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Original Article

ENHANCEMENT OF SOLUBILITY AND DISSOLUTION OF IBUPROFEN BY SOLID DISPERSION TECHNIQUE AND FORMULATION OF SUSTAINED RELEASE TABLETS CONTAINING THE OPTIMISED BATCH OF SOLID DISPERSION

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ABSTRACT

Objective: The present study was aimed to enhance the solubility of poorly water soluble drug Ibuprofen using solid dispersion technique and to develop sustained release tablets containing solid dispersion granules of the optimized batch. Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) with analgesic, antipyretic, and anti-inflammatory properties

Methods: Solid dispersions of Ibuprofen were prepared by using PEG 20000 and Poloxamer 407 in different weight ratios by fusion and solvent evaporation method. Drug-carrier physical mixtures were also prepared. Solid dispersions were characterized by saturation solubility, drug content, *in vitro* dissolution, FTIR and DSC analysis. Solid dispersion formulation, SDF9 (PEG 20000 and Poloxamer 407, 1:3:3) prepared by solvent evaporation method was considered as the optimized batch. Sustained release tablets containing the solid dispersion granules of the optimized batch were prepared by direct compression method using HPMC K100M at three concentrations (10%, 14%, 18% w/w). The prepared formulations were evaluated for hardness, thickness, weight variation, friability, *in vitro* dissolution studies and release kinetics modelling.

Results: Solid dispersion formulation, SDF9showed 95.09% drug release in 60 min and considered as the optimized batch. Tablet formulation, FT3 (HPMC K100M 18% w/w) showed 96% drug release for 12 h.

Conclusion: Solid dispersions of ibuprofen using a combination of PEG 20000 and poloxamer 407 by solvent evaporation method may result in higher aqueous solubility of the drug. Also sustained release tablets containing solid dispersion granules of ibuprofen, using HPMC K100M may be a promising approach to extend the release rate of the drug from the solid dispersion for 12 h.

Keywords: Solid dispersion, Ibuprofen, PEG, Poloxamer, Sustained Release, HPMC K100M

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INTRODUCTION

The poor aqueous solubility and dissolution rate of a drug is one of the biggest challenges in pharmaceutical development. Especially the compounds belonging to BCS Class II, which are poorly soluble and highly permeable, tend to present solubility or dissolution rate-limited absorption. Despite their high permeability, these drugs often have low oral bioavailability because of their slow and limited release of drug in gastrointestinal fluid [1].

One of the most successful strategies to improve the dissolution of poorly soluble drugs is solid dispersion technique. The term solid dispersions have been defined as a dispersion of a drug in an inert carrier or matrix at the solid state prepared by solvent, melting or solvent–melting method. Numerous studies on solid dispersions have been published and have showed many advantageous properties of solid dispersions in improving the solubility and dissolution rate of poorly water soluble drugs. These advantages include reducing particle size, possibly to the molecular level, enhancing wet ability and porosity, as well as changing drug crystalline state, preferably into the amorphous state [4].

Oral route is the most oldest and convenient route for the administration of drugs because of low cost of therapy and higher patient compliance. During the past three decades, numerous oral drug delivery systems have been developed from which the drug can be released over a defined period of time at a predetermined and controlled rate. The sustained release, controlled release, extended release, timed release etc. are terms used to identify drug delivery system that are designed to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose [7]. The oral sustained release formulation has been developed for those drugs that are easily absorbed from the gastrointestinal tract (GIT) and have a short half-life, which are eliminated quickly from the blood circulation. They release the drug slowly into the GIT and maintain a constant drug concentration in the plasma within the therapeutic range for a longer period of time. Sustained release dosage forms provide advantages like reduction of dosing frequency, less local and systemic side effects and greater patient compliance [8].

Ibuprofen, a propionic acid derivative, is a non-steroidal anti-inflammatory drug (NSAID) with analgesic, antipyretic and anti-inflammatory properties. Its pharmacological effects are due to inhibition of COX-2which decreases the synthesis of prostaglandins involved in mediating inflammation, pain, fever and swelling. Antipyretic effects may be due to action on the hypothalamus, resulting in an increased peripheral blood flow, vasodilation and subsequent heat dissipation. Inhibition of COX-1 is thought to cause some of the side effects of ibuprofen including GI ulceration. Ibuprofen is a BCS class II drug and thus possesses dissolution rate-limited absorption which leads to low oral bioavailability. It has a biological half-life of 1.3-3 h. [5]

The aim of the present study was to enhance the aqueous solubility and dissolution of ibuprofen by solid dispersion technique using selected hydrophilic polymers like PEG 20000 and poloxamer 407. Also to fabricate sustained release tablets containing solid dispersion granules of the optimised batch, using HPMC K100M to extend the release rate of the drug from the solid dispersion for 12 h.

MATERIALS AND METHODS

Materials

Ibuprofen was obtained from Yarrow Chem, Mumbai-37, India. Methanol and ethanol were obtained from Changshu Yangyuan

Chemical Co., Ltd., Sozhou, China. Hydrochloric acid, potassium dihydrogen phosphate, sodium hydroxide, PEG 20000, Poloxamer 407,HPMC K100M,Aerosil®200 were obtained from Merc Specialist Pvt. Ltd., Shiv sagar estate, Mumbai-400018, India. Spray dried lactose and talc were obtained from Balaji Drugs, Mumbai-37, India. All chemicals used were of analytical grade.

Methods

Preparation of solid dispersions

Melting or fusion method [2]

The prerequisite for this technique is crystalline starting materials. Solid dispersions of Ibuprofen were prepared by melting or fusion method using PEG 20000 and Poloxamer 407 as hydrophilic carriers respectively at weight ratios of 1:1, 1:2 and 1:3 (drug: carrier). The required amount of drug and carrier were melted in a petri-dish on a hot plate maintained at 80 °C. The molten mass was then mixed thoroughly with a glass rod for homogeneous mixing. Then the mass was cooled at room temperature, powdered in a mortar, sieved through a 60-mesh screen and stored in a desiccator for further evaluation.

Solvent evaporation method [4]

An important prerequisite for the manufacture of solid dispersion using this method is that both the drug and the carrier should be soluble in the solvent. Solid dispersions of Ibuprofen were prepared by solvent evaporation method using a combination of PEG 20000 and Poloxamer 407 at weight ratios of 1:1:1, 1:2:2 and 1:3:3 (drug: carrier: carrier). The respective amount of PEG 20000 and poloxamer 407 were dissolved in sufficient quantity of methanol in a petri dish and then the required amount of drug was added slowly with continuous stirring to obtain a clear solution. The solution was then heated on a water bath until the solvent is evaporated. The resultant solid dispersions were allowed to dry at room temperature, powdered in a mortar, sieved through a 60-mesh screen and stored in a desiccator for further evaluation.

Table 1: Formulation of solid dispersions by melting/fusion method

Ingredients	SDF1	SDF2	SDF3	SDF4	SDF5	SDF6
Ibuprofen(mg)	500	500	500	500	500	500
PEG 20000(mg)	500	1000	1500			
Poloxamer 407(mg)				500	1000	1500

Table 2: Formulation of solid dispersions by solvent evaporation method

Ingredients	SDF7	SDF8	SDF9
Ibuprofen(mg)	500	500	500
PEG 20000(mg)	500	1000	1500
Poloxamer 407(mg)	500	1000	1500

Preparation of physical mixture [3]

The physical mixtures in the same weight ratio as the solid dispersions mentioned above were prepared by thoroughly mixing the appropriate amounts of ibuprofen and carrier(s) for 10 min in a mortar. The mixtures were sieved through a 60-mesh screen and stored in a desiccator for further evaluation.

Table 3: Formulation of physical mixtures

Formulation	Ibuprofen (mg)	PEG 20000 (mg)	Poloxamer407(mg)
PMF1	500	500	
PMF2	500	1000	
PMF3	500	1500	
PMF4	500		500
PMF5	500		1000
PMF6	500		1500
PMF7	500	500	500
PMF8	500	1000	1000
PMF9	500	1500	1500

Evaluation of solid dispersions

Drug content [3]

An amount equivalent to 25 mg of ibuprofen from each formulation was taken and dissolved in 50 ml of methanol in stoppered conical flasks. The sealed flasks were agitated on a rotary shaker for 1 h. The solutions were filtered and diluted suitably with methanol and assayed using a UV–VIS Spectrophotometer for drug content at 221 nm.

Percent drug content= (practical drug content in solid dispersions/ theoretical drug content in solid dispersions) x 100

Saturation solubility determination [3]

The saturation solubility of the formulations was determined in distilled water, 0.1N HCl and phosphate buffer pH 6.8 by the following procedure: the Excess amount of each formulation was taken and dissolved in a measured amount of solution of each solvent in a volumetric flask to get a saturated solution. Each solution was shaken in a rotary shaker for a period of 24 h. After 24hs the solutions were filtered and diluted suitably. The concentration of ibuprofen in each solution was analysed by UV-VIS spectrophotometer using distilled water, 0.1N HCl and phosphate buffer pH 6.8 as blank respectively.

***In vitro* dissolution studies [6]**

Powder dissolutions were performed using USP Type-II dissolution apparatus, thermostatically controlled at 37°C ± 0.5°C and phosphate buffer pH 6.8 was used as dissolution media. Samples of drug, solid dispersions and physical mixtures equivalent to 100 mg of ibuprofen were introduced into the 900 ml of dissolution medium, stirred at 50 rpm. Samples were withdrawn at 15, 30, 45, and 60 min. The volume withdrawn at each time interval was replaced with a fresh quantity of the dissolution medium. The samples were filtered, diluted accordingly and analysed spectrophotometrically in UV–VIS Spectrophotometer.

Fourier transform infrared spectroscopy study [3]

The FT-IR study was performed for the drug ibuprofen, PEG 20000, poloxamer 407 and selected solid dispersion formulations-SDF7, SDF8, SDF9. Another FT-IR study was performed for the physical mixture of SDF9 and HPMC K100M to assess the drug-excipient compatibility before the formulation of sustained release tablets. A small amount of each sample was taken in a mortar and triturated. The triturated sample was taken in the sample chamber of the instrument and scanned from 400 cm-1 to 4000 cm-1 in Bruker FT-IR spectrophotometer. The spectra obtained were compared and interpreted for the functional group peaks.

Differential scanning calorimetry study [6]

Differential scanning calorimetry (DSC) of the drug and a selected formulation SDF9 were performed using Perkin Elmer DSC 4000 for the measurement of heat loss or gain resulting from physical or chemical changes within a sample as a function of temperature. About 6-7 mg of the sample was weighed in aluminium DSC pans and hermetically sealed capsules were prepared with aluminium lids. An initial ramp was used to jump the temperature to 30 °C and then a constant heating rate of 10 °C/min was used up to 400 °C under nitrogen atmosphere.

Preparation of sustained release tablets containing solid dispersion granules

Solid dispersion formulation SDF9 was chosen the optimised formulation based on the dissolution characteristics and sustained release tablets containing the solid dispersion granules of the optimised batch was prepared. Sustained release tablets containing the solid dispersion granules equivalent to 100 mg of ibuprofen were prepared by direct compression method using HPMC K100M as release retarding polymer at three different concentrations (10%, 14% and 18% w/w). Spray dried lactose was used as directly compressible diluent. Other excipients were Aerosil® 200 (colloidal silicon dioxide) as a Glidant and Talc as a lubricant. The solid dispersion granules and all other excipients were weighed accurately and individually passed through sieve number 60 and mixed thoroughly by triturating up to 15 min. The powder mixture was compressed using 12 mm diameter, flat punches in a single punch tablet compression machine [8].

Table 4: Formulation of sustained release tablets containing solid dispersion granules

Ingredients	FT1	FT2	FT3
Solid dispersion(Equivalent to 100 mg Ibuprofen)	416 mg	416 mg	416 mg
Spray Dried Lactose	110 mg	86 mg	62 mg
HPMC K100M	60 mg (10%)	84 mg (14%)	108 mg (18%)
Aerosil® 200	5 mg	5 mg	5 mg
Talc	9 mg	9 mg	9 mg
Total	600 mg	600 mg	600 mg

Evaluation of post-compression parameters of sustained release tablets

Weight variation [7]

20 tablets were selected from each batch, weighed individually and the average weight was calculated. The individual weight of the tablets was then compared to the average weight. The percentage of weight variation was calculated using the following formula-

% weight variation= (Individual Weight–Average Weight)/(Average Weight) × 100

Thickness [7]

Thickness of 10 randomly selected tablets from each formulation was examined by using Vernier callipers.

Hardness [9]

The hardness of the tablets was determined using Monsanto hardness tester. It was expressed in kg/cm^2. 3 tablets were randomly picked from each batch and analysed for hardness.

Friability [8]

10 tablets of each batch were weighed and put into Roche friabilator and operated for 4 min at 25 rpm. The tablets were recovered and freed from dust and weighed. Friability was calculated from the following formula:

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Drug content [9]

3 tablets from each batch were weighed and powdered. Powder equivalent to 100 mg of drug was weighed and dissolved in 100 ml of phosphate buffer pH 6.8, filtered, diluted suitably and analysed for drug content at 221 nm using UV-VIS spectrophotometer.

***In vitro* dissolution studies [8]**

The release rate of all designed formulations was studied up to 12 h. The procedure was determined using USP Type II dissolution test apparatus. The dissolution test was performed using 900 ml of Phosphate Buffer of pH 6.8 at 37±0.5 °C and 50 rpm. A sample of 10 ml of the solution was withdrawn from the dissolution apparatus at 1 h intervals with the replacement of fresh dissolution medium for 12 h. The samples were filtered and diluted to a suitable concentration with phosphate buffer. The absorbance of these solutions was measured at 221 nm using a Shimadzu UV-1800 double-beam spectrophotometer.

Kinetics and mechanism of release analysis [8]

To study the release kinetics, the data obtained from *in vitro* drug release studies were plotted in various kinetic models like zero order, first order, Higuchi's model, Korsmeyer-Peppas power law equation and Hixson-Crowell cube root equation.

RESULTS

Table 5: % Drug content of solid dispersions and physical mixtures

Formulation	% drug content
PM1	98.45
PM2	98.02
PM3	98.78
SDF1	97.65
SDF2	97.23
SDF3	98.65
PM4	98.74
PM5	98.50
PM6	98.63
SDF4	98.23
SDF5	98.25
SDF6	98.45
PM7	98.65
PM8	98.21
PM9	98.36
SDF7	97.65
SDF8	96.36
SDF9	98.87

Table 6: Saturation solubility of solid dispersions and physical mixtures

Formulation	Distilled water (mg/ml)	Phosphate buffer pH 6.8(mg/ml)	0.1N HCl(mg/ml)
PM1	0.122±0.05	0.465±0.06	0.187±0.14
PM2	0.150±0.06	0.529±0.09	0.201±0.07
PM3	0.154±0.05	0.641±0.19	0.205±0.05
SDF1	0.223±0.09	0.552±0.05	0.223±0.09
SDF2	0.284±0.06	0.767±0.03	0.245±0.06
SDF3	0.456±0.05	0.924±0.09	0.263±0.09
PM4	0.254±0.09	0.487±0.15	0.230±0.06
PM5	0.326±0.11	0.502±0.09	0.245±0.08
PM6	0.354±0.07	0.574±0.05	0.260±0.14
SDF4	0.369±0.06	0.560±0.14	0.356±0.09
SDF5	0.451±0.14	0.841±0.05	0.398±0.19
SDF6	0.545±0.06	1.002±0.11	0.402±0.05
PM7	0.288±0.05	0.767±0.06	0.304±0.09
PM8	0.365±0.06	0.784±0.08	0.365±0.09
PM9	0.463±0.06	0.965±0.04	0.398±0.05
SDF7	0.596±0.12	1.008±0.17	0.589±0.06
SDF8	0.742±0.05	1.103±0.09	0.841±0.07
SDF9	1.009±0.09	1.589±0.11	1.203±0.12

***In vitro* dissolution study of solid dispersions**

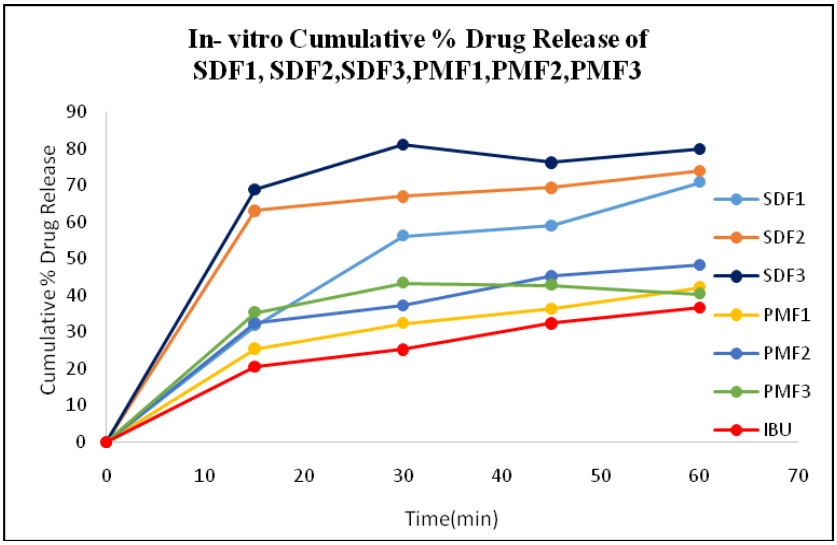

Fig. 1: *In vitro* cumulative % drug release of solid dispersions using PEG 20000

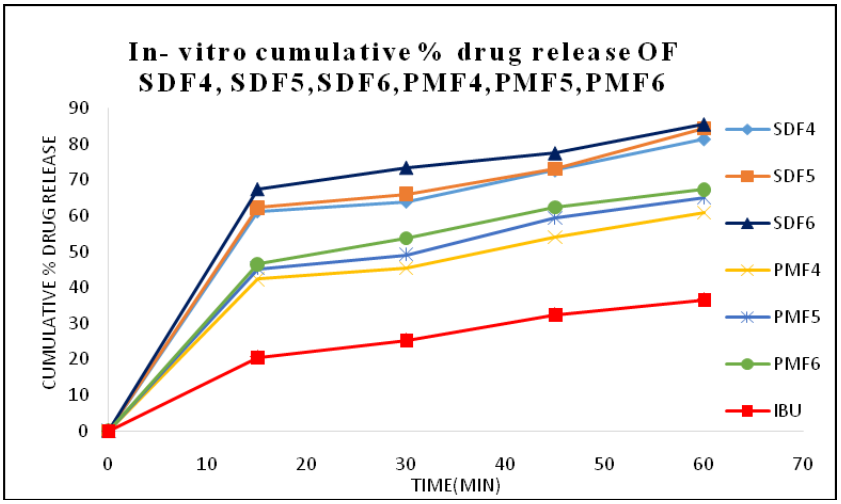

Fig. 2: *In vitro* cumulative % drug release of solid dispersions using poloxamer407

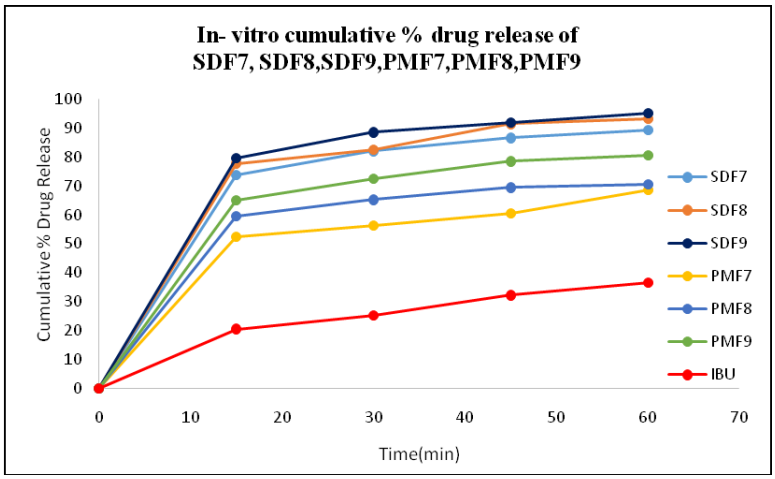

Fig. 3: *In vitro* cumulative % drug release of solid dispersions using combination of PEG 20000 and poloxamer 407

FT-IR study

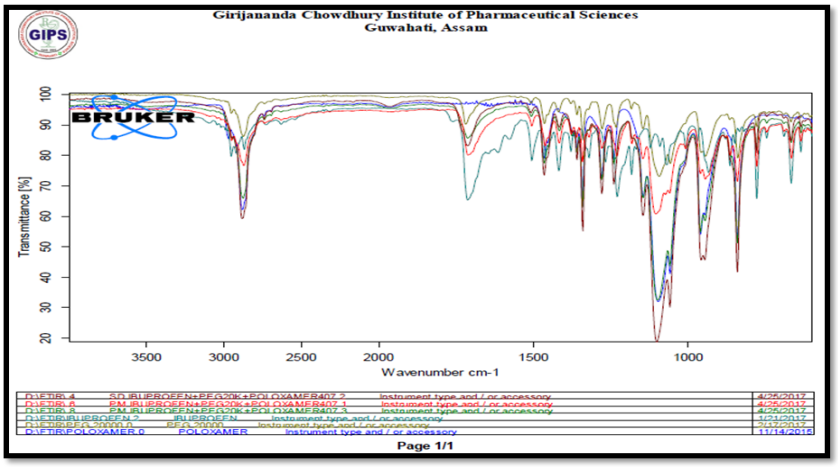

Fig. 4: IR spectra of ibuprofen, PEG 20000, poloxamer 407 and solid dispersions SDF7, SDF8, SDF9

Table 7: IR spectra interpretation of drug ibuprofen

S. No.	Interpretation	IR absorption bands(cm^{-1})
1	C-H	2953.83
2	C-C	1069.13
3	C=O	1712.94
4	C=C	1717.94
5	O-H	3088.96

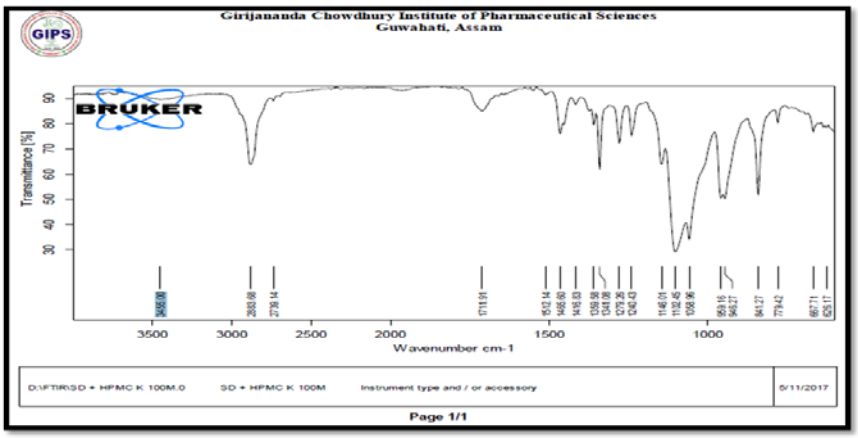

Fig. 5: IR spectra of SDF9 and HPMC K100M

Differential scanning calorimetry (DSC) analysis

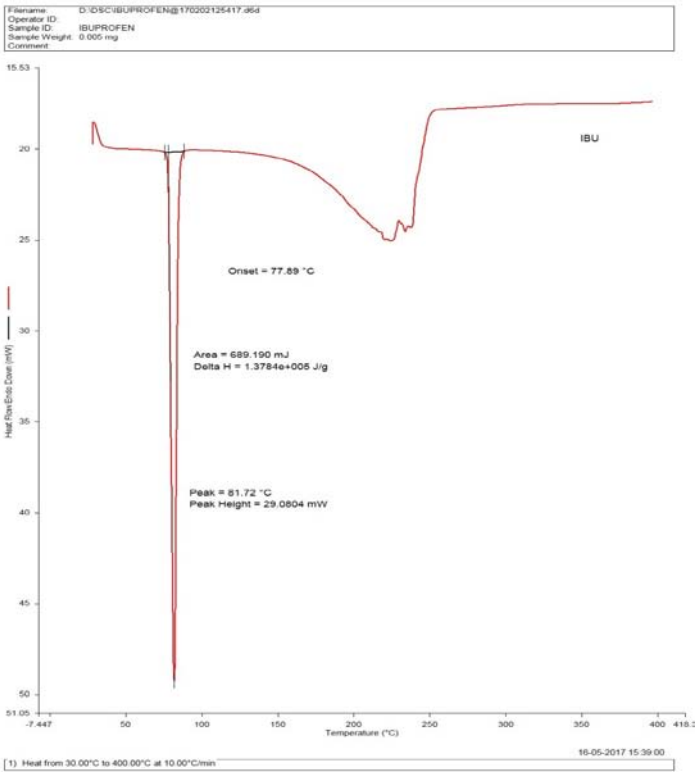

Fig. 6: DSC of ibuprofen

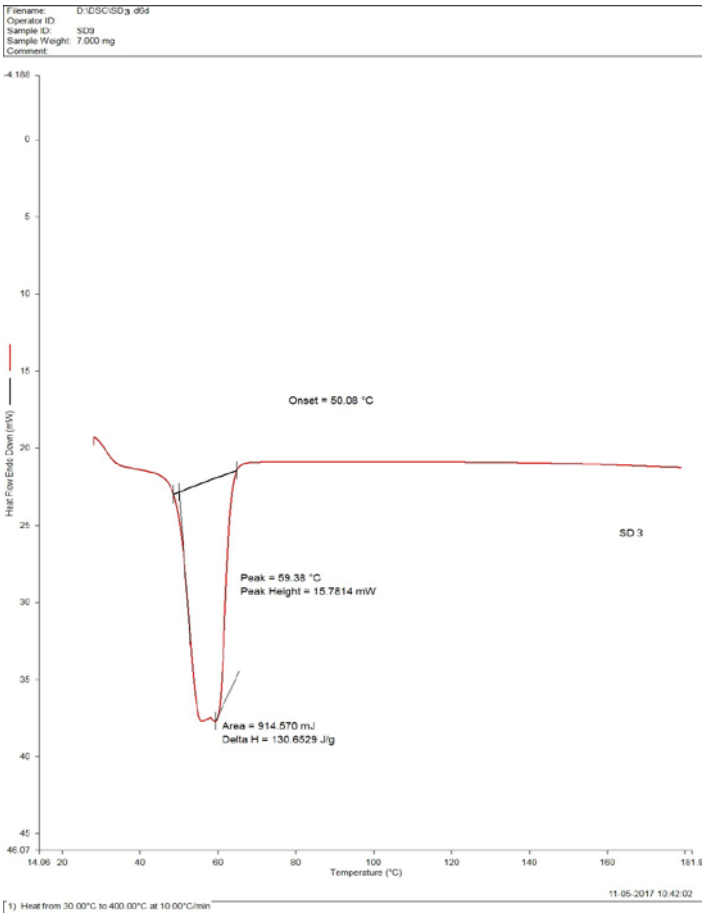

Fig. 7: DSC of IBU+PEG 20000+POLO 407 solid dispersion (1:3:3) [SDF9]

Evaluation of post compression parameters of tablet

Table 8: Evaluation of post compression parameters of tablet

	Post compression parameters				
Formulation code	**% weight variation**	**Thickness (mm)**	**Hardness (kg/cm2)**	**% friability**	**% drug content**
FT1	0.14±0.02	4.61±0.06	6.25±0.06	0.15±0.09	98.18±0.98
FT2	0.85±0.03	4.56±0.04	6.54±0.04	0.17±0.02	96.58±0.09
FT3	0.75±0.05	4.82±0.04	6.71±0.02	0.15±0.04	99.42±0.92

***In vitro* dissolution study of tablet formulations**

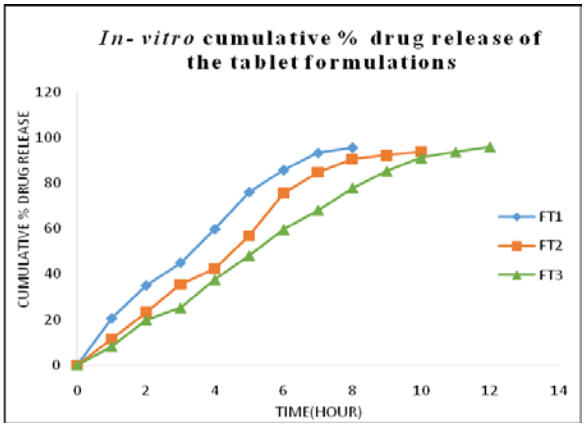

Fig. 8: *In vitro* cumulative % drug release of the tablet formulations

Table 9: Release kinetics data for evaluation of drug release mechanism

Formulation code	**Zero order**		**First order**		**Higuchi**		**Korsmeyer-peppas**			**Hixson-crowell**	
	k0	R2	k1	R2	kH	R2	kKP	N	R2	kHC	R2
FT1	13.615	0.9546	0.263	0.9617	32.362	0.9423	21.418	0.747	0.9903	0.072	0.986
FT2	10.799	0.9604	0.199	0.9328	28.301	0.8899	14.842	0.842	0.9731	0.056	0.9646
FT3	8.98	0.9778	0.163	0.936	25.613	0.8877	11.844	0.873	0.9858	0.046	0.9695

DISCUSSION

The solid dispersions of Ibuprofen and the sustained release tablets containing the optimised batch were prepared and evaluated for various parameters. FT-IR studies indicated that no chemical interactions took place between drug and the polymers used for the preparation of solid dispersions. Further, the FT-IR study of a physical mixture of the optimised formulation SDF9 and HPMC K100M also exhibited no drug-excipient incompatibility.

The DSC thermogram of pure ibuprofen showed a sharp endothermic peak at 81.72 °C which corresponds to its melting point. The DSC thermogram of Ibuprofen-PEG 20000-Poloxmer 407 (1:3:3) solid dispersion prepared by a solvent evaporation method (SDF9) showed the endothermic peak at temperature 59.38 °C with some changes in the characteristics of the peaks. It showed that no possible interaction took place between the drug and carriers and the loss of peak sharpness indicated the conversion of a crystalline form of the drug to amorphous form.

All the solid dispersions showed a better release profile as compared to the drug and physical mixtures. Solid dispersions of ibuprofen SDF7 (1:1:1), SDF8 (1:2:2) and SDF9 (1:3:3) prepared by using a combination of PEG 20000 and Poloxamer 407 by solvent evaporation technique showed faster and better drug release as compared to other formulations and physical mixtures. Formulations SDF7 (1:1:1) and SDF8 (1:2:2) showed a good drug release of 89.24% and 93.17% respectively in 60 min. Formulation SDF9 (1:3:3) showed a release of 95.09% in 60 min, which was the best among all the prepared solid dispersions and thus considered as the optimised batch.

The tablet formulations containing the granules of the optimised batch of solid dispersion (SDF9) were evaluated for post-compression parameters and the results were found within the pharmacopoeial standards. The different batches were found uniform with respect to a hardness within the range of 6.25±0.06 to 6.71±0.02 kg/cm^2. Another measure of a tablet's strength is friability. The percentage friability of all the formulations was found to be not more than 0.17% which is well within the limit of<1%. In weight variation test, the pharmacopoeial limit for percentage deviation for tablets of more than 250 mg is±5% and all the formulations were found to comply with the specifications. Good uniformity in drug content was found among the formulations, and percentage of drug content was more than 90%.

In vitro release rate of all designed formulations were studied up to 12 h. Formulations FT1 and FT2 failed to sustain the release of drug upto12 h. FT1 showed 95.58% of drug release in 8 h while FT2 showed 93.74 % of drug release in 10 h. Formulation FT3 only succeeded to allow a sustained release of drug upto12 h. At the end of 12 h the release was 96% and so it was considered as the optimised batch.

To describe the kinetics of drug release from the tablet formulations, the data obtained from *in vitro* drug release studies were plotted in various kinetic models that is zero order, first order, Higuchi's model, Korsmeyer-Peppas model and Hixson-Crowell cube root equation. The models with highest regression coefficient value (r^2) were judged to be the most appropriate ones. From the release kinetics data, it was concluded that all the tablet formulations have Korsemeyer-Peppas as best fit kinetic model for drug release with r^2 values of 0.9903, 0.9731, 0.9858 and respectively. The release exponents (n) for the formulations were found 0.747, 0.842 and

0.873 respectively which appears to indicate a coupling of diffusion and erosion mechanisms, so-called non-Fickian or anomalous diffusion.

CONCLUSION

The present study was aimed to increase the solubility of Ibuprofen by solid dispersion technique and to develop sustained release tablets containing solid dispersion granules of the optimised batch. Solid dispersions of Ibuprofen were prepared by using PEG 20000 and poloxamer 407 in different weight ratios by fusion method and solvent evaporation method. Drug-carrier physical mixtures were also prepared to compare the dissolution characteristics with the solid dispersions. The saturation solubility and *in vitro* dissolution studies revealed remarkable improvement in the solubility and dissolution from these newly formulated solid dispersions over the pure drug and physical mixtures. Formulations containing a combination of hydrophilic carriers showed better dissolution results than that of individual carriers. In every formulation, improved dissolution rate was observed with increase in polymer ratio. Solid dispersion of Ibuprofen containing PEG 20000 in combination with Poloxamer 407 in the ratio of 1:3:3 (SDF9) prepared by solvent evaporation method exhibited faster and higher drug release (95.09% in 60 min) as compared to other formulations and physical mixtures. The formulation thus selected as the optimised batch. FT-IR studies revealed no drug-carrier interaction. DSC result of the formulation indicated the transformation of crystalline ibuprofen to amorphous form which can be implicated for improved dissolution. Sustained release tablets containing the solid dispersion granules of the optimised batch were prepared by direct compression method using HPMC K100M as release retarding polymer at three different concentrations (10%, 14% and 18% w/w). FT-IR studies confirmed the drug-excipient compatibility. *In vitro* dissolution studies showed that with an increase in the concentration of HPMC K100M in the tablets, the release rate of the drug decreases. Formulations FT1 and FT2 showed 95.58% drug release in 8hs and 93.74% drug release in 10 h respectively. Formulation FT3 was found the best based on *in vitro* release profile of 96% drug release for 12 h. From the release kinetics data, it was concluded that all the tablet formulations have Korsemeyer-Peppas as best fit kinetic model for drug release with r^2values of 0.9903, 0.9731, 0.9858 and respectively. The release exponents (n) for the formulations were 0.747, 0.842 and 0.873 respectively which appears to indicate a coupling of diffusion and erosion mechanisms, so-called non-Fickian or anomalous diffusion. Thus, this study concluded that the preparation of solid dispersions using a combination of PEG 20000 and poloxamer 407 by solvent evaporation method may result in higher aqueous solubility of Ibuprofen than that of solid dispersions containing the individual polymers. Also, formulation of sustained release tablets containing solid dispersion granules of ibuprofen, using HPMC K100M (18% w/w) as release retardant polymer may be a promising approach to extend the release rate of drug from the solid dispersion for a prolonged period of 12 h.

CONFLICT OF INTERESTS

Declare none

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