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Formulation and *in vitro* evaluation of flurbiprofen-polyethylene glycol 20000 solid dispersions

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ABSTRACT

Solid dispersion is one of the most widely used methods to enhance the solubility and dissolution rate of poor water soluble drugs. In the present study, flurbiprofen solid dispersions were prepared using solvent evaporation method by incorporating polyethylene glycol 20000 and evaluated for solubility studies, drug-carrier compatibility studies and *in vitro* dissolution studies. From the solubility studies, formulations F4 were selected to prepare in the form of tablets and compared with control tablets (conventional tablets using pure drug). From the results of *in vitro* dissolution study, tablets containing polyethylene glycol 20000 showed almost complete drug release within the 15 min. The percent drug release in 15 min (Q_{15}) and initial dissolution rate for formulation F4 was 99.26±1.12%, 6.62%/min. These were very much higher compared to control tablets (34.95±1.29%, 2.33%/min). The relative dissolution rate was found to be 2.84 and dissolution efficiency was found to be 57.48 and it is increased by 3.5 fold with F4 formulation compared to control tablets (17.91). From the above results, it is concluded that the formulation of solid dispersions using polyethylene glycol 20000 is a suitable approach to improve the solubility and dissolution rate of flurbiprofen.

INTRODUCTION

One of the major challenges of pharmaceutical formulation scientists is to develop the oral dosage forms of poor aqueous solubility drugs, hence, two areas of pharmaceutical research that focus on improving the oral bioavailability of active agents include enhancing solubility and dissolution rate of poorly water-soluble drugs and enhancing permeability of poorly permeable drugs (Kaushik *et al.,* 2004). Enhancing the solubility and dissolution rate of drugs can be increased by a well-known process of fabricating solid dispersions (Patil *et al.,* 2009). This study focuses on the use of solid dispersion technologies to improve the dissolution of poorly water-soluble drugs and in turn their oral bioavailability. Solubility enhancement will increase the drug's acceptability and bioavailability by reducing the dose required and sometimes can result in faster onset of action (Chang *et al.,* 2000 & Bhaskar *et al.,* 2005). Solid dispersions are molecular dispersions of drugs in a polymer in solid form. These can be prepared by various methods. Solvent evaporation method and fusion method are widely used depending upon the requirement (Vippagunta *et al.,* 2002). Flurbiprofen (FLB) is a poor water soluble drug (pKa=4.42) that is available in the market as a non steroidal anti inflammatory agent (Veerareddy *et al.,* 2012). In the present study our efforts are towards making a solid dispersion of FLB that can increase the solubility and dissolution rate using PEG 20000. PEG act as continuous phase in the solid dispersion in which FLB is dispersed as internal phase. Some of the recent research examples for FLB fast dissolving systems are flurbiprofen fast disintegrating tablets (Vemula *et al.,* 2011), flurbiprofen fast dissolving tablets (Mettu *et al.,* 2013) and flurbiprofen solid dispersions (Patel *et al.,* 2011).

In the present study, solid dispersions of FLB were prepared using PEG 20000 by solvent evaporation method. Some of the reported drugs as PEGs solid dispersions are nisoldipine (El-Maghraby *et al.,* 2014), simmvastatin (Bolourchian *et al.,* 2013), diclofenac sodium (Cwietrnja 2013), clopidrogel (Singh *et al.,* 2011), gliclazide (Biswal *et al.,* 2009). From the support of above literature, it was planned to prepare the FLB-PEG 20000 solid dispersions to enhance the dissolution rate.

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MATERIALS AND METHODS

Materials

Flurbiprofen was gift sample from FDC Limited, Mumbai, India. PEG 20000 was obtained from CDH, Delhi, India and all other reagents used were of analytical grade and obtained from S.D. Fine Chemicals, Mumbai, India.

Preparation of solid dispersions by solvent evaporation method

Solid dispersion of FLB with PEG 20000 in different weight ratios were prepared by the solvent evaporation method (Table 1). Accurately weighed amount of drug and carriers in various ratios dissolved in ethanol in a round bottom flask and the solvent was evaporated at 45 °C temperature. Solid dispersions were subsequently stored in a vacuum oven at room temperature for 48 h to remove the residual solvent. The dried solid dispersions were grinded in a mortar and pestle and passed through sieve no. 60 and were stored in desiccators until use.

Table. 1: Formulation of FLB-PEG20000 solid dispersions.

Formulation Code	Flurbiprofen	FLB:PEG 20000 ratio
F1	50	1:0.5
F2	50	1:1
F3	50	1:2
F4	50	1:4
F5	50	1:6
F6	50	1:8

Table. 2: Solubility studies of FLB-PEG 20000 solid dispersions by solvent evaporation method in various solvents (mg/ml).

Formulation Code	FLB solubility in mg/ml		
	0.1 N HCl	Distilled Water	7.2 pH Buffer
Pure FLB	0.064±0.03	0.156±0.08	0.198±0.11
F1	0.129±0.57	0.338±0.49	0.412±0.81
F2	0.148±0.34	0.411±0.15	0.498±0.42
F3	0.170±0.54	0.486±0.37	0.572±0.28
F4	0.184±0.72	0.571±0.64	0.651±0.16
F5	0.187±0.48	0.573±0.56	0.654±0.42
F6	0.191±0.22	0.578±0.87	0.659±0.81

Solubility studies

The solubility studies of different solid dispersion formulations were conducted in 0.1 N HCl, distilled water and 7.2 pH phosphate buffers. An excess amount of FLB solid dispersion was weighed and transferred into conical flasks which contain 10 ml of media. The content in conical flask were sonicated for 2 h at room temperature, there after the samples were placed on a shaker, agitated at room temperature for 48 h. Subsequently, the suspensions were filtered through a Whatman filter paper. The filtrate was suitably diluted and analyzed spectrophotometrically at a wavelength of 247 nm using a double beam UV-Visible spectrophotometer.

Drug-carrier compatibility studies

The thermograms were recorded for drug, carrier, and physical mixture using differential scanning calorimeter (Shimadzu, Japan). About 2-4 mg sample in an open aluminium standard pan was heated at a scanning rate of 5 °C /min from a temperature 0 to 450 °C under a nitrogen gas flow.

Micromeritic properties of blend

The flow properties of powder are vital in the manufacture of tablets. The flow properties were studied through measuring the angle of repose, Carr's index. Powder mixtures of different formulations were evaluated for angle of repose, bulk density, tapped density and compressibility index. The fixed funnel method was employed to measure the angle of repose (θ) and it was calculated using the following formula:

$$Tan\ \theta = h/r \qquad \ldots [1]$$

In which, θ is the angle of repose, h is the height of the cone and r is radius of the cone base. To measure the angle of repose, a funnel was fixed to a stand so that the lower tip of funnel was 2.5 cm above the surface. A graph paper was placed on a flat surface. The powder blend was allowed to fall freely on the graph paper through the funnel (6.8 cm diameter), till the tip (8 mm diameter) of heap formed just touches the funnel. The radius of heap was noted and from this angle of repose was determined. The bulk density (ρ_b) of a powder is determined by measuring the volume of a known mass of powder sample that may have been passed through a screen, into a 50 ml graduated cylinder. Tapped density (ρ_{tap}) of powder samples were determined by a tap density apparatus. The apparatus was set for 500 tapings for 5 min at stroke height 20 mm at the rate of 100 strokes/min (Vemula *et al.,* 2013a). The Carr's Index is a measure of the propensity of a powder to be compressed and it is calculated using the following formula:

$$Carr's\ Index = [(\rho_{tap} - \rho_b) / \rho_b] / \times 100 \qquad \ldots [2]$$

Preparation of fast dissolving tablets

From the results of dissolution and solubility studies, the fast dissolving tablets (FDTs) were prepared for selected solid dispersion preparations (Table 4). The FDTs were prepared by direct compression method. The solid dispersion powder equivalent to 10 mg of FLB, Crosspovidone and other tabletting excipients were passed through a mesh no 60. The powdered solid dispersion was mixed with proper portion of Crosspovidone. Then excipients other than glidant and lubricant were added and mixed in a poly bag for 5-10 min. The obtained blend was lubricated with talc and magnesium stearate for another 5 min and the resultant mixture was directly compressed into tablets using rotary tabletting machine. In the similar way, the control tablets were prepared using pure FLB by direct compression method.

Evaluation of physical parameters

The designed formulations were studied for their physical properties like weight variation, hardness and friability. For estimating weight variation, 20 tablets of each formulation were weighed using an electronic weighing balance (AW 120, Shimadzu Corporation, Japan). The hardness of six tablets was measured using Monsanto tablet hardness tester. Friability was determined on ten tablets in a Roche friabilator (Electrolab, Mumbai, India). For estimation of drug content, ten tablets were crushed, and 100 mg of the powder was accurately weighed and transferred to a 100 ml volumetric flask. Initially about 50 ml of

7.2 pH phosphate buffer was added to the volumetric flask and allowed to stand for 6-8 h with intermittent shaking to ensure complete solubility of the drug. Then the volume was made up to 100 ml with buffer, filtered and analyzed for FLB content at 247 nm.

***In vitro* disintegration time**

In vitro disintegration time of FDT's was determined by following the procedure described by Gohel et al. Briefly, 10 ml of water at room temperature was taken in a petridish of 10 cm in diameter. The tablet was then carefully placed in the centre of petridish and the time required for the tablet to completely disintegrate into fine particles was noted. Measurements were carried out in triplicates (Gohel *et al.,* 2004).

***In vitro* Dissolution Study**

The release of FLB from FDTs was carried out using USP XXIV Type II dissolution apparatus (Electro lab, TDT-08L) at a rotation speed of 50 rpm, and a temperature of 37±0.5 °C. The drug release studies were carried out in 7.2 pH phosphate buffer. An aliquot of 5 ml was collected at predetermined time intervals and replaced with fresh dissolution medium. The samples were filtered, by passing through 0.45 µm membrane filters (Millipore, USA) and analyzed spectrophotometrically at 247 nm. Cumulative percent drug release was plotted as a function of time and percent drug release in 15 min (Q15) was calculated. Initial dissolution rate (IDR) was calculated as percentage dissolved of drug over the first 15 min per min. Dissolution efficiency (DE) was calculated from the area under the dissolution curve at time t (measured using the trapezoidal rule) and expressed as a percentage of the area of the rectangle described by 100% dissolution in the same time. Relative dissolution rate (RDR) is the ratio between amount of drug dissolved from optimized formulation and that dissolved from the control formulation at 15 min.

Stability studies

The stability studies of prepared tablets were planned on the best formulation according to ICH guidelines. The packed samples (n=3) were stored in the stability chamber maintained at 40±2 ^{0}C and 75±5% RH for six months. After six months of storage, the samples were collected and analyzed for assay and *in vitro* dissolution rate. Then the data was analyzed using paired t-test to test the significant variation at 0.05 level of significance (LS). Then the similarity index (F2) was calculated between dissolution rates of tablets before and after storage to prove the stability of tablets (Vemula *et al.,* 2013a & Vemula *et al.,* 2013b).

RESULTS

Solubility studies of FLB solid dispersions

The solubility studies were conducted in different media for all the prepared solid dispersions and compared with pure drug. The aqueous solubility of the solid dispersion formulations of different carriers was determined in different media i.e., 0.1 N HCl, distilled water and phosphate buffer pH 7.2. From the solubility studies, it was found that as the increase in pH of the media increased the solubility i.e. FLB showed greater solubility in 7.2 pH phosphate buffer when compared others. The solubility data of different formulations using different carriers showed in Table 2. From the results given in above tables, solid dispersions with PEG 20000 showed significant improvement in solubility with increasing PEG ratio up to 1:4 ratios, but after no significant improvement in solubility by increasing the ratio of carrier. From all the solid dispersions, formulation F4 showed highest solubility in 7.2 pH phosphate buffer.

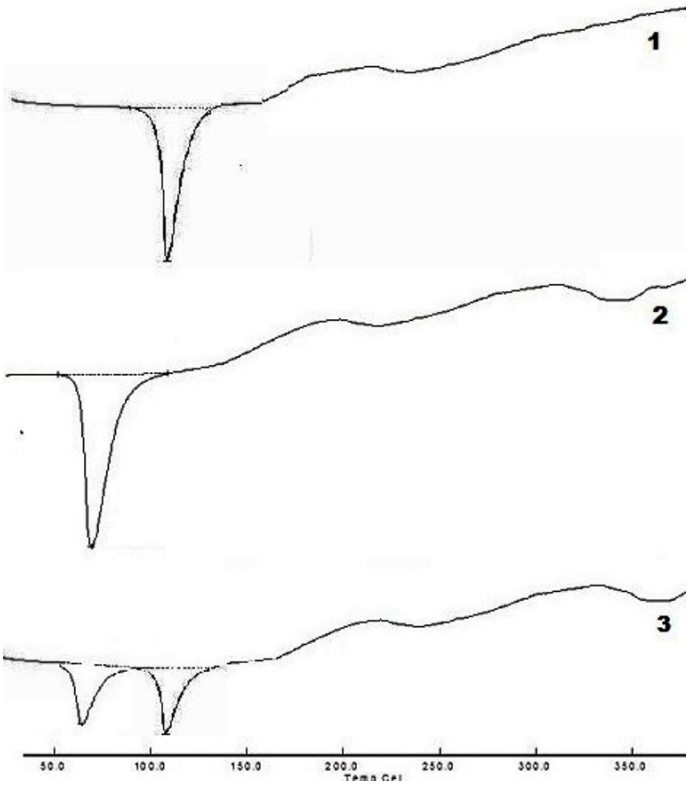

Fig. 1: DSC thermograms of A) FLB B) PEG 20000 C) F4 physical mixture.

Drug-carrier compatibility studies

The thermograms of the FLB, gelucire 44/14, of FLB with PEG 20000 were shown in Figure 1. The DSC thermograms of FLB exhibited physical mixture a sharp endothermal peak around 116°C corresponding to melting point. The DSC thermogram of PEG 20000 exhibited a broad endothermal peak around 69 ^{o}C corresponding to its melting point. The thermogram of physical mixture with PEG 20000 showed a short endothermal peak of drug at 115.8°C indicating that there were no interactions between drug and carrier.

Micromeritic properties of blend

The powder mixture for tablets were characterized with respect to angle of repose, bulk density, tapped density and Carr's index, (Table 3). Angle of repose was less than 35° and Carr's index values were less than 21 for the powder mixture of all the batches indicating good to fair flowability.

Table. 3: Evaluation of pre-compression parameters (Mean ± SD, n=3).

Formulation	Angle of Repose (^{0})	Bulk Density (gm/cc^3)	Tapped Density (gm/cc^3)	Carr's Index (%)
F4	27.87±1.56	0.324	0.382	15.18
Control	26.72±3.15	0.317	0.372	14.78

Table. 4: Composition of FLB tablets using selected solid dispersions.

Formulation Code	Ingredients in mg	
	F4	Control
FLB Solid dispersion equivalent to 50 mg FLB	250	-
Pure FLB	-	50
Crosspovidone (5%)	15	7.5
Spry-dried lactose	26	88
Magnesium stearate (1%)	3	1.5
Talc (2%)	6	3

Evaluation of Fast Dissolving Tablets

Based on the solubility studies, the better solid dispersions were converted into tablets. Table 5 showed all the physical parameters determined for FLB tablets. In weight variation test, the pharmacopoeial limits for the tablets of not more than 5% of the average weight. The tablet hardness and friability were found to be around 3.0 kg/cm^2 and 0.38%, demonstrating the integrity and strength of tablets. The tablets assay was found to contain 99.14±1.32%. From the disintegration test, the prepared tablets were disintegrated rapidly and it was found to be around 120 sec.

Table. 5: Physical Properties of FLB Tablets.

Formulation	Weight variation* (mg)	Hardness† (Kg/cm^2)	Friability (%)	Disintegration time‡ (sec)	Drug content‡ (%)
F4	301.72±1.26	3.0±0.21	0.38	121±4	99.14±1.32
Control	151.68±1.13	3.1±0.14	0.27	118±4	99.96±1.47

* All values represent mean ± standard deviation, n=20; † n=6; ‡ n=3

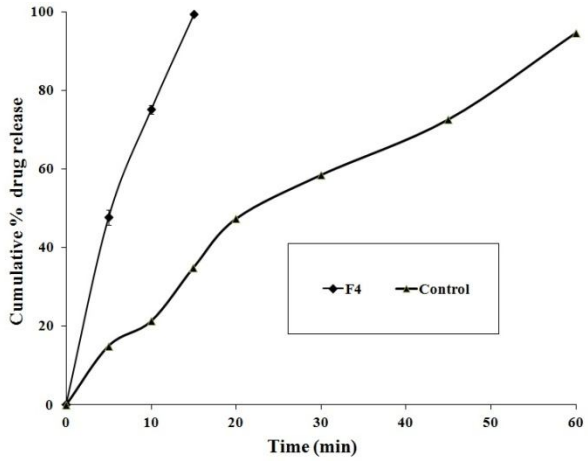

Fig. 2: Dissolution studies of FLB tablets containing FLB solid dispersions.

Dissolution Studies of Fast Dissolving Tablets

From the in vitro dissolution studies, tablets made from 1:4 ratio solid dispersion (F4) showed fast dissolution (99.26±1.12% in 15 min) than other formulations and improved significantly when compared to control tablet (94.61±1.51% in 60min). Figure 2 demonstrated the FLB release patterns by above formulations. The percent drug release in 15 min (Q_{15}) and initial dissolution rate (IDR) for formulation F4 was 99.26±1.12%, 6.62%/min. These were very much higher compared to pure drug (34.95±1.29%, 2.33%/min). The improvement in the dissolution characteristics of a drug described in terms of dissolution efficiency (DE) and relative dissolution rate (RDR). The RDR was found to be 2.84. The DE was found to be 57.48 and it is increased by 3.5 fold with optimized FDT formulation compared to control tablets i.e., 17.91 (Table 6).

Table. 6: Dissolution Parameters of FLB optimized tablets (F4) and conventional (Mean ± SD, n=3).

Formulation	(Q_{15})	IDR (%/min)	DE	RDR
F4	99.26±1.12	6.62	57.48	2.84
Control	34.95±1.29	2.33	17.91	

Stability studies

Manifest the prospective utility of the formulation, stability studies were carried out at 40±2°C and 75±5% RH for six months to measure the stability of drug. After storage of six months, the formulation F4 was subjected to a drug assay and i*n vitro* dissolution studies (Table 7) and from the statistical analysis there was no significant difference between before and after storage ($P < 0.05$). The similarity index value between dissolution profiles of optimized formulation before and after storage was found to be 91.67.

Table. 7: Stability Studies of FLB F4 tablets (n=3).

Time (min)	Before storage	After 6 months storage	*t*-test at 0.05 LS	Similarity Factor (F2)
0	0.00±0.00	0.00±0.00	Not	91.67
5	47.68±1.62	46.26±1.29	Significant	
10	75.12±1.78	73.98±1.61		
15	99.26±1.12	98.12±1.35		
% Assay	99.14±1.48	98.52±1.32	Not Significant	--

DISCUSSION

The current investigation is aimed to develop the FLB solid dispersions to improve the solubility and dissolution rate. In this study, FLB solid dispersions were prepared by using solvent evaporation method by incorporating PEG 20000 as carrier. After preparation of solid dispersions, measurement of aqueous solubility is one of the key factors, which govern the dissolution rate and it is the rate limiting step in absorption of poorly soluble drugs. The solubility of FLB solid dispersion formulations of different carriers was determined in different media i.e., 0.1 N HCl, distilled water and phosphate buffer pH 7.2. From the solubility studies of different formulations, it was found that as the increase in pH of the media increased the solubility. All the formulations exhibited significant increase in solubility in phosphate buffer pH 7.2. Similar type of results observed in Patel et al study i.e., the solubility of flurbiprofen was measured in four different media and the results showed that the solubility of the flurbiprofen was highest at pH 7.2, and decreased as the pH decreases (Patel *et al.*, 2011). From the formulations with PEG 20000 as hydrophilic carrier, as increasing the drug to polymer from 1:1-1:4 ratio, the solubility of FLB was increased at a

significant level, but after that, there was no proportional increase in solubility by increasing polymer ratio. From the solubility studies, all the formulations showed significant increase in solubility when compared to pure drug and physical mixture of drug-carrier. The DSC studies of pure drug, PEG 20000 and physical mixture of both showed that there was no interaction between drug and carrier.

After the completion of solubility studies, then the powder mixtures of solid dispersions were evaluated for physical parameters like angle of repose, tapped density, bulk density and Carr's index. The results of angle of repose (< 40) and Carr's index (< 22) indicates fair to passable flow properties of the powder mixture. Based on the above results, the prepared solid dispersions of F4 formulations were converted into tablets and evaluated for physical parameters as well as *in vitro* dissolution rate. The prepared tablets were studied for their physical properties like weight variation, hardness, friability and drug content uniformity and they were complied with pharmacopoeial limits. The average percentage deviation of all tablet formulations was found to be within the mentioned limit and. From the physical characterization, the prepared tablets were uniform in hardness, friability and drug content uniformity. Then the tablets were subjected to *in vitro* drug release studies in 7.2 pH phosphate buffer. From the *in vitro* dissolution studies, FLB in the form of solid dispersion (F4 formulation i.e., 1:4 ratio) showed significant increase in dissolution rate when compared to tablets with pure FLB. In the following reported study, similar type of solubility enhancement was observed with PEG 6000 solid dispersions (Singh *et al.,* 2011). The probable reasons and mechanisms of increased dissolution rates of solid dispersions have been proposed by Ford. It includes a decrease in crystallite size, solubilization effect of the carrier, absence of aggregation of drug crystallites, enhanced wettability and dispersability of the drug from the dispersion, dissolution of the drug in the hydrophilic carrier, drug conversion to amorphous state and finally, a combination of the mentioned mechanisms (Patil *et al.,* 2009).

Overall increase in the dissolution performance of the optimized formulation was described in terms of dissolution parameters (IDR, DE, RDR) and when compared with pure drug, all the above parameters were increased in case of F4 formulation. Similar type of improvement in IDR, DE, RDR was reported in the study of Vemula et al (Vemula, 2011). After storage of six months, the formulation was subjected to a drug assay and *in vitro* dissolution studies and the data showed that there was no significant change. The similarity index value was found as 91.67, which is more than 50 indicates similarity between the dissolution profile before and after storage (Vemula *et al.,* 2013a & Vemula *et al.,* 2013b). Further the pharmacokinetic evaluation is needed to prove the capability of PEG 20000 solid dispersions to improve the bioavailability of FLB.

CONCLUSION

In the present study, various weight ratios of flurbiprofen and carriers used to prepare the solid dispersions and evaluated for physiochemical properties. Dissolution rate of solid dispersion tablets was improved significantly when compared to control tablets due to intermolecular interactions between the polymer and drug. The percent drug release in 15 min (Q_{15}) and initial dissolution rate (IDR) for F4 tablets was 99.26±1.12%, 6.62%/min. These were very much higher compared to pure drug (34.95±1.29%, 2.33%/min). The improvement in the dissolution characteristics of a drug described in terms of dissolution efficiency (DE) and relative dissolution rate (RDR). The RDR was found to be 2.84. The DE was found to be 57.48 and it is increased by 3.5 fold with optimized FDT formulation compared to control tablets. In conclusion, development of the solid dispersions can be a promising alternative method to attain the fast dissolution rate and absorption for water-insoluble drugs like flurbiprofen and it was achieved with PEG 20000 as carrier. Further the pharmacokinetic evaluation is needed to prove the capability of PEG 20000 solid dispersions to improve the bioavailability of flurbiprofen.

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