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RESEARCH ARTICLE

DESIGN, DEVELOPMENT AND EVALUATION OF IMMEDIATE RELEASE TABLET OF IBUPROFEN SOLID DISPERSION

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ABSTRACT

At present approximately 40% of new chemical entities identified by pharmaceutical companies are poorly water soluble. The formulations of poorly water soluble drugs (BCS) Class II for oral delivery presents a greatest challenge to the formulation scientists. Oral bioavailability depends on its solubility and dissolution rate. Several techniques have been developed over the years to enhance the dissolution of the drug such as solid dispersion, micronization, solubilization, and complexation with polymers, salt formation using prodrugs and adding surfactant. In present study the attempts have been made to increase the dissolution of BCS class II drug Ibuprofen using hydrophilic polymers namely polyethylene glycol (PEG) 6000 and polyvinyl pyrrolidone (PVP) K30 by microwave induced solid dispersion and conventional fusion method. Drug-polymer complex was prepared using batch method. Maximum dissolution rate was obtained at complex prepared from (Ibuprofen+PEG6000+SLS). A successful solubility enhancement of drug complex was confirmed by taking drug release in 7.2 pH phosphate buffer. The drug was characterized according to different compendial methods, on the basis of identification by UV spectroscopy, organoleptic properties and other tests. In this microwave induced solid dispersion exhibit significant improvement in solubility and dissolution rate compared to that of pure drug. Thus microwave technology offers a simple, efficient, shorter preparation time, solvent free promising alternative method to solid dispersion of Ibuprofen with significant enhancement of the in vitro dissolution rate. After that among the all formulation batches, solid dispersion (F8) was selected for further tablet formulation batches with considerable increase in drug release as compared to marketed formulation , nine formulations were developed and studied. The values of pre-compression parameters evaluated, were within prescribed limits and indicated good free flowing properties. The data obtained of post-compression parameters such as weight variation, hardness, friability, wetting time, water absorption ratio, content uniformity, disintegration time and dissolution and was found to superior over conventional formulation. The F9 batch with disintegrating time 28.19±0.66 second and dissolution 99.89±1.06 % was selected as optimized formulation and was found superior. When F9 formulation was compared with marketed formulation it gives highest percent drug release than marketed formulation. Batch F9 was also subjected to stability studies for three months and was tested for its disintegrating time, drug contents and dissolution behaviour monthly. It was observed that the contents of the tablets remained same. By an appropriate selection and combination of excipients it was possible to obtained immediate release tablets.

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INTRODUCTION

Therapeutic success of a drug depends upon the bioavailability and ultimately upon the solubility of drug molecules (Chowdary and Kumar, 2013). But in fact, recently more than 40% NCEs (new chemical entities) developed in pharmaceutical industry are practically insoluble in water. These poorly water soluble drugs i.e BCS class II drugs absorption from the gastrointestinal tract can be limited by a number of factors; most significant contributors are poor aqueous solubility & poor membrane permeability of the drug molecule. (Malode *et al*., 2014) Therefore, the improvement of drug solubility thereby its oral bioavailability remains one of most challenging aspects of drug development process especially for oral drug delivery system. (Sridhar *et al*., 2013) Out of many categories, nonsteroidal anti-inflammatory drugs (NSAIDs) are the most widely prescribed medications in the world. As a therapeutic class, NSAIDs exhibit analgesic, anti-inflammatory, antipyretic, and platelet inhibitory properties. Ibuprofen is also non-steroidal anti-inflammatory (NSAID), analgesic and antipyretic agent. It is a weakly acidic drug having high permeability through stomach because it remain 99.9 % unionize in stomach (pKa of Ibuprofen - 4.43, pH of

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gastric fluid - 1.2). Ibuprofen mostly permeable through stomach but due to its solubility limitation it can't enter in to systemic circulation and gastric empting time is 30 min to 2 hr. After this time ibuprofen goes in to small intestine where it is solubilised but can't permeate through its membrane (Ibuprofen having pH depended solubility and permeability). So to improve dissolution of such drug is challenging and rational. (Patel *et al*., 2011) There are numerous approaches available and reported in literature to enhance the solubility of poorly water soluble drug, such as solid dispersions, complexation, micronization, supercritical fluid process, polymorphs and eutectic mixtures etc. Among the various approaches to improve solubility, the solid dispersion (SD) technique has often proved to be the most successful in improving the dissolution and bioavailability of poorly soluble drugs because it is simple, economic, and advantageous. (Shah *et al*., 2007) The term solid dispersion refers to a group of solid products consisting of at least two different components, generally a hydrophilic matrix and a hydrophobic drug. The matrix can be either crystalline or amorphous. The drug can be dispersed molecularly, in amorphous particles (clusters) or in crystalline particles. (Chiou and Riegelman, 1971) When the solid dispersion is exposed to aqueous media, the carrier dissolves and the drug releases as fine colloidal particles. The resulting enhanced surface area produces higher dissolution rate and bioavailability of poorly water soluble drugs. Recently a novel approach based on the use of microwave irradiation has been proposed for the preparation of SD. Microwaves irradiation (MW) is a well-known method for heating and drying materials. Microwaves, with their ability to penetrate any substance, allow the production of heat in any point of the sample at the same time. This is due to the presence in it of molecules characterized by a dipolar moment able to absorb microwave energy and convert it into heat. This phenomenon occurs when the microwave frequency is close to the resonance frequency of the polar molecules. The efficient heating of materials by microwaves depends on the capacity of a specific material to absorb microwave energy. Microwave energy has been employed to change the crystalline state of a drug, instead of conventional heating. (Sharma *et al*., 2013)

The only preparation of solid dispersion is not sufficient as the formulation concern, it is always essential to convert solid dispersion into some suitable dosage form, hence in the present study it is decided to prepare immediate release tablet of solid dispersion. Oral route of administration is one of the most preferred for the drug delivery because of ease of administration and low processing for the drug formulation development. Among the oral dosage form solid dosage forms have many advantages over other types of oral dosage forms. Therefore, most of the new chemical entities under development these days are intended to be used as a solid dosage form. Tablet is the most popular among all dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing; however in many cases immediate onset of action is required than conventional therapy. To overcome these drawbacks, immediate release pharmaceutical dosage form has emerged as alternative oral dosage forms. Immediate release tablets are those which disintegrate rapidly and get dissolved to release the medicaments. The basic approach used in development tablets is the use of Superdisintegrants like Croscarmellose sodium, Sodium starch glycolate, Crospovidone etc. which provide instantaneous disintegration of tablet after administration. The development of immediate release therapy also provides an opportunity for a line extension in the marketplace. (Rathod *et al*., 2013; Verma and Sachan, 2013; Jadhav *et al*., 2014; Nyol and Gupta, 2013)

MATERIALS AND METHODS

Materials

All materials used in present research were commercial samples. Active pharmaceutical ingredient: Ibuprofen (Cipla pharmaceuticals Pvt. Ltd, Patalganga), Hydrophilic polymers: Poly vinylpyrrolidone K30, Polyethylene glycol 6000, Sodium lauryl sulphate (Fusion scientific laboratories Pvt. Ltd. Mumbai), Excipients: Croscarmellose sodium, Sodium starch glycolate, Crospovidone, (Research lab fine chem. Islampur), Microcrystalline cellulose, Magnesium stearate, Mannitol, Talc (Research lab fine chem. Mumbai)

Analysis of Ibuprofen

The received sample of Ibuprofen was characterized according to different compendial methods and was found to be a white crystalline powder with characteristic odour. The melting point was determined by using melting point apparatus (PMP-D, Veego) by introducing small amount of substance in the capillary attached to graduated thermometer and constant heat was supplied to the assembly suspended in the paraffin bath. The temperature at which drug melted was recorded it was found to have a melting point in range of 75ºC-76ºC, $\lambda_{max\ of}$ 221nm, all the findings matched the official reports.

Scanning of Ibuprofen in 7.2 pH phosphate buffer

The solution containing 20µg/ml of Ibuprofen in 7.2 pH phosphate buffer was prepared and scanned over range of 200-400 nm against 7.2 pH phosphate buffer as a blank using Shimadzu UV-1800 double beam spectrophotometer. The λ_{max} was found to be 221nm, which confirms to the reported values.

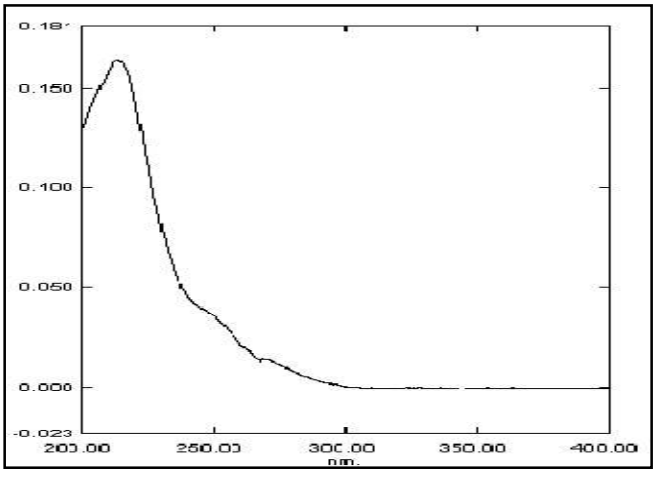

Figure 1. UV spectra of Ibuprofen in 7.2 pH phosphate buffer

The UV spectrum of Ibuprofen was obtained in 7.2 pH phosphate buffer which showed absorbance maximum (λ max) at 221 nm. The reported λmax value of Ibuprofen in 7.2 pH phosphate buffer was 221nm. So the given value similar with the reported value indicates that the given sample of Ibuprofen was in pure form.

Preparation of dissolution medium for standard calibration curve

In the present work, Ibuprofen was estimated by UV spectrophotometry in phosphate buffer 7.2 pH. Phosphate buffer prepared by using accurately weighed 7.34 gm Di-sodium hydrogen phosphate and 1gm sodium hydroxide was taken and dissolved in small amount of distilled water, volume was adjusted to 1 liter with the same solvent to prepare 1 liter phosphate buffer. The pH of the buffer solution was adjusted using a pH meter.

Preparation of standard calibration curve in 7.2 pH phosphate buffer

Various drug concentrations (5-50µg/ml) in phosphate buffer were prepared and the absorbance was measured at 221 nm.

For the standard calibration curve, stock solution was prepared by dissolving 10 mg of accurately weighed Ibuprofen in 100 ml of 7.2 pH phosphate buffer in 100 ml volumetric flask to get 100 µg/ml solutions. From this, 0.5,1.0, 1.5.....5.0 ml solutions were pipette into a series of 10 ml volumetric flask and were made up to 10ml with phosphate buffer of pH 7.2 to get a series of standard solutions containing Beer's Lambert's range of concentration from 5, 10, 15, 20, 25, 35, 40 ,45 and 50 µg /ml solutions of Ibuprofen respectively. The absorbance of resulting solutions was measured at 221 nm against the blank. All spectral absorbance measurement was made on Shimadzu 1800 UV-visible spectrophotometer. A graph was plotted by taking concentration on X-axis and absorbance on Y-axis. The absorbances of different concentration of Ibuprofen are reported in Table 1 and the calibration curve is shown in Figure 2

The plot is developed absorbance against the concentration of drug in µg/ml and which showed the linearity with R^2 value 0.9992.The plot showed linearity in concentration range 1 µg/ml-50 µg/ml, thus Beers-lamberts range was found to be 1-50 µg/ml. The results indicate that there is a linear relationship between concentrations (0-50µg/ml).

Preparation of solid dispersion of Ibuprofen (Zawar and Bari, 2013)

Solid dispersion of drug and polymer was prepared by conventional fusion method and microwave induced fusion method in various ratios such as, Ibuprofen+PVP K 30 (1:1), Ibuprofen+PVP K30+SLS (1:1:1), Ibuprofen+ PEG 6000 (1:1) and Ibuprofen+PEG6000+SLS (1:1:1).Solid dispersions prepared by conventional fusion method were F1,F2,F3,F4 and solid dispersions prepared by microwave induced fusion method F5,F6,F7,F8 respectively. The composition of drug and polymer prepared by various methods is shown in **Table 2.**

Conventional Fusion Method for Solid Dispersion

In this method the polymer was heated to molten mass and to this weighed amount of Ibuprofen was added with continuous stirring with or without SLS until mixture get melt completely and drug molecules are get dispersed uniformly in polymer occur. Solidification was allowed to occur at room temperature. The product was stored in a dessicator for 24 h and then pulverized using a porcelain mortar and pestle. The pulverized powder was passed through 100 # sieve to get uniform particle size.

Microwave Induced Fusion Method

In this method microwave energy used to prepare solid dispersions. The drug and hydrophilic polymer will get fused together to form solid dispersion. Solid dispersion are prepared by placing the mixture of drug and polymer in porcelain dish and subjected to microwave radiation.

Table 1. Data for standard calibration curve of Ibuprofen in 7.2 pH phosphate buffer

Concentrations (µg/ml)	0	5	10	15	20	25	30	35	40	45	50
Mean Absorbance	0.00	0.514	0.875	1.317	1.668	2.07	2.525	2.90	3.334	3.756	4.143
±S.D	0.00	±0.23	±0.14	±0.15	±0.10	±0.27	±0.11	±0.18	±0.12	±0.21	±0.18

Results are mean of three determinations

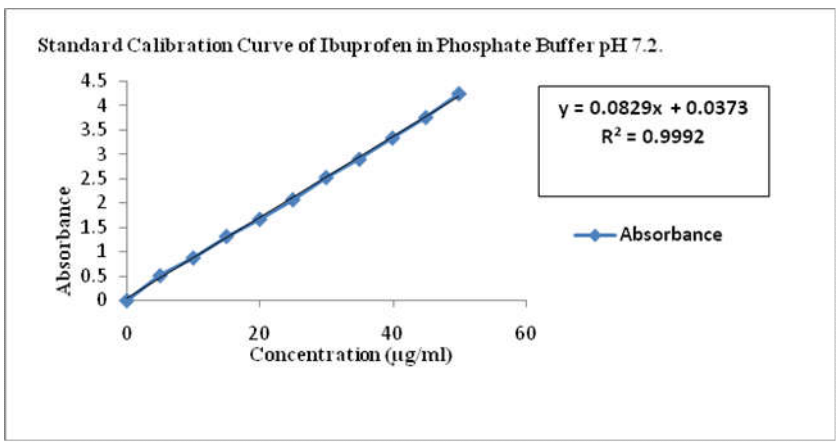

Figure 2. Standard Calibration Curve of Ibuprofen in Phosphate Buffer pH 7.2

Only one sample is place at a time inside the microwave oven. Porcelain dish is place in room temperature to solidify molten mass. The solid dispersion is place in desiccators for 24 hour and then product is pulverize using a porcelain mortar and pestle. The pulverize powder is pass through 100 # sieve.

Table 2. Formulations of Drug and Polymer

Formulations	Composition	Method	Ratio
F1	Ibuprofen+PVP K30	Conventional Fusion Method	1:1
F2	Ibuprofen+PVP K30+SLS	Conventional Fusion Method	1:1:1
F3	Ibuprofen+PEG 6000	Conventional Fusion Method	1:1
F4	Ibuprofen+PEG 6000+SLS	Conventional Fusion Method	1:1:1
F5	Ibuprofen+PVP K30	Microwave Induced Fusion Method	1:1
F6	Ibuprofen+PVP K30+SLS	Microwave Induced Fusion Method	1:1:1
F7	Ibuprofen+PEG 6000	Microwave Induced Fusion Method	1:1
F8	Ibuprofen+PEG 6000+SLS	Microwave Induced Fusion Method	1:1:1

Evaluation of solid dispersion

The solid dispersion of Ibuprofen were evaluated for no. of parameters like physical appearance, % practical yield, Solubility study, in vitro dissolution study and compatability study.

Physical appearance

All batches of Ibuprofen solid dispersions were evaluated for color and appearance. The physical appearance of each formulation is shown in **Table 3**

Table 3. Physical appearance of formulations Drug and Polymers

Formulations	Physical Appearance	
	Colour	Appearance
F1	White	Powder (Crystalline)
F2	White	Powder (Crystalline)
F3	White	Powder (Crystalline)
F4	White	Powder (Crystalline)
F5	White	Powder (Crystalline)
F6	White	Powder (Crystalline)
F7	White	Powder (Crystalline)
F8	White	Powder(Crystalline)

The physical appearance of formulations, F1 to F8 was found to be white and a crystalline powder.

Solubility Study of Solid Dispersion

The amount of S.D Powder containing 2.5 mg equivalent Ibuprofen was weighed accurately in Volumetric flask was dissolved 5ml Distilled water or phosphate buffer pH 7.2 By sonication for 15 minute Subsequently, the solutions were filtered through a whatman filter paper no 1. Filtered solution was diluted properly with distilled water or phosphate buffer pH 7.2 The diluted solution was analyzed for the Ibuprofen in UV at 221 nm. The measurements of solubility shown in Table 4

Table 4. Solubility study of solid dispersion

Formulations	Drug : carrier ratio	Solubility µg /ml
Pure drug	Pure drug	2.05
F1	Ibuprofen+PVPK30 (1:1)	9.16
F2	Ibuprofen+PVPK30+SLS(1:1:1)	21.64
F3	Ibuprofen+PEG6000(1:1)	19.22
F4	Ibuprofen+PEG6000+SLS(1:1:1)	23.09
F5	Ibuprofen+PVPK30(1:1)	11.81
F6	Ibuprofen+PVPK30+SLS(1:1:1)	12.29
F7	Ibuprofen+PEG6000(1:1)	14.26
F8	Ibuprofen+PEG6000+SLS(1:1:1)	27.15

Solubility study of various solid dispersion trial batches was performed .Solid dispersion prepared by microwave induced fusion method improved solubility of Ibuprofen as compared to pure drug and solid dispersion prepared by conventional fusion method. The batch F8 was more soluble than pure drug and other formulation batches.

Percentage Practical Yield Study of Solid Dispersion

Prepare solid dispersion from raw material and weigh amount of sample obtained to that with theoretical weight of sample. Calculate % yield from following formula.

PY (%) = (Practical weight/Theoretical weight (Drug + Carrier)) × 100

Where,
a = Practical weight of Solid Dispersion obtained,
b = Theoretical weight of Solid Dispersion preparation.
It was calculated to know about %practical yield or efficiency of any method which will help in selection of appropriate method. The practical yield for each formulation is shown in Table 5.

Table 5. Percentage practical yield study of solid dispersion

Formulations	Ratio	Initial Weight	Final weight	%Yield
F1	1:1	0.325	0.289	88.9%
F2	1:1:1	0.458	0.415	92.7%
F3	1:1	0.345	0.287	86.08%
F4	1:1:1	0.550	0.515	95.45%
F5	1:1	0.318	0.276	89.9%
F6	1:1:1	0.438	0.396	94.9%
F7	1:1	0.360	0.334	92.7%
F8	1:1:1	0.558	0.540	98.2%

Different trial batches of solid dispersion show % practical yield from range 86.08 %to 98.2%. Batch F8 showed 98.2 % practical yield.

Drug Excipients Compatibility Studies

Fourier Transform Infra red Spectroscopy (FTIR) Interpretation

To study the interaction between drug and polymers used in the preparation of solid dispersion. FTIR spectrum of pure Ibuprofen, polymer and drug: polymer complexes were recorded over the wave number 4000 to 600 cm^{-1}. The spectrum of the pure drug, polymer and drug: polymer

complex is shown in **Figures 3-7** respectively. The assignments are represented in **Tables 6-7** respectively.

1. Ibuprofen pure drug

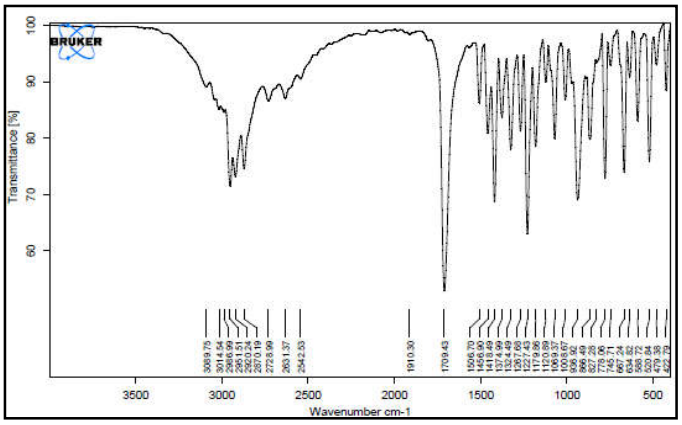

Figure 3. Infrared spectra of Ibuprofen plain drug

Table 6. Interpretation of FTIR spectrum of Ibuprofen plain drug

S.No.	Reference Peak Wavenumber (cm^{-1})	Observed Peak Wavenumber (cm^{-1})	Functional group
1.	3000-2850	2951	C-H stretch(alkane)
2.	1725-1700	1709.43	C=O(Carboxylic acid)
3.	1600-1475	1506.70	C=C (Aromatic)
4.	3100-3000	3089.75	C-H Stretch(alkene)
5.	1450-1375	1418.49	-CH3 (Bend)
6.	900-690	718.06	Aromatic C-H

2. PEG 6000

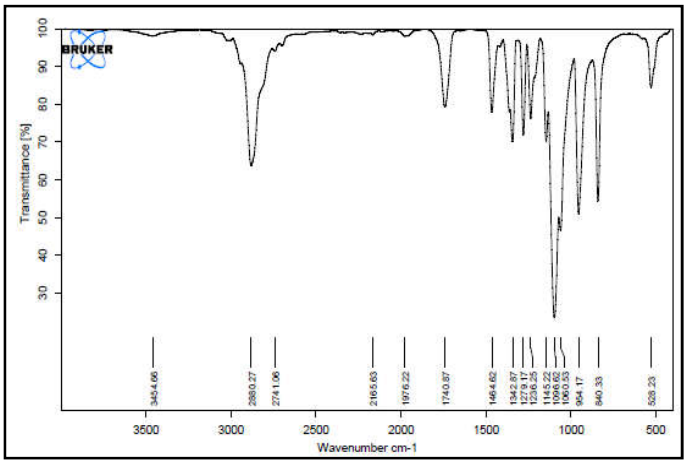

Figure 4. Infrared spectra of PEG 6000

Table 7. Interpretation of FTIR spectrum of PEG 6000

S.No.	Reference Peak Wave number (cm-1)	Observed Peak Wave number (cm-1)	Functional group
1.	1300-1000	1145.22	C-O (Carboxylic acids)
2.	1600-1475	1464.62	C=C (Aromatic)
3.	3200-3400	3454.66	O-H(alcohols H-bonded)
4.	3000-2850	2880.27	-CH3 (bend)
5.	1300-1000	1096.62	C-O (stretch)

3. Sodium lauryl sulphate

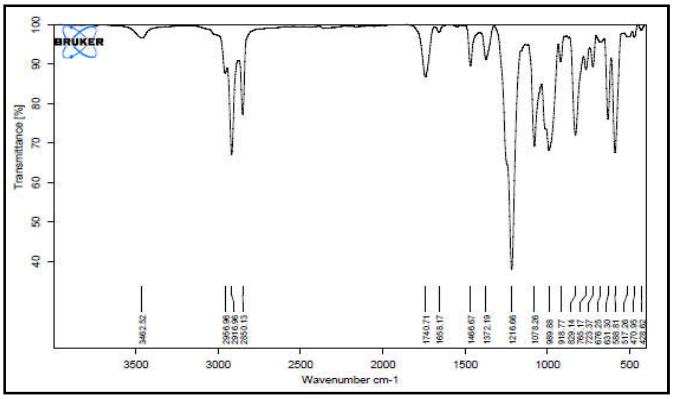

Figure 5. Infrared spectra of sodium lauryl sulphate

Table 8. Interpretation of FTIR spectrum of sodium lauryl sulphate

S.No.	Reference Peak Wave number (cm^{-1})	Observed Peak Wave number (cm^{-1})	Functional group
1.	1350-1140	1216.66	S=O (Sulfates)
2.	1375-1450	1372.19	$-CH_3$ (bend)
3.	3000-2850	2916.96	C-H (alkanes) Stretch
4.	1300-1000	1078.26	C-O(Carboxylic acids)
5.	1465	1466.67	$-CH_2$(bend)

4. Solid dispersion of Ibuprofen+PEG6000+SLS by conventional fusion method

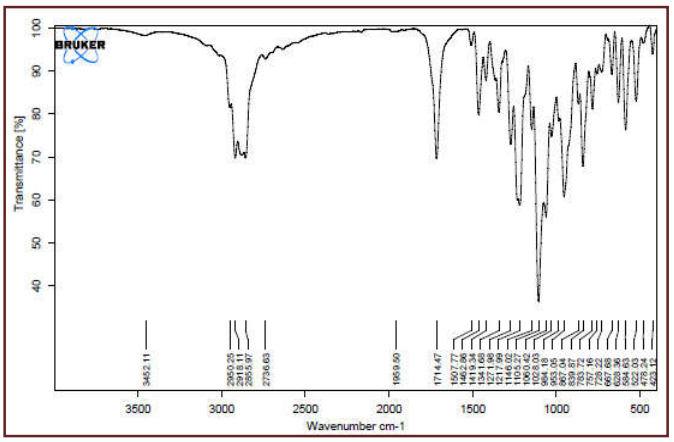

Figure 6. Infrared spectra of solid dispersion Ibuprofen+PEG6000+SLS by conventional fusion method

Table 9. Interpretation of FTIR spectrum of solid dispersion Ibuprofen+ PEG6000 + SLS by conventional fusion method

S.No.	Reference Peak Wave number (cm^{-1})	Observed Peak Wave number (cm^{-1})	Functional group
1.	1300-1000	1105.27	C-O(Esters)
2.	3000-2850	2950.25	C-H Stretch(Alkane)
3.	1725-1700	1714.47	C=O(Carboxylic acids)
4.	3400-3200	3452.11	O-H(Alcohols H-bonded)
5.	1350-1140	1217.99	S=O (Sulphates)
6.	1000-650	953.05	C-H Alkenes (Out of plane bend)

5. Solid dispersion of Ibuprofen+PEG6000+SLS by microwave induced fusion method

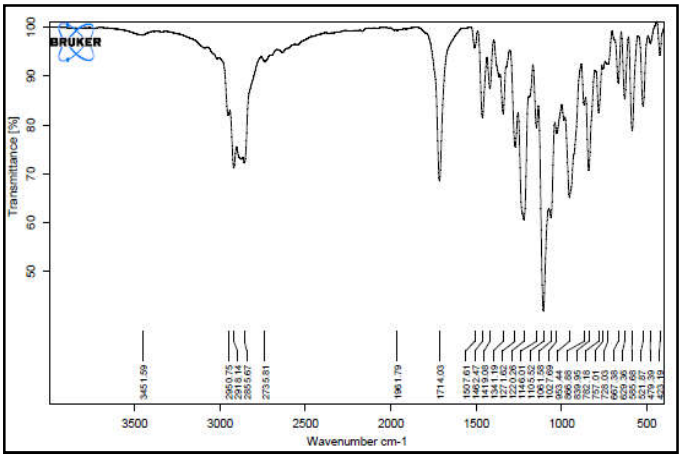

Figure 7. Infrared spectra of solid dispersion of Ibuprofen+PEG6000+SLS by microwave induced fusion method

Table 10. Interpretation of FTIR spectrum of solid dispersion Ibuprofen +PEG6000 + SLS by microwave induced fusion method

S.No.	Reference Peak Wave number (cm^{-1})	Observed Peak Wave number (cm^{-1})	Functional group
1.	1300-1000	1105.52	C-O (Esters)
2.	3000-2850	2950.75	C-H Stretch(Alkane)
3.	1725-1700	1714.03	C=O (Carboxylic acid)
4.	3400-3200	3451.59	O-H (alcohols H-bonded)
5.	1350-1140	1220.26	S=O (sulphates)
6.	100-650	953.44	C-H Alkene (Out of plane bend)

The IR spectra did not show any significant difference from those obtained for their physical mixture. These obtained results indicate that there was no positive evidence for the interaction between Ibuprofen and polymer material. These results clearly indicate that the above polymers can be used without any interaction for preparation of solid dispersion and further immediate release tablet formulation.

2. Differential Scanning Calorimetery (DSC)

Mettler Toledo (*SW920) Differential Scanning Calorimeter using aluminium pans equipped with an intracooler and a refrigerated cooling system was used to analyze the thermal behavior of Ibuprofen, PEG 6000 and drug: polymer complex of Ibuprofen : PEG6000 : SLS. Indium standard was used to calibrate the DSC temperature. The thermal behavior of hermetically sealed samples (5-10 mg) heated at 10°C/min is shown in Figures 8 - 10. The data obtained is shown in the Table 11.

Table 11. DSC of drug and solid drug: polymer complexes

Sample	Endothermic Peak (^{0}C)
Ibuprofen (plain drug)	78.59
PEG 6000	61.26
Drug –polymer complex	56.96 and 51.14

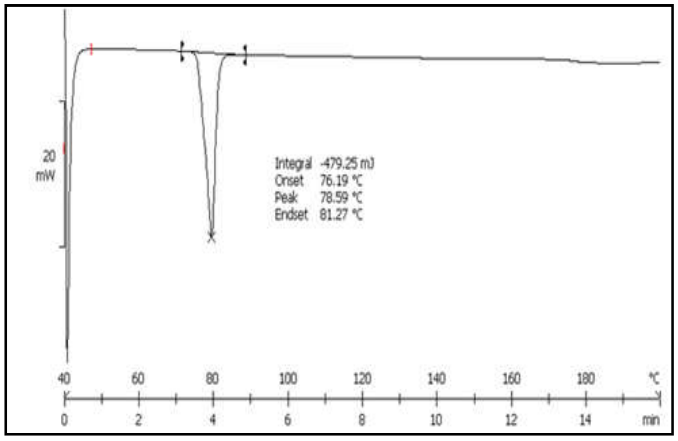

Figure 8. DSC curve of Ibuprofen plain drug

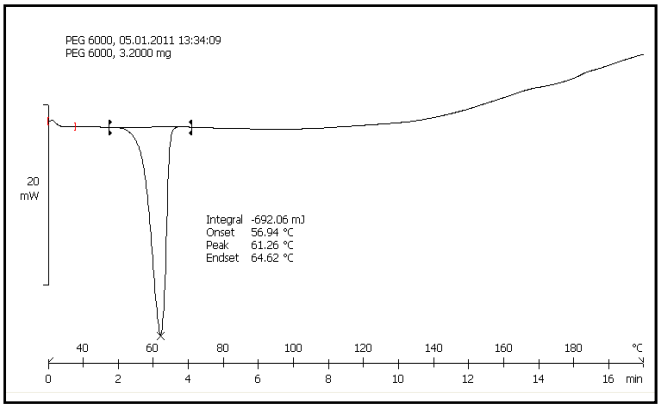

Figure 9. DSC curve of PEG6000

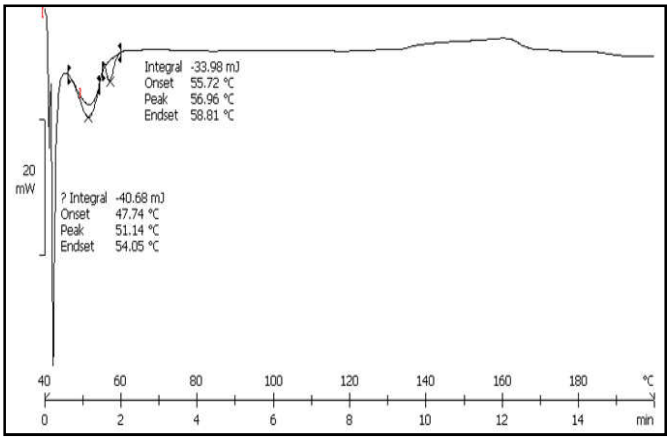

Figure 10. DSC curve of drug-polymer complex

Thermal behavior of pure drug, polymer and drug polymer complex are depicted in **Figure 8, 9 and 10**. The DSC curve of solid dispersion shown progressive broadening and lowering of drug melting temperature and concomitant reduction of its enthalpy with increasing in carrier content in mixture until total disappearance of drug melting endotherm. This finding could be considered indicative of drug amorphization as a consequence of interaction between components. It also shows the progressive drug dissolution in the melted carrier before achieving its melting carrier, as was previously observed for other the drug-PEG combination.

3. Powder X-Ray Diffraction

X-ray powder diffractometry was carried out to investigate the effect of complexation process on crystallanity of drug. Powder X-ray diffractometry were carried out using a D8 Advance (Bruker) scanner with filter Ni, Cu, Kα radiation, voltage 40kV and a current of 20 mA. The scanning rate employed was 1°/min over the 5°to 50° diffraction angle (2θ) range. The XRPD patterns of drug powder, polymer (PEG 6000), and drug-polymer complex were recorded.

The comparative XRPD patterns of pure drug, polymer (PEG 6000) and drug- polymer complex were given in Figures 11 - 15.

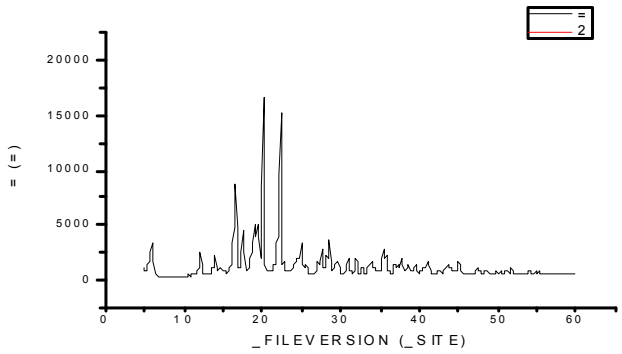

Figure 11. X-Ray Diffraction of Ibuprofen plain drug

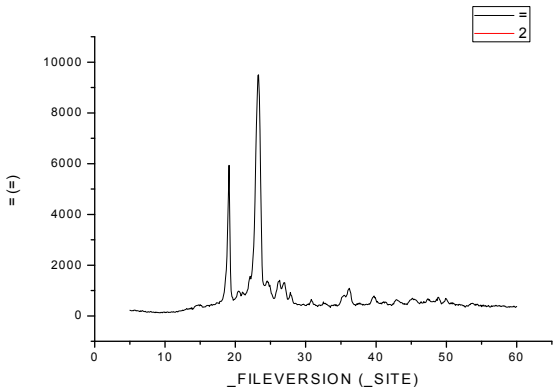

Figure 12. X-Ray Diffraction of PEG 6000

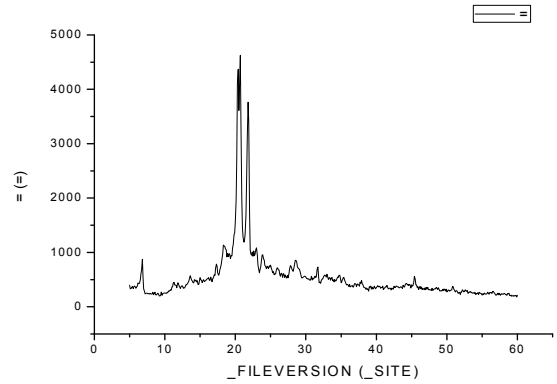

Figure 13. X-Ray Diffraction of sodium lauryl sulphate

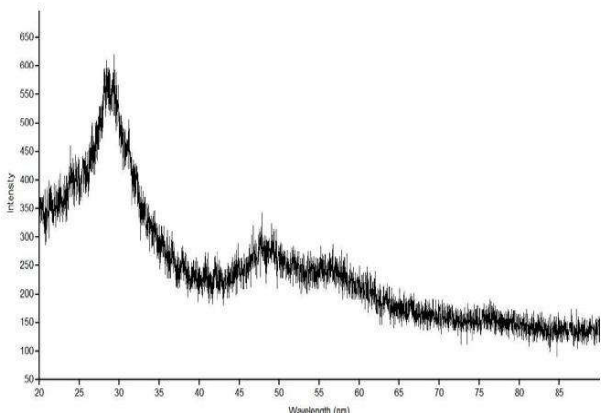

Figure 14. X-Ray Diffraction of solid dispersion (Ibuprofen+PEG6000+SLS) by conventional fusion method

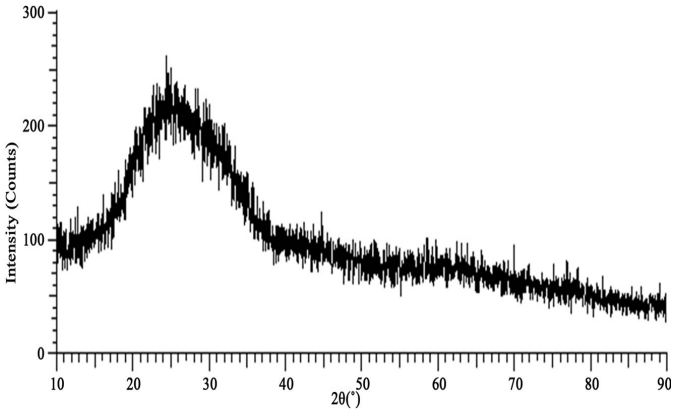

Figure 15. X-Ray Diffraction of solid dispersion (Ibuprofen +PEG6000+SLS) by microwave induced fusion method

Figure: 11 to 15 shows x ray diffraction pattern of Ibuprofen, Polyethylene glycol 6000, Sodium lauryl sulphate and solid dispersions of conventional fusion method and microwave induced fusion method respectively. XRD of Ibuprofen have intense and sharp peak of 100% relative intensity at 14.5353θ position which has height 688.82 cts, and d' spacing of 6.08 A˚ indicates crystalline nature of Ibuprofen. Similarly XRD of PEG 6000 shows 100% relative intensity peak at 23.25 θ position having 530.55 cts height with 3.82 A˚ d' spacing.XRD of PEG 6000 shows crystalline nature. XRD of Solid dispersion shows peak of 100% relative intensity at 22.99 θ position which having 459.65 cts height, with 3.86 A˚ d' spacing. As peak height and d' spacing of solid dispersion decreased as compared to XRD of Ibuprofen it can be conclude that crystalline nature of Ibuprofen is converted into amorphous nature.

In vitro Dissolution Study and Observation

The dissolution study of pure drug and all formulations were carried to calculate the %drug release.

1. Dissolution study of pure drug

Dissolution studies were performed assuring sink condition according to the paddle method (USP) using USP XXIII

apparatus type-II (electro lab TDT-08L). The dissolution medium was 900 ml 7.2pH phosphate buffer kept at 37˚C ± 0.5˚C. The drug containing 200 mg of Ibuprofen was taken in a muslin cloth and tied to the rotating paddle kept in the vessel of dissolution apparatus, the paddle was rotated at 50 rpm. Samples of 5 ml were withdrawn at specified time intervals and analyzed spectrophotometrically at 221 nm using Shimadzu-1800 UV-visible spectrophotometer; the samples withdrawn were replaced by fresh buffer solutions. Each preparation was tested in triplicate and then mean values were calculated which is shown in Table 12 and accordingly the graph was plotted to calculate % drug release of pure drug in phosphate buffer and it is shown in Figure 16

Table 12. Dissolution profile of Ibuprofen pure drug

Time (min.)	Cumulative % drug release
0	0.00
5	2.30±0.23
10	3.51±0.32
15	5.450.44
20	8.35±0.56
25	9.32±0.60
30	12.47±0.12
40	13.45±0.14

Results are mean of three determinations

The cumulative % drug release of pure drug after 40 minutes was 13.45% each reading is taken was triplicate and then mean values were calculated.

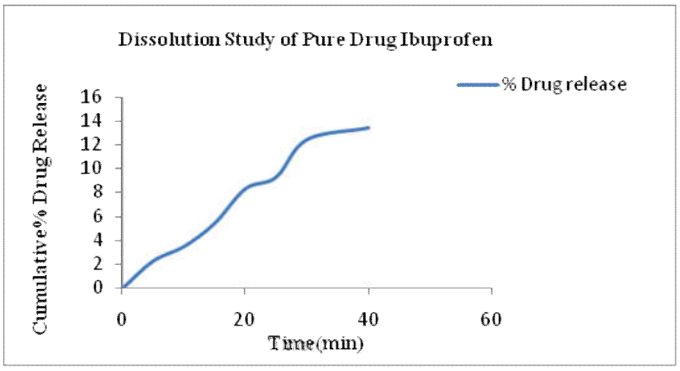

Figure 16. Dissolution Study of Pure Drug Ibuprofen

2. Dissolution Profile of Solid Dispersions prepared by Conventional Fusion Method

Dissolution studies were performed assuring sink condition according to the paddle method (USP) using USP XXIII apparatus type-II (electro lab TDT-08L). The dissolution medium was 900 ml 7.2 pH phosphate buffer kept at 37˚C ± 0.5˚C. The complex containing 200 mg of Ibuprofen andPVP K 30 (in ratio 1:1),Ibuprofen, PVP K30and Sodium Lauryl Sulphate(1:1:1), Ibuprofen and PEG 6000(1:1), Ibuprofen, PEG 6000and Sodium Lauryl Sulphate (1:1:1)was taken in a muslin cloth and tied to the rotating paddle kept in the vessel of dissolution apparatus, the paddle was rotated at 50 rpm. Samples of 5 ml were withdrawn at specified time intervals and analyzed spectrophotometrically at 221 nm using Shimadzu-1800 UV-visible spectrophotometer; the samples withdrawn were replaced by fresh buffer solutions. Each preparation was tested in triplicate and then mean values were calculated which is shown in **Table 13** .and accordingly the graph was plotted to calculate % drug release of pure drug in phosphate buffer and it is shown in **Figure 17.**

Table 13. Dissolution profile of solid dispersions prepared by conventional fusion method

Time (min)	Cumulative %Drug Release			
	F1	**F2**	**F3**	**F4**
0	0	0	0	0
5	1.34±0.12	3.51±0.32	3.87±0.10	4.23±0.26
10	11.23±0.14	14.61±0.15	17.27±0.24	22.34±0.18
15	28.38±0.52	35.38±0.48	42.86±0.14	48.18±0.20
20	36.49±0.42	49.05±0.16	53.17±0.18	72.60±0.16
25	48.72±0.13	56.59±0.18	66.38±0.26	77.27±0.75
30	55.17±0.15	63.29±0.20	69.34±0.30	80.25±0.21
40	56.31±0.22	64.44±0.12	70.27±0.44	81.42±0.14

Results are mean of three determinations

Out of four formulations F4 shown maximum drug release i.e. 81.42%.Solid dispersion (F4) of Ibuprofen with polymer PEG 6000 and surfactant SLS prepared by conventional fusion method significantly improved its solubility and dissolution rate. Increased wetting and solubilizing effect of PEG 6000 and SLS as well as the molecular dispersion of drug in solid dispersion and alteration of surface properties of drug particle may be responsible for the enhanced dissolution rate of Ibuprofen from solid dispersion compared to pure Ibuprofen.

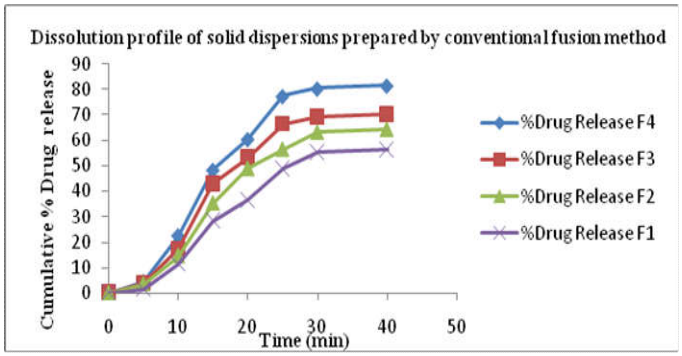

Figure 17. Dissolution Profile of Solid Dispersions Prepared by Conventional Fusion Method

3. Dissolution Profile of Solid Dispersions prepared by Microwave Induced Fusion Method

Dissolution studies were performed assuring sink condition according to the paddle method (USP) using USP XXIII apparatus type-II (electro lab TDT-08L). The dissolution medium was 900 ml 7.2 pH phosphate buffer kept at 37˚C ± 0.5˚C. The complex containing 200 mg of Ibuprofen and PVP K30 (in ratio 1:1) ,Ibuprofen, PVP K30and Sodium Lauryl Sulphate (1:1:1), Ibuprofen and PEG 6000(1:1), Ibuprofen , PEG6000 and Sodium Lauryl Sulphate (1:1:1) was taken in a muslin cloth and tied to the rotating paddle kept in the vessel of dissolution apparatus, the paddle was rotated at 50 rpm. Samples of 5 ml were withdrawn at specified time intervals and analyzed spectrophotometrically at 221 nm using Shimadzu-1800 UV-visible spectrophotometer; the samples withdrawn were replaced by fresh buffer solutions. Each

preparation was tested in triplicate and then mean values were calculated which is shown in **Table 14** and accordingly the graph was plotted to calculate %drug release of pure drug in phosphate buffer and it is shown in **Figure 18.**

Table 14. Dissolution profile of solid dispersions prepared by microwave induced fusion method

Time (min)	Cumulative %Drug Release			
	F5	**F6**	**F7**	**F8**
0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
5	5.32±0.085	7.13±0.52	6.29±0.30	9.06±0.48
10	12.08±0.25	27.65±0.44	13.65±0.45	36.34±0.54
15	26.69±0.16	48.43±0.36	34.42±0.21	58.33±0.32
20	42.41±0.22	66.34±0.32	51.83±0.58	76.01±0.22
25	57.17±0.14	78.72±0.28	67.21±0.24	86.23±0.28
30	69.09±0.18	83.39±0.24	76.09±0.28	99.22±0.42
40	70.10±0.28	84.45±0.22	77.86±0.36	99.86±0.18

Results are mean of three determinations

Out of four formulations F8 showed maximum drug release i.e 99.86%. Solid dispersion (F8) of Ibuprofen with polymer PEG 6000 and surfactant SLS prepared by microwave induced fusion method significantly improved its solubility and dissolution rate. Increased wetting and solubilizing effect of PEG 6000 and SLS as well as the molecular dispersion of drug in solid dispersion and alteration of surface properties of drug particle may be responsible for the enhanced dissolution rate of Ibuprofen from solid dispersion compared to pure Ibuprofen and other formulations.

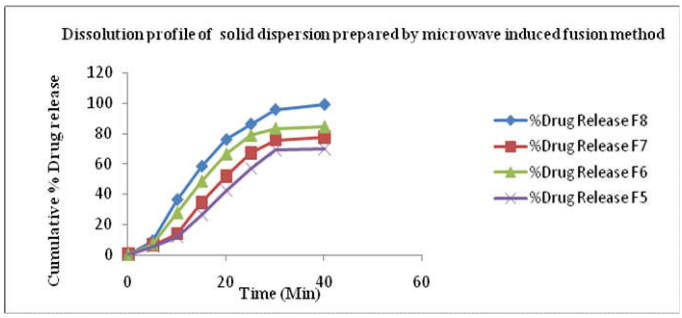

Figure 18. Dissolution Profile of Solid Dispersions Prepared by Microwave Induced Fusion Method

Comparative Dissolution Study

For the selection of best solid dispersion method the dissolution of pure drug was compared with solid dispersion by conventional fusion method (F4) and microwave induced fusion method (F8) which is shown in **Table 15** and graph was plotted to show %drug release which was represented in **Figure 19.**

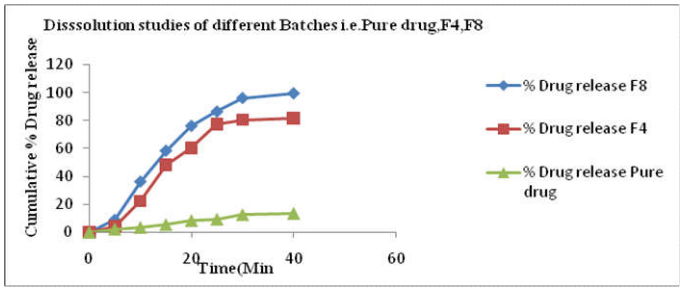

Figure 19. Dissolution Studies of Different Batches i.e. Pure Drug, F4 and F8

Table 15. Percent drug release of pure drug Ibuprofen and solid dispersions by conventional fusion method (F4) and microwave induced fusion method (F8)

Time (min.)	Cumulative % Drug release		
	Pure drug	F4	F8
0	0.00	0.00	0.00
5	2.30	4.23	9.06
10	3.51	22.34	36.34
15	5.45	48.18	58.33
20	8.35	60.30	76.01
25	9.32	77.27	86.23
30	12.47	80.25	99.22
40	13.45	81.42	99.86

Results are mean of three determinations

According to graph **19** it was concluded that the F8 formulation gives highest drug release i.e 99.86%. In this microwave induced solid dispersion exhibit significant improvement in solubility and dissolution rate compared to that of pure drug. Thus microwave technology offers a simple, efficient, shorter preparation time, solvent free promising alternative method to solid dispersion of Ibuprofen with significant enhancement of the in vitro dissolution rate. Hence batch **F8** was use for further factorial design.

Formulation of immediate release tablet of microwave induced solid dispersion of Ibuprofen

According to comparative dissolution study showed in **Figure 19 & Table 15** it is concluded that the solid dispersion prepared by microwave induced fusion method in that containing Ibuprofen+ PEG 6000+SLS was shown maximum percent drug release as compared to other solid dispersions. Hence, the solid dispersion F9 is selected for further tablet formulations.

Direct Compression

The best batch of solid dispersion of Ibuprofen was chosen and formulated into immediate release tablet. Immediate release tablets can be prepared according to the formula given in **Table 16.** A total number of nine formulations were prepared. Required amount of solid dispersion (equivalent to 200 mg of Ibuprofen) and all ingredients were passed through 60 mesh sieve separately and collected. The ingredients were weighed and mixed in a geometrical order. First microcrystalline cellulose, talc and superdisintegrants (crosscarmellose sodium, sodium starch glycolate, and crospovidone) were mixed together. Solid dispersion of Ibuprofen was then added and was mixed for 10-15 min. Finally to this blend mannitol and magnesium stearate were added and mixed further for 10-15 min. The tablets were compressed using 10mm size punches to get a tablet of 500mg weight. Before tablet preparation ,the mixture blend of all the formulations were subjected to pre-compression parameters like angle of repose, bulk density, tapped density, % compressibility and flowability. The Immediate release tablets prepared subjected to post-compression parameters like, content uniformity, hardness, friability, weight variation, dissolution and in vitro disintegration. Batches were prepared by direct compression method. Direct compression is the preferred method for preparation of tablets.

Table 16. Formulation of Immediate Release Tablet

Formulations	F1	F2	F3	F4	F5	F6	F7	F8	F9
Ingredients	Unit formula (mg per tablet)								
Ibuprofen : PEG6000 : SLS (Equivalent to 200 mg Ibuprofen)	404	404	404	404	404	404	404	404	404
Sodium starch glycolate	2.5	5	7.5	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	2.5	5	7.5	-	-	-
Crospovidone	-	-	-	-	-	-	2.5	5	7.5
Microcrystalline cellulose	45.5	43	40.5	45.5	43	40.5	45.5	43	40.5
Mannitol	46	46	46	46	46	46	46	46	46
Magnesium stearate	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1
Total	500	500	500	500	500	500	500	500	500

Table 17. Evaluation of Tablet Blend for Immediate Release Tablets

Formulations	Angle of Repose(Θ) (º)	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Hausner'Ratio (H_R)	Carr's Compressibility Index (%)
F1	26.03±0.36	0.57±0.50	0.67±0.86	1.17±0.47	14.62±0.38
F2	26.80±0.42	0.57±0.72	0.67±0.50	1.16±0.32	13.74±0.48
F3	26.76±0.57	0.57±0.91	0.67±0.30	1.17±0.38	14.55±0.51
F4	26.73±0.41	0.57±0.80	0.66±0.50	1.16±0.20	13.62±0.67
F5	27.61±0.33	0.55±0.95	0.64±0.88	1.17±0.16	14.55±0.46
F6	27.76±0.62	0.55±0.70	0.64±0.85	1.17±0.22	14.48±0.50
F7	25.46±0.72	0.56±0.91	0.65±0.70	1.16±0.71	13.43±0.42
F8	25.35±0.45	0.56±0.96	0.66±0.50	1.16±0.38	13.95±0.60
F9	26.11±0.60	0.57±0.86	0.67±0.36	1.18±0.28	14.95±0.41

Table 18. Evaluation of Immediate Release Tablets

Formulations	Weight variations (mg)	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Content uniformity (%)	Disintegration time (sec)	Wetting time (Sec)	%Water absorption ratio
F1	500±0.28	4.38±0.048	3.18±0.20	0.53±0.036	98.69±0.05	39.49±1.04	12.09±1.47	120±0.021
F2	501±0.51	4.50±0.035	3.03±0.28	0.56±0.045	98.59±0.13	33.59±0.75	11.60±0.90	122±0.032
F3	501±1.23	4.65±0.013	3.06±0.29	0.52±0.012	99.12±0.22	31.10±0.60	10.60±0.61	129±0.023
F4	503±0.47	4.68±0.022	3.10±0.27	0.56±0.021	98.18±0.07	36.21±0.76	13.12±1.31	112±0.073
F5	500±0.85	4.61±0.021	3.15±0.14	0.58±0.044	98.76±0.26	35.07±0.56	12.68±1.21	127±0.023
F6	498±0.67	4.58±0.015	3.03±0.16	0.55±0.024	98.38±0.24	29.48±0.48	11.34±0.63	123±0.042
F7	502±0.93	4.45±0.015	3.11±0.24	0.58±0.059	97.56±0.32	31.55±0.44	10.92±0.40	168±0.027
F8	501±0.16	4.58±0.010	3.02±0.30	0.59±0.047	97.92±0.27	30.02±1.34	10.52±1.01	171±0.032
F9	500±0.92	4.51±0.008	3.0±0.26	0.50±0.052	99.78±0.31	28.19±0.66	10.04±0.56	184±0.045

Table 19. *In vitro* % Drug release from tablets

Time (Min)	**Cumulative % drug release**								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0	00	00	00	00	00	00	00	00	00
5	21.73±1.93	24.38±1.78	29.57±1.56	32.47±1.34	39.10±2.33	41.15±1.45	37.53±3.12	41.39±1.22	48.15±1.98
10	42.62±1.44	49.14±1.09	56.26±1.45	46.13±2.45	53.74±1.93	57.36±1.65	51.81±2.78	68.34±1.43	71.37±2.67
15	55.43±1.30	59.91±1.27	70.17±1.20	59.06±2.11	62.20±2.07	72.10±1.76	65.34±1.43	73.08±1.34	79.84±1.45
20	68.24±2.63	68.97±1.89	89.12±0.78	70.29±1.70	71.14±1.05	77.06±1.90	70.30±1.17	78.27±1.33	88.29±2.23
25	84.42±1.89	86.35±0.76	95.30±2.35	85.14±1.45	90.33±1.98	95.29±1.04	85.26±1.98	95.89±2.45	99.40±1.46
30	93.24±1.55	95.30±1.23	96.27±1.89	94.09±0.78	94.94±1.17	97.84±1.58	97.62±1.54	98.20±1.65	99.65±1.88
40	93.61±0.97	96.03±1.76	96.63±1.06	94.46±1.89	96.03±0.88	98.32±2.67	97.36±1.92	98.44±1.46	99.89±1.06

Table 20. Comparison of optimized formulation with conventional marketed tablet

Time (min)	Cumulative %release from conventional marketed tablet	Cumulative % release from optimized batch
00	00	00
5	15.80±2.88	48.15±1.98
10	24.67±5.98	61.37±2.67
15	32.49±2.12	79.84±1.33
20	38.99±1.23	88.17±2.23
25	47.20±3.95	99.40±1.46
30	58.03±1.39	99.65±2.88
40	58.53±1.77	99.89±1.06

Results are mean of three determinations

Evaluation of tablet blend for immediate release tablets

The characterization of mixed blend was done for determination of mass-volume relationship parameters. The evaluated parameters are angle of repose, bulk density, tapped density, Hausner's ratio and compressibility index was reported in **Table 17.**

Results are mean of three determinations

From the results of precompression studies of the batch F1-F9, it is concluded that powder mixtures has good flow property and compressibility property. The angle of repose values was found to be in the range of 25.35 ^{o} to 27.76^{o} all formulations showed the angle of repose within 30^{o}. It indicates that all formulations showed good flow properties. The bulk density of tablet blend was found to be in the range of 0.55 and 0.57 gm/cm^3, indicating good packaging capacity of tablets. The tapped density was found to be within range of 0.64 to 0.67 gm/cm^3, indicating good packaging capacity of tablets and Hausner's ratio was in the range of 1.16 to 1.18. The values of Carr's index were found to be within the range of 13.43 % to 14.95%. All formulations are showing good compressibility. The powder blend was compressed using direct compression technique. Tablets prepared by direct compression method have found to be good without any chipping, capping and sticking.

Evaluation of Immediate release tablets

All the formulations were subjected for weight variation, thickness, hardness, friability, drug content, *in vitro* disintegration time, wetting time, water absorption ratio, *in vitro* dissolution studies were carried out. All the formulations were passed the evaluation parameters which were reported in **Table 18.**

Results are mean of three determinations.

Various physical parameters like weight variation, thickness, hardness, friability, drug content, *in vitro* disintegration time, wetting time, water absorption ratio, *in vitro* dissolution studies were measured to evaluate tablets. It was found that average thickness of the tablets also range between 4.38 ±0.048 mm to 4.68±0.022mm , however all the tablets passed weight variation test as the % variation was within the pharmacopoeial limit of ± 5%. Hardness was maintained to be within 4.0±0.26 kg/cm^2 to 4.45±0.14 kg/cm^2. Friability was found well within the approved range of 0.50 % to 0.58 % i.e. less than 1 %. The drug content of the tablets was found between 97.56±0.32 % to 99.78 ±0.31% of Ibuprofen. All the formulations show disintegration time less than 60 seconds. The tablets containing crosspovidone superdisintegrant in 7.5 % concentration shows better disintegration properties i.e. 28.19 seconds when compared with other formulation. The absorption ratio values of formulations found in the range of 112±0.073 to 184±0.045. Cumulative % drug release was calculated on the basis of mean amount of Ibuprofen present in the respective tablet. The results obtained in the *In-vitro* drug release for the all formulations F1 to F9 are tabulated in **Table 19.** The plots are presented in **Figure 20**

Results are mean of three determinations.

The rapid dissolution was observed in formulation F9 releases 99.89% at the end of 40 minutes. Formulations F7, F8, release 97.36 %, 98.44%, of drug respectively, at the end of 40 minutes and formulations F4, F5 and F6 which shows drug release 94.46%, 96.03%, 98.32% respectively at the end of 40 min. Formulations F1, F2, F3 releases 93.61%, 96.03%, 96.63 % respectively at the end of 40 minutes. This rapid dissolution might be due to fast breakdown of particles and rapid absorption of drug. The drug release was completely achieved in a shorter duration of time. In all the formulations the drug release within 40 minutes. High dissolution may occur due to faster breakdown.

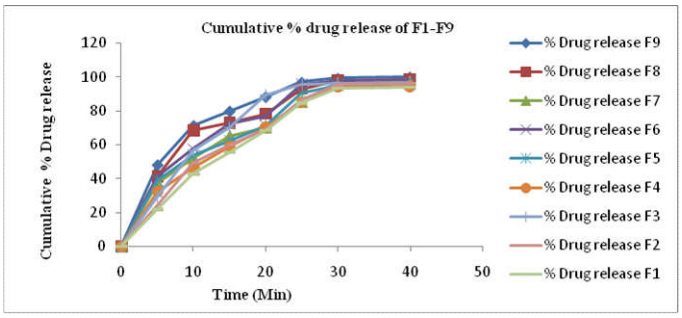

Figure 20. Cumulative % drug release of F1-F9 formulations

In comparative study F9 formulation gives higher percent drug release compare to other remaining eight formulations at the end of 40 minutes and graphical representation is shown in **Figure 20.** Therefore it was concluded that the best optimized batch was found to be F9 because of lesser disintegration time and highest percentage drug release at the end of 40 min among all the formulations. Because of it containing crospovidone superdisintegrant with fast wetting time and highest swelling property.

Comparison of optimized formulation with conventional marketed tablet

In vitro dissolution studies for batch F9 and conventional tablet were carried out using USP apparatus type II at 50 rpm, which shows that drug release was more than 80%within 15 minutes which is better than conventional marketed tablet. The results are shown in Table 20; a plot of comparison is shown in Figure 21.

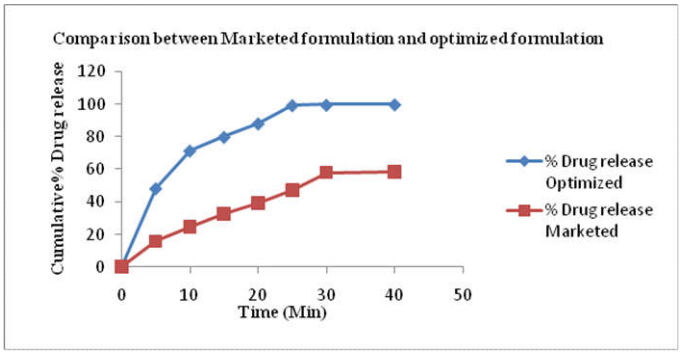

Fig. 21. Comparison between Marketed Formulation & Optimized Batch

The tablet formulation F9 prepared by microwave induced fusion method (Drug+ PEG 6000+SLS) showed drug release 99.89% in 40 minutes whereas the marketed product was found to release only 58.53% of the drug in 40 minutes in the phosphate buffer pH 7.2.

Stability study

The formulations F9 was selected for stability studies on the basis of their high cumulative % drug release and also result of *in vitro* disintegration time studies. Stability study was conducted by storing tablet at 40ºC±2ºC/75±5% relative humidity for three months. The content and dissolution behaviours from immediate release tablets were tested monthly for three months, which is shown in Table 21-22. Each tablet was individually weighed and wrapped in a aluminium foil and packed in black PVC bottle and put at above specified conditions in a heating humidity chamber for three months. After each month tablet sample was analysed for hardness, disintegration time, dissolution and drug content. The results are shown in the form of plots in **Figure 22.**

From results showed in **Table 26-27** and **Figure 22** it was concluded that, formulation F9 is physically stable and retained their original properties, when stored at 40±2ºC and 75 ± 5% RH for three months and there was no significant difference in dissolution for optimized formulation.

RESULTS AND DISCUSSION

- Ibuprofen ((+/ -) 2-(*p*-isobutylphenil propanoic acid is well known as a non-steroidal anti-inflammatory (NSAID), analgesic and antipyretic agent. Ibuprofen mostly permeable through stomach but due to its solubility limitation it can't enter in to systemic circulation and gastric empting time is 30 min to 2 hr. After this time ibuprofen goes in to small intestine where it is solubilised but can't permeate through its membrane. To improve dissolution of such drug is challenging and rational.
- In present study the attempts have been made to increase the dissolution of BCS class II drug Ibuprofen using hydrophilic polymers namely polyethylene glycol (PEG) 6000 and polyvinyl pyrrolidone (PVP) K30 by

Table 21. Stability data for optimized formulation F9 at 40^0C/ 75%RH

Formulation	Parameters Evaluated	Initial	After 1 Month	After 2 Months	After 3 Months
F9	Hardness(kg/cm^2)	3.0±0.26	3.96±0.16	4.0±0.21	4.0±0.05
	Friability (%)	0.50±0.052	0.52±0.023	0.48±0.012	0.50±0.08
	Disintegration time (sec)	28.19±0.66	28.19±0.43	29.20±0.77	30.05±0.053
	Content uniformity (%)	99.78±0.31	99.78±0.14	98.17±0.08	97.98±0.54

Results are mean of three determinations

Table 22. Dissolution profile of optimized formulation F9 at 40^0C/ 75%RH

Time (min)	Cumulative % Drug release			
	Initial	After 1 Month	After 2 Months	After 3 Months
0	00	00	00	00
5	48.15±1.98	48.15±1.09	47.23±2.88	46.25±4.03
10	61.37±2.67	71.37±3.93	69.42±1.27	68.85±2.50
15	79.84±1.33	79.84±2.88	78.12±2.67	76.87±1.09
20	88.17±2.23	88.29±1.09	85.24±1.09	84.76±1.27
25	99.40±1.46	96.87±2.88	94.08±0.45	93.54±0.98
30	99.65±2.88	99.17±0.98	98.54±1.18	97.23±0.96
40	99.89±1.06	99.89±0.80	99.05±2.54	99.78±1.24

Results are mean of three determinations

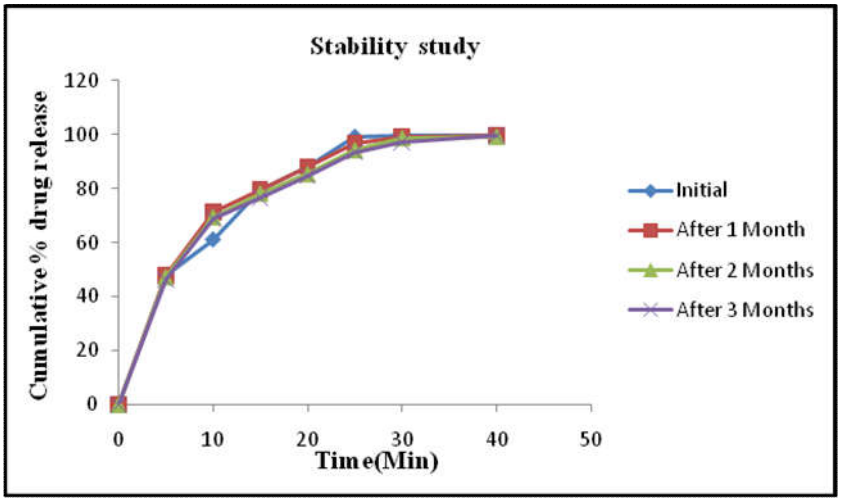

Figure 22. Dissolution profile for 40ºC/ 75%RH

Microwave induced solid dispersion and conventional fusion method. Drug-polymer complex was prepared using batch method. Maximum dissolution rate was obtained at complex prepared from (Ibuprofen +PEG6000+SLS). A successful solubility enhancement of drug complex was confirmed by taking drug release in 7.2 pH phosphate buffer.

- The formulation of solid dispersion prepared by both methods i.e. conventional fusion method and microwave induced fusion method i.e F1,F2,F3,F4 and F5,F6,F7,F8 respectively. The solid dispersion of Ibuprofen were evaluated for no. of parameters like physical appearance, % practical yield, solubility study, in vitro dissolution study and compatibility study. The physical appearance of formulations, F1 to F8 was white and amorphous powder.
- The cumulative % drug release of pure drug after 40 minutes was 13.45% each reading is taken was triplicate and then mean values were calculated. Dissolution profile of solid dispersions prepared by conventional fusion method (F1,F2,F3,F4) 56.31%, 64.40%, 70.27% and 81.42% respectively. Out of four formulations F4 showed maximum drug release i.e. 81.42%. And Dissolution profile of solid dispersions prepared by microwave induced fusion method (F5,F6,F6,F7,F8) 70.10%,84.45%,77.86% and 99.86%. Out of four formulations F8 shown maximum drug release i.e 99.86%
- After that among the all formulations, solid dispersion (F8) was selected for further tablet formulations with considerable increase in drug release, nine formulations (F1-F9) were developed by using various superdisintegrants like croscarmellose sodium, sodium starch glycolate, and crospovidone in (2.5%,5%,7.5%) concentrations.
- The values of pre-compression parameters evaluated, were within prescribed limits and indicated good free flowing properties.
- The data obtained of post-compression parameters such as weight variation, hardness, friability, wetting time, water absorption ratio, content uniformity, disintegration time and dissolution and was found to superior over conventional formulation. The F9 batch with disintegrating time 28.19±0.66 and dissolution 99.89±1.06 was selected as optimized formulation and was found superior. When F9 formulation was compared with marketed formulation it gives highest percent drug release than marketed formulation.
- Batch F9 was also subjected to stability studies for three months at 40ºC /75% RH and was tested for its disintegrating time, drug contents and dissolution behaviour monthly. It was observed that the contents of the tablets remained same.

Conclusion

- Solid dispersion of ibuprofen was prepared by conventional fusion method and microwave induced fusion method using carrier PVP K 30, PEG 6000 and SLS in (1:1, 1:1:1) ratios.
- Overall, the results concluded that suitably formulated solid dispersion (F8) of Ibuprofen with polymer PEG 6000 and surfactant SLS prepared by microwave induced fusion method significantly improved its solubility and dissolution rate. Increased wetting and solubilizing effect of PEG 6000 and SLS as well as the molecular dispersion of drug in solid dispersion and alteration of surface properties of drug particle may be responsible for the enhanced dissolution rate of Ibuprofen from solid dispersion compared to pure Ibuprofen and significantly enhance bioavailability.
- It can be concluded that among all tablet formulation batches, the batch (F9) which containing crospovidone superdisintegrant (7.5mg) was found to be more effective and gives more percent drug release than other superdisintegrants because of its high swelling capacity. It was observed that increased concentration of superdisintegrants shows increased drug release. It is developing a novel, cost effective one step immediate release tablet manufacturing process. By an appropriate selection and combination of excipients it was possible to obtained immediate release tablets.

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