ORIGINAL ARTICLE

Formulation and evaluation of irbesartan fast dissolving tablets

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Solid dispersions of irbesartan with poly ethylene glycol (PEG-6000) were prepared and further compressed as tablets by using superdisintegrants such as croscarmellose sodium, crospovidone, sodium starch glycolate (SSG). The solid dispersions of irbesartan with PEG-6000 at different ratios were prepared by physical mixing, solvent evaporation and kneading methods. The rapid release of poorly soluble irbesartan from solid dispersions was influenced by the proportion of polymer and the method employed for its preparation. Among the three methods employed kneading method was found to be suitable for improving the dissolution rate of irbesartan. The release was found to follow the first order kinetics. Solid dispersions prepared by the kneading method were further formulated into tablets with superdisintegrants such as croscarmellose sodium, crospovidone, SSG. All the tablet preparations containing superdisintegrants were formed to release the drug in the order SSG > cross carmellose sodium > cross povidone. The dissolution rate of such tablet formulations were found to release the drug at a faster rate than the tablets prepared with plain drug.

Key words: *Fast dissolving tablets, irbesartan, poly ethylene glycol-6000, solid dispersion*

INTRODUCTION

Most preferred method of drug delivery is by oral route due to its convenience and ease of ingestion. Although the oral route of administration is preferred, for many drugs it can be a problematic and inefficient mode of delivery for a number of reasons. Limited drug absorption resulting in poor bioavailability is paramount amongst the potential problems that can be encountered when delivering an active agent through the oral route.[1-3] Drug absorption from the gastrointestinal (GI) tract can be limited by a variety of factors with the most significant contributors being poor aqueous solubility and/or poor membrane permeability of the drug molecule. When delivering an active agent orally, it must first dissolve in gastric and/or intestinal fluids before it can then permeate the membranes of the GI tract to reach systemic circulation. Therefore, a drug with poor aqueous solubility will typically exhibit dissolution rate limited absorption and a drug with poor membrane permeability will typically exhibit permeation rate limited absorption. Hence, two areas of pharmaceutical research that focus on improving the oral bioavailability of active agents include: (i) enhancing solubility and dissolution rate of poorly water-soluble drugs and (ii) enhancing permeability of poorly permeable drugs.[4] Solid dispersions can be used to increase the dissolution rate of poorly soluble drugs and they have proven to increase the amount of dissolved drug at the absorption site sometimes to supersaturated concentrations and consequently improve the bioavailability. Solid dispersions are investigated in many studies because they are highly versatile in their application. They can form the basis of products applied for various routes of administration and for various dosage forms, including the most popular dosage form, the tablet. 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 In the

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Biopharmaceutical Classification System (BCS) drugs with low aqueous solubility and high membrane permeability are categorized as Class II drugs; therefore, solid dispersion technologies are particularly promising for improving the oral absorption and bioavailability of BCS Class II drugs.[5]

The advantages of solid dispersion over other approaches is that solid dispersions are better than other particle size reducing techniques to enhance the solubility, because the other size reduction techniques reduces the size to a limit approximately 2-5 microns which doesn't cause enough enhancement in drug solubility or drug release in the small intestine and to improve the bioavailability.[6] Apart from absorption enhancement, the solid dispersion technique may have numerous pharmaceutical applications such as to stabilize the unstable drug, to formulate sustained release regimen of soluble drugs by using poorly insoluble carrier. Irbesartan is an anti-hypertensive drug. It is one of the class-II drugs under BCS classification. Irbesartan is an Angiotensin-II type, receptor antagonist. Irbesartan blocks the vasoconstricting and aldosteron secreting effects of Angiotensin-II by selectively blocking the binding of Angiotensin-II to the AT_1 receptor in vascular smooth muscle. Its action is therefore independent of the pathways for Angiotensin-II synthesis. Irbesartan shows low, pH dependent solubility irbesartan is rapidly and completely bioactivated by ester hydrolysis to irbesartan during absorption from the GI tract. Irbesartan appears to be eliminated in a biphasic manner with a terminal elimination half-life ($t_{1/2}$) of approximately 11-15 h. Irbesartan shows linear pharmacokinetics over the therapeutic dose range. Steady-state levels of irbesartan are achieved within 3 days and limited accumulation of irbesartan (<20%) is observed in plasma upon repeated once-daily dosing. The absolute bioavailability of irbesartan is approximately 60-80%. Following oral administration, the peak plasma concentration (Cmax) of irbasartan is reached after 1.5-2 h. The present research work has been carried out with an aim in increasing the solubility of irbesartan and bringing out an optimized formulation of superdisintegrants in the preparation of the irbesartan as fast dissolving tablets to improve hardness as well as reduce disintegration time and finally to improve the drug release characteristics.

MATERIALS AND METHODS

Irbesartan was a Gift sample from Dr. Reddy's Lab, Hyderabad. Cross carmellose sodium (CCS), cross povidone (CP), sodium starch glycolate (SSG) were gift samples from M/s. NATCO Pharma Ltd., Hyderabad poly ethylene glycol (PEG-6000), potassium dihydrogen phosphate, methanol, directly compressible Lactose, Talc, Magnesium stearate were prepared from S.D. Fine Chem., Ltd., Mumbai. All other materials used were of pharmacopieal grade.

Saturated solubility studies

Saturated solubility studies of irbesartan were performed in different dissolution media. 500 mg of irbesartan was weighed and transferred into different conical flask. 50 ml of different dissolution media were transferred into individual conical flask and were closed appropriately. All conical flasks were placed in the REMI incubator shaker. The shaker was allowed to operate at 50 rpm at 37°C ± 1°C for 24 h.[7] Then the conical flasks were removed from the incubator shaker and the samples were filtered by using Whatmann filter paper. The clear solution obtained by filtration was suitably diluted with appropriate dissolution media and the absorbance values were noted at 244 nm by using corresponding dissolution media as blank solutions.

Preparation of solid dispersions

Irbesartan solid dispersions with PEG-6000 were prepared by using three methods such as:

Physical mixing

Specified quantity of drug (irbesartan) and polyethylene glycol 6000 were weighed separately and passed through sieve no. 80. The materials passed through sieve no. 80 were collected and transferred into a clean and dry glass mortar. Irbesartan and PEG 6000 were triturated together for 5 min and again screened through sieve no. 80. The mixture passed through sieve no. 80 is collected and packed in a wide mouthed amber colored glass container and was hermetically sealed.[8]

Kneading method

In this method, Irbesartan and PEG-6000 were taken in a glass marker and few ml of water was added and triturated vigorously until damp mass was obtained. Then the mass was dried at ambient conditions to get dry mass. Then, the mixture was passed through sieve no. 80. This was collected and packed in a wide mouthed amber colored glass container and was hermetically sealed.[9]

Solvent evaporation

Specified quantity of irbesartan and PEG-6000 were taken in a china dish and to that few ml of methanol was added and slightly heated until both drug and polymer dissolves. Then it is subsequently allowed to evaporate. The obtained mixture was dried, passed through the sieve no. 80, packed in a wide mouthed amber colored glass container and was hermetically sealed and stored.[10]

Various compositions of solid dispersions are given in Table 1.

Evaluation of solid dispersions

Solid dispersions prepared by using various methods were evaluated for particle size, flow properties and the drug content. Particle size was determined by sieve analysis and flow properties of solid dispersions were determined by angle of repose and Carr's index.

Estimation of irbesartan in solid dispersions

Solid dispersions of irbesartan from a batch were taken

at random and were transferred into a 100 ml volumetric flask and 70 ml of methanol was added to it. It was shaken occasionally for about 30 min and the volume was made up to 100 ml by adding methanol. About 10 ml of the solution from the volumetric flask was taken and centrifuged. The supernatant solution from the centrifuge tube was collected and again filtered by using Whatmann filter. Then the filtrate was subsequently diluted with 1.2 pH buffer and the absorbance was measured at 244 nm.

Dissolution rate studies on irbesartan

The dissolution test for the solid dispersions was carried out in United States Pharmacopei (USP) Apparatus Type II (paddle) [USPNF, 2007] with 900 ml of 1.2 pH buffer as the dissolution medium. The samples were drawn at 5, 10, 15, 20, 30, 45, 60 min. Fresh volume of the medium was replaced with the withdrawn volume to maintain the sink conditions and constant volume throughout the experiment. Samples withdrawn were suitably diluted with same dissolution medium and the amount of drug dissolved was estimated by ELICO SL-210 double beam spectrophotometer at 244 nm and subsequently analyzed for the cumulative percentage of drug released. The dissolution studies on each formulation were conducted in triplicate. Based upon the data obtained from the dissolution studies various parameters such as T_{50}, T_{90}, zero order and first order release rate constants were estimated. The dissolution profiles of solid dispersions were shown in Figure 1. The *in vitro* dissolution parameters of various solid dispersions were given in Table 2.

Characterization of solid dispersions

Among the various solid dispersions prepared one of the solid dispersion (Ik4) was optimized and characterized by differential scanning calorimetry (DSC), powder X-ray diffraction (PXRD). The DSC thermogram, PXRD of Solid dispersions were shown in Figures 2 and 3.

Preparation of irbesartan fast dissolving tablets with solid dispersions

Among the solid dispersions prepared and based on the dissolution studies performed, one optimized dispersion was selected for the preparation of tablets. The selected solid dispersion was blended with super disintegrants such as CCS, SSG and CP directly compressible lactose as diluent 1% magnesium sterrate and talc as lubricant and glidant. The powder blend was directly compressed into tablets by using lostatin mini press (ELITE). The compositions of various tablet formulation were given in the Table 3.

Table 1: Saturated solubility studies of irbesartan

Solvent	Amount soluble (irbesartan) in µg/ml
1.2 pH buffer	0.451
pH 2.0 hydrochloric acid buffer	0.145
pH 3.0 acid phthalate buffer	0.091
pH 4.5 neutralized phthalate buffer	0.065
pH 6.8 phosphate buffer	0.181
pH 7.2 phosphate buffer	0.201
Distilled water	0.005

Table 2: Compositions of various solid dispersions of irbesartan

Composition	Ratio (Drug: Carrier)
Physical mixtures	
IP1	1:0.5
IP2	1:1
IP3	1:1.5
IP4	1:2
Kneading method	
IK-1	1:0.5
IK-2	1:1
IK-3	1:1.5
IK-4	1:2
Solvent evaporation method	
IS-1	1:0.5
IS-2	1:1
IS-3	1:1.5
IS-4	1:2

*One part is equal to 75 mg

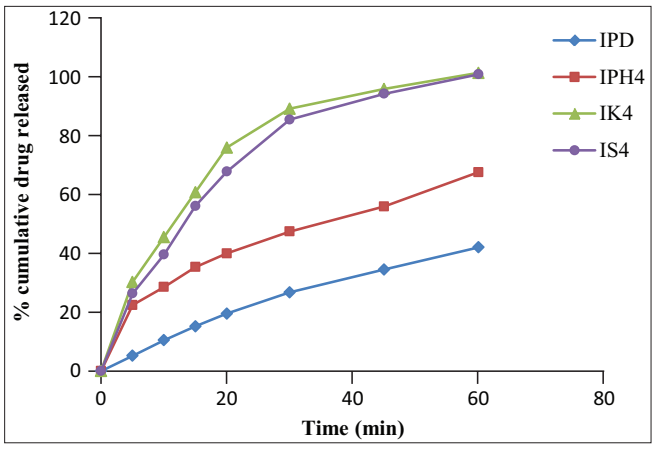

Figure 1: Comparitive dissolution profile of irbesartan solid dispersions prepared by various techniques

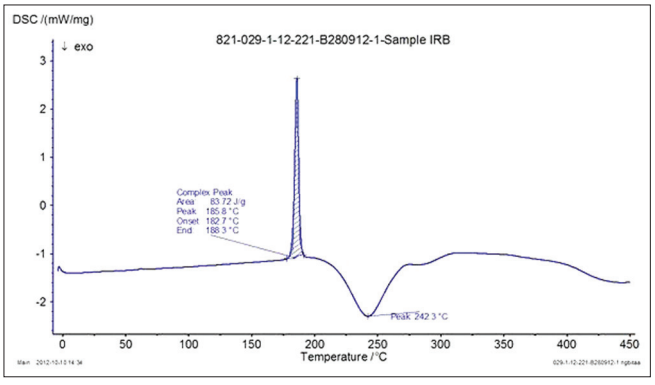

Figure 2a: Differential scanning calorimetry thermogram of pure irbesartan

Table 3: Dissolution parameters of irbesartan solid dispersions

Solid dispersion	% drug released at 60 min	T_{50} (min)	T_{90} (min)	DE_{30} %	Zero order		First order		Hixon crowell	
					K (min)	R^2	K (min^{-1})	R^2	K ($min^{-1/3}$)	R^2
IPD (pure drug)	41.43	>60	>60	53.84	0.681	0.952	0.008	0.993	0.029	0.894
IP1	46.12	>60	>60	61.66	0.743	0.932	0.010	0.992	0.027	0.927
IP2	51.23	59	>60	63.62	0.779	0.87	0.011	0.986	0.024	0.953
IP3	58.92	47	>60	65.67	0.857	0.739	0.013	0.973	0.022	0.946
IP4	66.56	36	>60	67.31	0.936	0.635	0.016	0.964	0.021	0.942
IK1	77.34	23	>60	61.32	1.224	0.807	0.024	0.991	0.029	0.844
IK2	85.56	17	>60	65.23	1.345	0.737	0.031	0.985	0.028	0.804
IK3	91.34	13	56	67.32	1.397	0.615	0.040	0.990	0.025	0.808
IK4	99.84	09	43	71.64	1.502	0.519	0.096	0.994	0.024	0.762
IS1	73.12	27	>60	61.12	1.200	0.842	0.022	0.985	0.030	0.862
IS2	80.15	21	>60	64.83	1.265	0.760	0.026	0.981	0.028	0.832
IS3	87.75	15	>60	66.77	1.345	0.661	0.034	0.987	0.026	0.798
IS4	97.35	12	48	70.22	1.546	0.656	0.041	0.953	0.027	0.802

IPD: Irbesartan pure drug

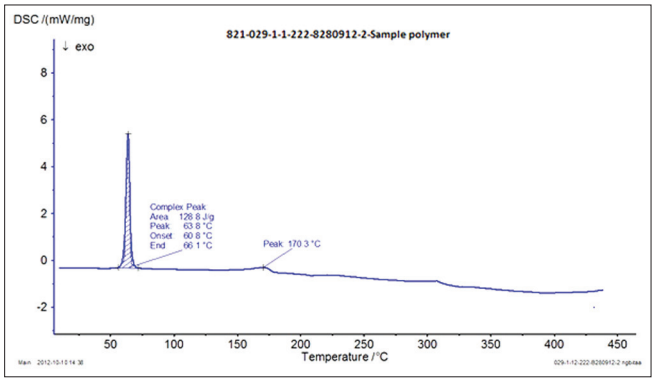

Figure 2b: Differential scanning calorimetry thermogram of poly ethylene glycol-6000

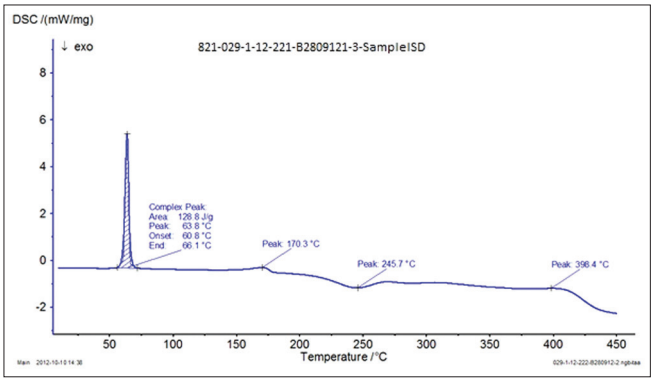

Figure 2c: Differential scanning calorimetry thermogram of irbesartan solid dispersion prepared by kneading method

Evaluation of physical parameters for irbesartan tablets

The compressed tablets were further evaluated for their physical parameters such as weight uniformity, hardness, friability and drug content.

Dissolution studies on irbesartan fast dissolving tablets

Dissolution rate studies of irbesartan tablets were performed in USP Apparatus Type II (paddle) A per the procedure described earlier. Based upon the data obtained from the dissolution studies various parameters such as T_{50}, T_{90}, zero order, first order release rate constants and Hixon-crowell were estimated. The dissolution parameters such as T_{50} and T_{90} were measured directly from the dissolution profile curves.

Accelerated stability studies

The formulations, which showed good *in vitro* performance, were subjected to accelerated stability studies. The solid dispersion F7 was subjected to accelerated stability studies. These studies were conducted using stability testing chamber at a temperature and relative humidity (RH) of 25 + 2°C, 60 + 5% RH for 6 months and at 40 + 2°C, 75 + 5% RH for 3 months. The tablets were evaluated after storage for physical parameters and drug release studies.

RESULTS AND DISCUSSION

Saturated solubility studies revealed that irbesartan show maximum solubility in 1.2 pH buffer medium than the other dissolution medium used. The drug concentration was measured at an absorption maximum of 244 nm using ultraviolet spectrophotometer (ELICO SL-120) for all dissolution medium. The absorbance values and their corresponding solubilities were shown in Table 1.

The solid dispersions were prepared with a hydrophilic carrier such as PEG 6000 by physical mixing, fusion, kneading methods as per the compositions shown in the Table 2. All dispersions were prepared under similar conditions to avoid batch to batch variation. The dispersions were found to be uniform in their characteristics. All solid dispersions were in the size range of 172 ± 3-179 ± 2 μm. The angle of repose values and the Carr's index values of all the solid dispersions were in the range of 13.2-38.2° and 9.4-35.1% respectively. The drug content estimated in all solid dispersions was highly uniform in the range of 99.95 ± 0.3-97.10 ± 0.9% indicated the uniformity.

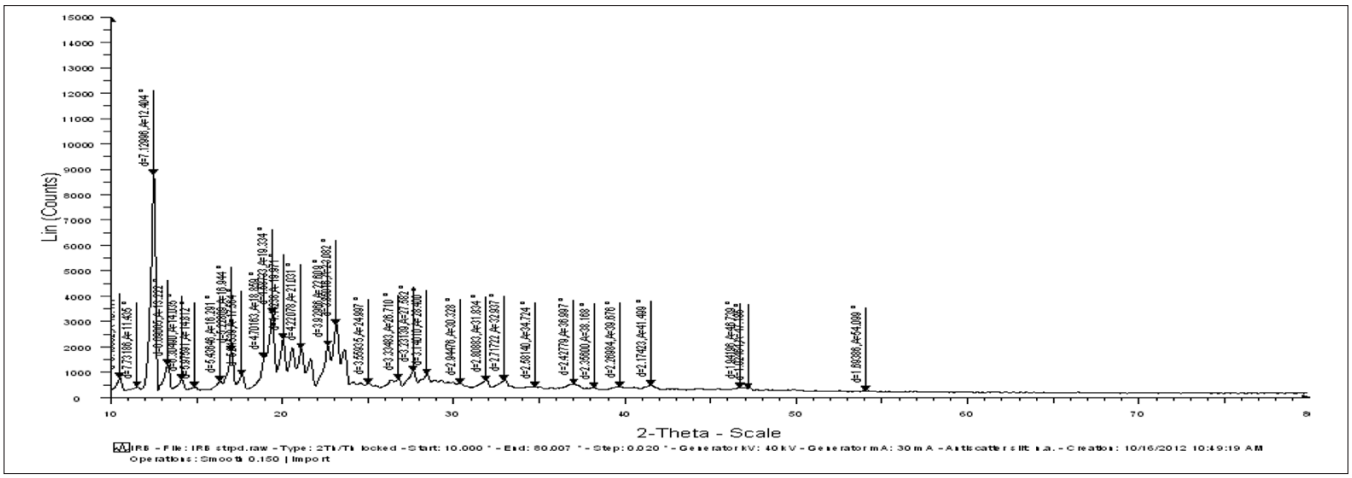

Figure 3a: Powder X-ray diffraction of irbesartan application programming interface

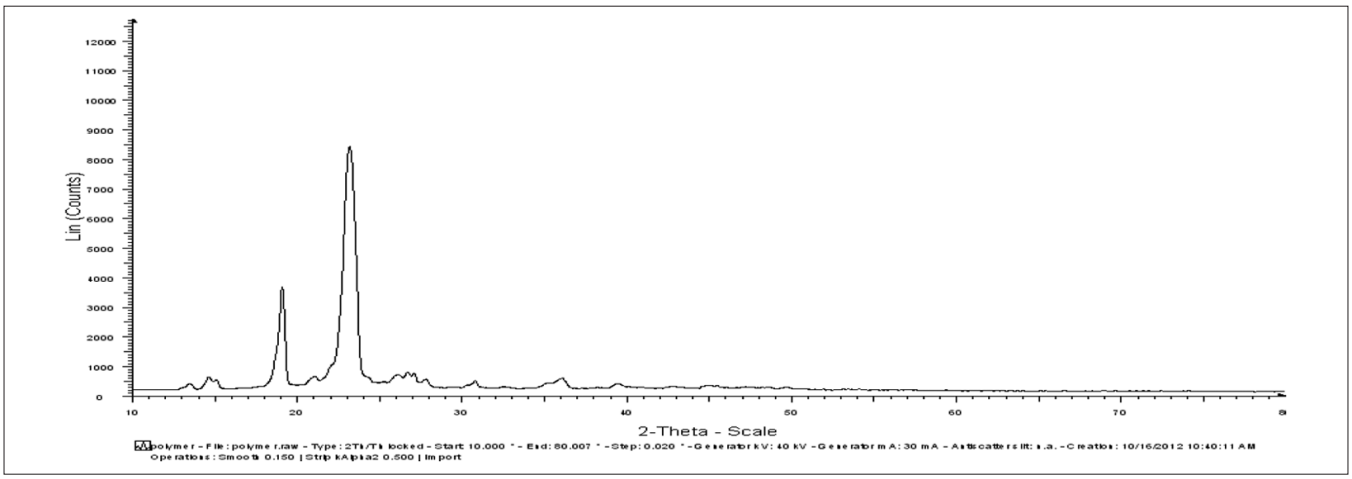

Figure 3b: Powder X-ray diffraction of poly ethylene glycol-6000

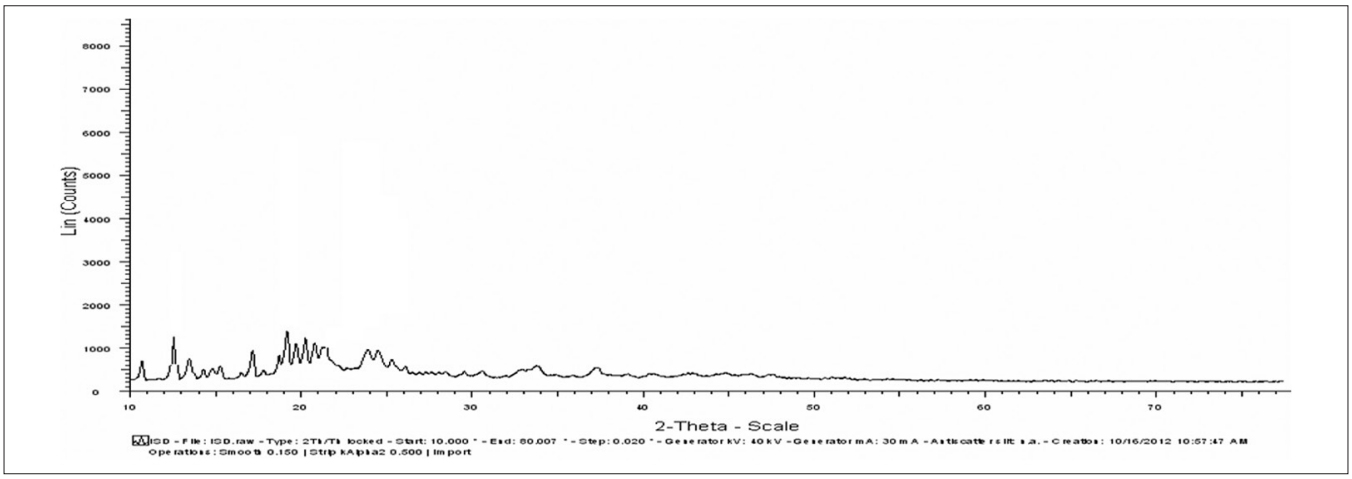

Figure 3c: Powder X-ray diffraction of irbesartan soild dispersion prepared by kneading method

The Dissolution studies of irbesartan solid dispersions prepared were performed in 1.2 pH buffer by using the paddle method. The dissolution study of solid dispersions were found to be rapid than its pure drug. The T_{50}, T_{90} and $DE_{30\%}$ values of all the formulation indicated there rapid drug dissolution than the pure drug of irbesartan. The drug release profiles of the prepared solid dispersions were shown in the Figure 1. The kinetics of drug release from all the formulation

follows first order kinetics and the results were shown in the Table 3. It was also observed that as the concentration of PEG-6000 increases the rate of dissolution of drug was also increased. Solid dispersions prepared by kneading method using drug to carrier ratio of 1:2 was found to undergo rapid dissolution rates than the others; hence, solid dispersion IK4 was characterized by DSC, XRD and IR studies.

The DSC revealed that a broad endothermic peak was observed at 188.3°C. Endothrmic peak for the carrier PEG-6000 was observed at 66.1°C. DSC thermogram of irbesartan solid dispersion prepared by kneading method indicates that the drug is entrapped in the carrier PEG-6000. The XRD of irbesartan showed sharped intense peaks this is due to the crystalline nature of irbesartan. The diffractionogram of irbesartan solid dispersion prepared by kneading method showed the complete disappearance of sharp peaks indicates the crystalline nature of irbesartan has converted to amorphous form. Hence the solid dispersion IK4 prepared by kneading was further selected for the preparation of fast dissolving tablets by using superdisintegrants such as CCS, CP, SGS. The DSC thermograms and PXRD patterns were shown in Figures 2 and 3.

The compositions of various tablets prepared were shown in Table 4. All the solid dispersions were compressed under identical conditions to avoid processing variables. The physical parameters such as weight uniformity, hardness, friability, drug content, wetting time and dispersion time were evaluated for all the tablets prepared. The physical parameters evaluated were highly uniformed and all tablets were found to be within the I.P. specified limits. The weight uniformity values were in the range of 298 ± 3.0-301 ± 3.5 mg, hardness was found to be 3.5 ± 0.4 kg/cm^2, friability values were in the range 0.47-0.82% and drug content values were in the range of 74.72 ± 0.2-75.74 ± 0.2 mg/tablet for the irbesartan matrix tablet formulations. The dissolution studies on irbesartan marketed tablet and all the tablet formulations were performed by using 1.2 pH buffer using paddle method. The dissolution rate of the tablet formulations were found to be rapid when compared to marketed tablet of irbesartan. The dissolution profiles of ibuprofen tablets were shown in Figure 4. The rate of drug release from all tablets followed first order kinetics and the results were shown in the Table 5. Among the tablets prepared with the superdisintegrants such as CCS, CP and SSG tablets with the crosspovidine as superdisintegrants tend to exhibit rapid dissolution. The rate of rapid drug release is in the order of CP > SSG > CCS in the tablet formulations. Among the various tablet formulations F7 shows rapid and 99.97% drug release when compared to marketed formulation (86.76%). This can be attributed improved wettability and dispersibility as well as increased amorphous fraction of drug. It was also found that as the conc of superdisintegrants increases, the tablets undergo rapid dissolution and drug release. This may be due to rapid intake of water by superdisintegrants, which leads to faster dissolution of the tablets and showed the improved dissolution profiles of poorly soluble irbesartan.

The formulations, which showed good *in vitro* performance, were subjected to accelerated stability studies. The formulation F7 was subjected to accelerated stability studies.

Table 4: Compositions of various irbesartan fast dissolving tablets

Formulation	Ingredients							Total weight of tablet (mg)
	IK4 (mg)	CCS (mg)	SSG (mg)	CP (mg)	DCL (mg)	Magnesium stearate (mg)	Talc (mg)	
F1	225	-	-	-	72	1.5	1.5	300
F2	225	30	-	-	72	1.5	1.5	300
F3	225	45	-	-	42	1.5	1.5	300
F4	225	-	30	-	27	1.5	1.5	300
F5	225	-	45	-	42	1.5	1.5	300
F6	225	-	-	15	27	1.5	1.5	300
F7	225	-	-	30	42	1.5	1.5	300

CCS: Cross carmellose sodium, SSG: Sodium starch glycolate, CP: Cross povidone, DCL: Dust control systems

Table 5: Dissolution parameters of irbesartan tablet formulations

Tablet formulations	% drug released at 60 min	T_{50} (min)	T_{90} (min)	DE_{30} %	Zero order		First order		Hixon crowell	
					K (min)	R^2	K (min^{-1})	R^2	K (min$^{-1/3}$)	R^2
F1	29.84	>60	>60	48.72	0.523	0.9466	0.006	0.9705	0.029	0.8037
F2	60.78	43	>60	64.12	0.993	0.8924	0.015	0.9871	0.030	0.8434
F3	72.72	32	>60	67.94	1.142	0.8668	0.020	0.9926	0.029	0.8794
F4	68.56	36	>60	66.32	1.091	0.8862	0.018	0.9912	0.030	0.871
F5	99.56	12	47	67.37	1.586	0.8148	0.046	0.9975	0.032	0.8531
F6	89.04	18	>60	70.25	1.416	0.8133	0.035	0.9925	0.031	0.8334
F7	99.97	11.5	32	73.45	1.547	0.5309	0.072	0.995	0.026	0.7269
MF	87.76	16	47	70.95	1.586	0.7732	0.049	0.9993	0.031	0.8033

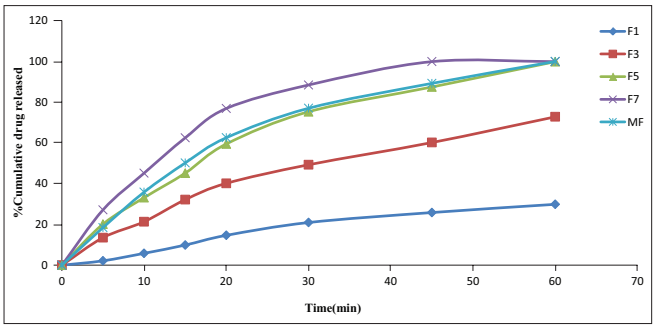

Figure 4: Dissolution profile of irbesartan tablets prepared from solid dispersion using superdisintegrants (kneading method) in comparision with marketed formulation

These studies were conducted, using the stability testing chamber at temperature and relative humidity of 25 + 2°C, 60 + 5% RH for 6 months and 40 + 2°C, 75 + 5% RH for 3 months. The tablets were evaluated after storage for physical parameters and drug release studies.

The accelerated stability studies for selected fast dissolving tablets F7 were carried by investigations the effect of temperature of the physical properties of the tablets and on drug release of the tablets. The results of accelerated stability studies were shown in Figure 5. The results indicated that there was no visible and physical changes observed in the irbesartan fast dissolving tablets after storage. It was also observed that there was no significant change in drug release from the tablet formulations. Thus, the drug release characteristics of irbesartan fast dissolving tablets designed were found to be stable.

CONCLUSION

The present study has shown that it is possible to increase the dissolution rate of poorly soluble drug irbesartan by preparing it as solid dispersions with carriers like PEG-6000. Among the various methods employed for the preparation of solid dispersions. Dispersions prepared by kneading method in the ratio of 1:2 for drug and carrier to exhibit rapid dissolution rate when compared with pure drug. Fast dissolving tablets of irbesartan prepared using various superdisintegrants also shows the rapid dissolution and drug release when compared with marketed tablets. Based on the study, it may be concluded that irbesartan tablets prepared by using solid dispersions with crospovidone as superdisintegrant was found to be ideal for rapid dispersion and for improving dissolution rate, which in turn increases the bioavailability.

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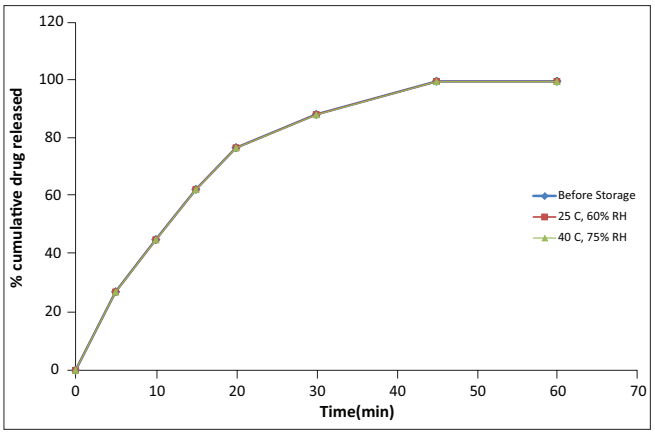

Figure 5: Dissolution profile of irbesartan fast dissolving tablet formulation (f13) before and after storage at different conditions

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