starting material. In contrast, the XRD pattern of Flurbiprofen SDA shows the similar XRD pattern to the API but the intensity of the peak is low as compared to pure API.



**Figure 4:** XRD Spectra of Flurbiprofen and Flurbiprofen SDA

### Drug Content & Practical Yield

The Prepared SDA batches F1-F18 was checked for drug content analysis. All the batches were checked for drug content and found well within acceptable range. The inclusion of drug into the carrier found satisfactory. Also, the practical yield of the SDS was checked and found satisfactory. The same was recorded into the below table;

**Table 4:** Results of Drug content & Practical Yield

Formulation Code	Drug Content (%)± SD	Practical Yield(%)± SD
F1	92.4 ± 2.5	77.5 ± 2.5
F2	91.0 ± 4.3	72.9 ± 3.1
F3	94.3 ± 3.1	76.2 ± 2.6
F4	92.9 ± 4.3	71.8 ± 3.4
F5	94.8 ± 3.9	75.4 ± 1.9
F6	92.2 ± 2.4	73.2 ± 1.8
F7	96.7 ± 2.8	81.7 ± 3.2
F8	95.2 ± 3.6	75.3 ± 3.3
F9	94.2 ± 3.9	81.0 ± 2.4
F10	92.2 ± 4.8	72.1 ± 1.5
F11	93.7 ± 5.1	69.9 ± 2.7
F12	94.5 ± 3.4	73.5 ± 3.3
F13	93.7 ± 2.9	82.6 ± 1.3
F14	94.6 ± 3.7	78.4 ± 2.3
F15	95.8 ± 4.1	71.6 ± 3.3
F16	94.3 ± 3.4	75.3 ± 1.3
F17	93.6 ± 2.8	72.7 ± 3.1
F18	92.1 ± 3.6	71.8 ± 2.3

### Saturation Solubility Study

The solubility study of the pure API along with the prepared SDA was checked. The results are tabulated in below table. It was observed that the solubility of pure API is very less in water. Prepared SDA was increased the solubility of pure drug. The PEG 4000 was able to increase the solubility up to 10 folds as compared to pure API. However, the Poloxamer 188 was able to increase the solubility of drug up to 17 folds.

**Table 5:** Solubility of Drug and Solid Dispersions

Formulation	Solubility in water (mg/ml)± SD	Carrier
API	0.03± 0.01	-
F1	0.12 ± 0.01	PEG 4000
F2	0.19 ± 0.02	
F3	0.26 ± 0.01	
F4	0.14 ± 0.03	
F5	0.19 ± 0.02	
F6	0.27 ± 0.01	
F7	0.18 ± 0.02	
F8	0.22 ± 0.01	
F9	0.29 ± 0.03	
F10	0.19 ± 0.02	
F11	0.27 ± 0.04	Poloxamer 188
F12	0.31 ± 0.02	
F13	0.24 ± 0.01	
F14	0.51 ± 0.04	
F15	0.49 ± 0.03	
F16	0.29 ± 0.01	
F17	0.42 ± 0.02	
F18	0.46 ± 0.04	

### In Vitro Drug Release Study

The Prepared SDA batches F1-F18 was checked for drug release study. The details were recorded into the below table;

**Table 6:** Drug release study of F1-F18

Batch	% Drug Release in (min)					
	5	10	15	30	45	60
API	8.5 ± 4.5	14.2 ± 3.9	20.7 ± 2.8	29.3 ± 2.5	38.7 ± 2.4	46.9 ± 1.9
F1	13.8 ± 3.1	25.1 ± 2.7	32.9 ± 3.1	41.7 ± 2.9	52.3 ± 2.7	59.1 ± 2.5
F2	15.9 ± 2.9	28.7 ± 2.5	34.9 ± 3.9	45.2 ± 3.4	54.8 ± 3.3	62.9 ± 3.1
F3	19.5 ± 3.8	33.8 ± 3.6	39.7 ± 2.5	49.5 ± 2.3	59.1 ± 2.1	66.8 ± 2.0
F4	15.8 ± 2.7	28.3 ± 3.1	34.1 ± 2.7	44.8 ± 2.4	55.3 ± 2.2	62.8 ± 1.7
F5	16.8 ± 4.1	30.1 ± 2.9	35.9 ± 3.2	48.7 ± 2.8	58.3 ± 2.7	64.1 ± 1.6
F6	22.4 ± 3.5	35.9 ± 2.5	41.3 ± 4.6	53.8 ± 4.1	63.2 ± 3.6	69.7 ± 3.5
F7	19.7 ± 3.1	33.2 ± 3.1	38.2 ± 3.7	49.5 ± 3.2	58.2 ± 3.1	64.1 ± 2.8
F8	22.5 ± 2.6	34.9 ± 3.9	41.3 ± 2.8	53.7 ± 2.4	62.1 ± 2.2	66.8 ± 2.1
F9	29.8 ± 3.4	38.6 ± 2.8	48.9 ± 3.7	57.4 ± 3.5	68.5 ± 3.1	72.3 ± 2.7
F10	20.4 ± 3.4	35.6 ± 2.4	40.1 ± 3.4	51.9 ± 3.1	59.7 ± 2.8	66.2 ± 2.5
F11	23.9 ± 3.7	36.8 ± 3.1	43.2 ± 2.8	55.8 ± 2.1	64.3 ± 1.9	71.9 ± 1.7
F12	31.2 ± 2.9	39.7 ± 4.5	50.1 ± 3.1	59.3 ± 2.7	69.2 ± 2.4	75.8 ± 2.1
F13	24.1 ± 4.3	36.2 ± 3.8	44.2 ± 3.7	55.9 ± 3.2	65.4 ± 2.7	69.7 ± 2.4
<b>F14</b>	49.8 ± 4.1	64.9 ± 2.9	70.1 ± 2.6	79.3 ± 2.2	86.4 ± 1.8	91.2 ± 1.4
F15	39.5 ± 3.9	55.2 ± 3.7	63.7 ± 3.7	70.2 ± 3.4	77.3 ± 2.6	82.5 ± 2.3
F16	30.2 ± 3.2	39.7 ± 2.9	50.3 ± 2.6	59.4 ± 2.1	70.1 ± 1.9	74.8 ± 1.4
F17	32.1 ± 3.7	45.8 ± 3.5	53.7 ± 2.1	64.3 ± 1.9	71.5 ± 1.7	77.9 ± 1.5
F18	34.1 ± 3.9	49.7 ± 2.6	58.5 ± 3.0	69.2 ± 2.8	74.3 ± 2.4	80.2 ± 1.9

Dissolution results of F1 to F18 formulation were recorded along with pure API results. It found that the pure API drug release and dissolution is very slow as the solubility of pure API is poor. However, the dissolution of solid dispersion adsorbates is comparatively good as pure API. The formulations of Poloxamer 188 are faster than the PEG 4000 SDA. The most satisfactory formulation was F14 which gives almost 90% drug release in 60 mins. The F14 formulation has a drug to carrier ratio 1:1 and drug to adsorbent ratio 1:2.

### Evaluation of Tablets

Prepared tablets of pure drug and SDA of Flurbiprofen were evaluated for various parameters which were given below and the same results recorded in table 6.8. Drug release study for both type of tablets checked and recorded in table 6.7. Pure drug tablets were unable to release more than 20 % drug release in 60 min. SDA tablets gives more than 90 % drug release within 60 min.

**Table 7:** Evaluation of tablets

Parameters	Tablets of Pure Drug	Tablets of SDA
Weight Variation (mg)	101.5 ± 2.4	100.9 ± 1.9
Thickness (mm)	2.6 ± 0.3	2.5 ± 0.2
Hardness (kg/cm <sup>2</sup> )	3.5 ± 0.4	3.7 ± 0.3
Friability	0.41 ± 0.05	0.40 ± 0.03
Disintegration Time (min)	24 ± 5	21 ± 3
% Drug Content	98.3 ± 1.5	99.5 ± 1.2
<b>% Drug release</b>		
<b>5 min</b>	2.8 ± 1.1	10.9 ± 1.5
<b>15 min</b>	5.6 ± 1.6	31.8 ± 1.2
<b>30 min</b>	11.9 ± 1.3	65.9 ± 1.1
<b>60 min</b>	20.9 ± 1.0	92.8 ± 0.8



## Stability Study

Stability study of Optimized batch SDA tablets performed for 1 month. Sample withdrawal after 1 month; it showed no change in *in-vitro* drug release profile. Results of stability study do not show any remarkable change in the release profile of the tablet after the stability.

## CONCLUSION

Flurbiprofen solid dispersion Adsorbate (SDA) has been prepared using PEG 4000 and Poloxamer 188 as carrier and Neusilin as adsorbent material. The SDA of Flurbiprofen was prepared by using Fusion method in various drugs to carrier ratios. The phase solubility study concludes that both polymers have ability to improve the aqueous solubility of flurbiprofen. Pure API Flurbiprofen and final formulation samples of SDA are characterised by FTIR, DSC and X-ray diffraction spectroscopy. X-ray powder diffraction and DSC study indicated that the drug was present in amorphous form. FTIR study revealed that the characteristic peaks in spectra of pure Flurbiprofen are also present in spectra of SDA's. Drug found compatible with the excipients. The highest improvement in solubility and *in-vitro* drug release were observed in solid dispersion prepared with Poloxamer 188 (F14) by fusion method. The increased dissolution rate of drug from solid dispersion adsorbates may be due to surface tension lowering effect of polymer to the medium and increased wettability and dispersibility of drug. Hence, F14 Solid dispersion adsorbates with the Poloxamer carrier in 1:2 ratio considered as most satisfactory among all solid dispersion adsorbates.

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