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Development of Formulation and Evaluation of Irbesartan Prepared by Solid Dispersion Using Complexing Agent

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ABSTRACT:

Irbesartan is poorly water-soluble drug. The objective of the research was to increase the solubility and dissolution rate of drug by formulating a solid dispersion with Pluronic polymer F108 using hot melt method. The dissolution profiles of developed formulations were studied. Drug–polymer interactions were also investigated using differential scanning calorimetry (DSC) and Fourier transform infrared spectroscopy (FTIR). For the preparation of Irbesartan fast-dissolve tablets, a 1:3 solid dispersion with Pluronic F108 was used with Crospovidone as disintegrants and Microcrystalline cellulose as diluent. Also studied various physical parameters along with drug released.

The results showed that a dispersion of the drug in polymer considerably enhanced the dissolution rate. The drug-to-carrier ratio is the controlling factor for dissolution improvement. FTIR spectra show no chemical incompatibility between the drug and Pluronic polymers F108. FTIR and DSC data indicate that Irbesartan was in the amorphous form, which explains the faster dissolution rate of the drug from its solid dispersions. In the optimization study, different analysis showed that an optimum concentration of disintegrants are required for obtaining rapidly dissolving tablets.

KEYWORDS:

Irbesartan, Solid Dispersion, Fast dissolving tablets.

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MATERIALS AND METHODS

Irbesartan was received as a gift sample from Unichem Laboratories Ltd, Gaziabad. Microcrystalline cellulose was procured from Wockhardt Limited, Aurangabad (Make: BASF Chemicals).



Figure 1: Structure of Irbesartan

FORMULATION OF SOLID DISPERSION OF DRUGS

Solid dispersions containing 1:1, 1:2, 1:3, 1:5, 1:7 ratio of drug loading in carriers were prepared by melted fusion. The drug and the polymer were heated until the polymer melt. The molten mixture was stirred until the drug was dissolved completely in the melt and a homogeneous solution was obtained. The solution was brought to solidification cooling. This was then powdered and passed through mesh to get fine solid dispersion.

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The different composition and solubility profile of all the dispersions are tabulated in **Table 1 & 2**.

Table 1: Preliminary solubility studies ofIrbesartan Solid dispersion

Drug:	Amount in 1 ml (0.1mg/ml)
Carrier	F 108 (mg/ml)
Pure drug	0.02
1:1	0.03
1:2	0.055
1:3 (SDI 3)	0.063 (SDI 3)
1:5	0.039
1:7	0.040

EVALUATIONS OF SOLID DISPERSION Bulk density (g/ml)

Sufficient quantity of powder was passed through 1mm sieve. Approximately 100 g of the test sample (m) weighed with 0.1 per cent accuracy was gently introduced without compacting into a dry graduated cylinder of 250 mL (readable to 2 mL). This was then carefully level without compacting, and unsettled apparent volume (V0) to the nearest graduated unit was read. The bulk density was then calculated in g per mL by the formula m/V0.

Tapped Density (g/ml) Apparatus

The apparatus (Figure 3.01-3) consists of the following.

- A 250 mL graduated cylinder (readable to 2 mL) with a mass of 220 ± 44 g.

- A settling apparatus capable of producing, in 1 min, either nominally 250 ± 15 taps from a height of 3 ± 0.2 mm, or nominally 300 ± 15 taps from a height of 14 ± 2 mm. The support for the graduated cylinder, with its holder, has a mass of 450 ± 10 g.

Procedure

Proceed as described above for the determination of the bulk volume (V0). Secure the cylinder in the holder. Carry out 10,500 and 1250 taps on the same powder sample and read the corresponding volumes V10, V500 and V1250 to the nearest graduated unit. If the difference between V500 and V1250 is less than 2 mL, V1250 is the tapped volume. If the difference between V500 and V1250 exceeds 2 mL, repeat in increments such as 1250 taps, until the difference between succeeding measurements is less than 2 mL. Fewer taps may be appropriate for some powders, when validated. Calculate the tapped density (g/mL) using the formula m/Vf in which Vf is the volume. final tapped Generally, replicate determinations are desirable for the determination of this property. Specify the drop height with the results. If it is not possible to use a 100 g test sample, use a reduced amount and a suitable 100 mL graduated cylinder (readable to 1 mL) weighing 130 ± 16 g and mounted on a holder weighing 240 ± 12 g. The modified test conditions are specified in the expression of the results.

Angle of Repose

The material is poured through a funnel to form a cone. The tip of the funnel should be held close to the growing cone and slowly raised as the pile grows, to minimize the impact of falling particles. Stop pouring the material when the pile reaches a predetermined height or the base a predetermined width. Rather than attempt to measure the angle of the resulting cone directly, divide the height by half the width of the base of the cone. The inverse tangent of this ratio is the angle of repose.

Angle of Repose tan (α)= Height/0.5 Base

Compressibility index:

Compressibility Index = $100 (V_0 - V_f)/V_0$

Hausner ratio

Hausner ratio = V_0/V_f

% Practical Yield

Percentage practical yield was calculated to know about percent yield or efficiency of any method, thus its help in selection of appropriate method of production. The percent yield of irbesartan solid



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dispersions can be determined by using the following expression: Percent yield = (weight of prepared solid dispersion / weight of drug +carriers) x 100

Table 2: Evaluation of solid dispersion for micromeritics.

Batch no.	Bulk density (g.ml)	Tapped Density (g/ml)	Angle of Repose	% Compressibility	Hausner ratio	% Practical yield
SDI 3	0.58	0.68	26.56±0.70	14.71	1.18	95.07%

Method establishment (Assay/ Drug Content) Drug content Estimation

The percentage drug content in Solid dispersion was estimated by dissolved 50 mg quantities of solid dispersion in 0.1 N HCl, mixed thoroughly by shaking and the volume was made up to the mark with solvent (0.1N HCl). The solution was filtered and the filtrate was diluted suitably with 0.1N HCl (1.2 pH) and absorbance was measured at 231 nm using UV/Visible spectrophotometer.

Table 3: Drug content determination with different polymers

SN	Formulation	Theoretical Amount of drug in 150 mg of dispersion	Theoretical Amount of drug in %	Assayed drug content (mg)	% Drug Content
1	SDI 3	50mg	100%	49.14	98.28





Figure 2: IR of Irbesartan



Figure 3: IR of Irbesartan + Poloxamer 108.



Figure 4: IR of Drug+ Microcrystalline Cellulose



Figure 5: IR of Drug + Crospovidone

The FT-IR Spectrum Shows peaks which was identical to the standard reported peaks of specific functional group, which present in Irbesartan. This concluded that the drug sample obtained was of pure quality.

Measure the FTIR spectra of Irbesartan alone and it's combination with Pluronic F108 used to increase solubility. Using Fourier Transform Infra-Red



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spectrophotometer (FTIR) (Jasco FT/IR-4100) with diffuse reflectance principle. Sample preparation involved mixing the samples potassium bromide (KBr), triturating in glass mortar and finally placing in the sample holder. The spectrum was scanned over a frequency range 400-4000 cm-1.

DSC

Weigh the sample of solid dispersion about 10mg in standard open aluminium pans, and scanned from 20-300oC, at a heating rate of 10oC/minute while being purged with dry nitrogen in a differential scanning calorimeter (DSC 60, Shimadzu). Obtain the DSC curves of solid dispersions prepared by solvent evaporation representing the rate of heat uptake.



Figure 6: DSC chromatogram of Solid Dispersions of API with Pluronic F 108 (1:3)

SEM (Scanning Electron microscope) studies

The surface morphology of the layered sample was examined by using SEM. The small amount of powder was manually dispersed onto a carbon tab (double adhesive carbon coated tape) adhered to an aluminum stubs. These sample stubs were coated with a thin layer (30Å) of gold by employing POLARON-E 3000 sputter coater. The samples were examined by SEM and photographed under various magnifications with direct data capture of the images onto a computer. Results are displayed in Figures.



Figure 7: SEM micrographs of F108



Figure 8: SEM micrographs of SDI 3 (1:3).

In-vitro Dissolution Studies

The release profile of an entrapped drug predicts how a delivery system might function and gives valuable insight into its in vivo behavior. In vitro release profile for each solid dispersion as well as pure drug were performed using USPXXII type 2 dissolution apparatus (TDP-06P, Electro lab, Mumbai, India). Solid dispersion equivalent to 100 mg of drug was added to 900 ml of 0.1 N HCl at 37± 0.5°C and stirred at 50 rpm. Aliquot of 5ml was withdrawn at time intervals of 5, 10, 15, 20, 30, 45, 60 and 90 min. The withdrawn volume was replaced with the same volume of dissolution medium in order to keep the total volume constant. The absorbance of the samples was measured at respective λ max after suitable dilution if necessary, using appropriate blank.

Table: 4 In-vitro dissolution profile of Pure Drug& Solid Dispersions with polymers.



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Code	Drug : Carreier Ratio	Т5	T10	T15	T20	T30	T40
Pure Drug	Pure	4.05	9.07	11.09	14.98	25.90	35.92
SD -Poloxamer 108 (SDI 1)	1:1	15.38	49.60	60.41	65.23	69.98	76.91
SD -Poloxamer 108 (SDI 2)	1:2	23.83	52.11	64.43	69.73	75.22	81.00
SD -Poloxamer 108 (SDI 3)	1:3	31.95	57.61	77.09	82.25	88.19	93.81
SD -Poloxamer 108 (SDI 4)	1:5	29.59	48.69	69.74	73.85	81.90	88.72
SD -Poloxamer 108 (SDI 5)	1:7	25.30	39.80	50.41	61.28	70.88	83.51

PREPARATION OF TABLETS FROM SOLID DISPERSION

Drug fast-dissolve tablets were prepared according to the proportions given in Table 6 & 7. The raw materials were passed through a 40-mesh screen before mixing. A powdered 1:2 solid dispersion containing an amount of drug equivalent to 100 mg was mixed with the other excipients and directly compressed on a RIMEK rotary tablet machine using 12-mm diameter flat-face round punches (Karnavati Eng. Pvt. Ltd, Ahmedabad). The tablet weight was adjusted to approximately 500 mg. The compositions details are represented in **Tabel no.4**.

Tabel no. 5: Ingredients Used for Preparationof Enalapril Maleate Fast-Dissolve Tablets.

Ingredients		Formulation						
	Al	A2	A3	A4	A5	A6	A7	A8
SDI3	300	300	300	300	300	300	300	300
Crospovidone	-	-	-	5	15	20	15	20
Pearlitol	-	35	40	-	-	-	42.5	45
Talc	10	10	10	10	10	10	10	10
Magnesium stearate	5	5	5	5	5	5	5	5
Microcrystalline Cellulose	185	150	145	180	170	165	127.5	120

Evaluation of Prepared Tablets Hardness

Performed using the hardness tester.

Friability

20 Tablets are selected randomly, and weighed then placed in the friabilator chamber. The tablets are subjected to combined effect of abrasion and shocks by utilizing a plastic chamber that revolve at a speed of 25 rpm drop from height of 6" height per revolution for 4 minutes. The 20 tablets are then collected cleaned with a brush and weighed. Then calculate the % of weight loss, %Loss = 100*(weight before – weight after)/weight before Acceptable if 0.5- 1% of the tablet weight was lost.

Weight variation

Take 20 tablets and weigh them individually, then calculate average tablet weight, and percentage deviation for each tablet.

Disintegration

Disintegration time was measured according to the method described by Gohel et al. (18, 19). The disintegration times were measured using a modified disintegration method. For this purpose, a petri dish (10-cm diameter) was filled with 10 mL of water. The tablet was carefully put in the center of the petri dish, and the time for the tablet to disintegrate completely into fine particles was noted.

Wetting time

Five circular tissue papers of 10-cm diameter were placed in a 10-cmdiameter petri dish. Ten milliliters of water containing eosin (0.01%), a water-soluble dye, was added to the petridish. A tablet was carefully placed on the surface of the tissue paper. The time required for water to reach the upper surface of the tablets was noted as the wetting time.

Drug content

Tablets equivalent to 500 mg of bulk drugs was taken and dissolved separately in 500 ml standard flasks with 0.1N HCl. The solution was filtered and was further diluted such that the absorbance falls within the range of standard curve. The absorbance of solutions was determined at respective wavelength for each drug. From the absorbance total drug content in the batches was calculated and given in Tables.

In vitro dissolution studies

The release profile of an entrapped drug predicts how a delivery system might function and gives valuable insight into its in vivo behavior.



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In vitro release profile for each solid dispersion tablet as well as pure drug were performed using USPXXII type 2 dissolution apparatus (TDP-06P, Electro lab, Mumbai, India). Tablets equivalent to 1000 mg of drug was added to 900 ml , 0.1 N HCl pH 1.2 at $37\pm 0.5^{\circ}$ C and stirred at 50 rpm. Aliquot of 5ml was withdrawn at time intervals of 5, 10, 15, 20, 30, 45, 60 and 90 min. The withdrawn volume was replaced with the same volume of dissolution medium in order to keep the total volume constant. The absorbance of the samples was measured at respective λ max after suitable dilution if necessary, using appropriate blank.

Stability Studies

Stability testing was carried out to determine the quality of formulation under the influence of temperature humidity over time. and The representative samples of solid dispersions were placed in a controlled temperature and humidity cabinet (Firlabo, 6100). An accelerated term stability study was conducted according to the International Conference on Harmonization (ICH), stability protocol, $40^{\circ}C \pm 2^{\circ}C/75\%$ RH $\pm 5\%$ RH. In order to study the stability of the solid dispersions, there presentative samples of solid dispersions were sealed in aluminum foil and stored at room temperature conditions (silica gel to control moisture content) and in a controlled temperature cabinet at 40 °C (75% RH) (silica gel to control moisture content). The physicochemical properties of these dispersions were evaluated after 0, 3 and 6 months for accelerated and 0, 3 and 12 months for samples stored under ambient conditions.

Tabel 6: Evaluation of FDT-Irbesartan.

Properties		Formulation								
	Al	A2	A3	A4	A5	A6	A7	A8		
Weight (g)	0.498	0.497	0.494	0.499	0.496	0.495	0.494	0.493		
Thickness (mm)	3.01	3.01	3.01	2.98	3.09	3.0	3.02	3.01		
Diameter (mm)	11.02	11.05	11.06	11.08	11.02	11.01	11.02	11.03		
Hardness (g/cm ²)	3.3	3.3	2.9	3.7	3.7	3.9	3.1	3.4		
Friability (% loss)	0.14	0.21	0.32	0.31	0.22	0.24	0.22	0.33		
Disintegration time	210	145	180	154	173	178	110	135		
Wetting time(sec)	121	72	98	90	88	95	65	70		

Drug content

Tablets equivalent to 100 mg of bulk drugs was taken and dissolved separately in 500 ml standard flasks with 0.1N HCl. The solution was filtered and was further diluted such that the absorbance falls within the range of standard curve. The absorbance of solutions was determined at respective wavelength for each drug. From the absorbance total drug content in the batches was calculated and given in **Tables**

Table 7: Drug content determination of the FDT.

SN	Formulation	Theoretical Amount of drug in tablet.	Theoretical Amount of drug in %	Assayed drug content (mg)	% Drug Content
1	A1	100mg	100%	94.26	94.26
2	A2	100mg	100%	90.36	90.36
3	A3	100mg	100%	92.14	92.14
4	A4	100mg	100%	91.26	91.26
5	A5	100mg	100%	94.21	94.21
6	A6	100mg	100%	91.36	91.36
7	A7	100mg	100%	99.24	99.24
8	A8	100mg	100%	90.48	90.48

In vitro dissolution studies

The release profile of an entrapped drug predicts how a delivery system might function and gives valuable insight into its in vivo behavior. In vitro release profile for each solid dispersion tablet as well as pure drug were performed using USPXXII type 2 dissolution apparatus (TDP-06P, Electro lab, Mumbai, India).

Tablets equivalent to 100 mg of drug was added to 900 ml, 0.1 N HCl pH 1.2 at $37\pm 0.5^{\circ}$ C and stirred at 50 rpm. Aliquot of 5ml was withdrawn at time intervals of 5, 10, 15, 20, 30, 45, 60 and 90 min. The withdrawn volume was replaced with the same volume of dissolution medium in order to keep the total volume constant. The absorbance of the samples was measured at respective lambda max after suitable dilution if necessary, using appropriate blank. Results are displayed in.



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Table 8: In-vitro dissolution profile of FDT-Irbesartan.

Time	Cumulative % drug release									
(min)	A1	A2	A3	A4	A5	A6	A7	A8		
0	0	0	0	0	0	0	0	0		
5	36.24	38.94	37.84	36.48	33.68	36.41	42.36	38.94		
10	41.26	47.28	45.74	42.84	45.26	41.56	54.61	47.33		
15	49.85	58.19	52.64	58.36	51.29	50.27	64.8 7	56.84		
20	56.78	69.74	67.14	64.21	60.84	59.36	86.56	62.54		
25	69.37	74.26	74.26	71.26	72.48	67.15	89.26	75.01		
30	74.29	80.16	82.15	79.64	79.48	74.26	93.65	80.26		
40	81.59	88.29	89.63	82.67	86.25	82.36	98.45	88.69		

RESULTS Solubility Profile

The experimental had initiated with the solubility profile of physical mixture of the drug and the carrier. The table 1& 2 describes the influence of increasing drug to carrier ratio in solid dispersion and physical mixtures in pH 1.2(0.1 N HCl) Physical mixtures of different ratios (1:1, 1:2, 1:3, 1:5, 1:7 and 1: 9) were also subjected to solubility studies to compare and assess the solubility enhancement of Irbesartan in the presence of Pluronic F 108 mixture form. The drug dissolution increased with the increase in the carrier till ratio level of 1:3 content in the physical mixtures. The solubility enhancement in the case of physical mixtures was significantly in 1: 3.

Beyond 1: 3, the solubility either remained constant or decreased gradually until 1: 3 where the solubility reaches the lesser. Further increase in the concentration of carrier. showed an inverse correlation in solubility. Decrease in the dissolution of drug above the ratio 1: 5 (drug: carrier) has been observed. This can be ascribed to the formation of a viscous hydrophilic layer around the drug particles. The increase in solubility of Irbesartan in physical mixtures with greater ratios was found to be less enhanced compared to the 1:3

EVALUATION OF SOLID DISPERSIONS Micromeritics and morphology studies

Flowability of Irbesartan (Pure drug) and its solid dispersions was assessed by determination of Compressibility index (CI), Hausner's ratio (HR) and angle of repose. Micormeritic behaviors of the untreated Irbesartan powder and all prepared solid dispersions are listed in Table 2. Table 2 shows that the flowability represented in terms of Compressibility index, Hausner's ratio and angle of repose was much improved compared to those of original powders (untreated Irbesartan). In case of pure Irbesartan, powder could not pass through the funnel during the angle of repose experiment. The poor flow of Irbesartan could be due to the irregular shape and high fineness of the powder, The solid dispersion as such has limited commercial viability as a dosage form.

With an intention to develop convertible to Fast Dissolving Tablet dosage for, the solid dispersions were prepared. Thus it was mandatory that the solid dispersions displays good blend properties. Only the batches with ratio of drug to carrier 1:3 were also evaluated for different derived properties viz- bulk density (between 0.48 to 0.57 gm/cm3) & Tapped density (0.64 to 0.68g/cm3). The results angle of repose and compressibility indicated that the flowability of blend is significantly good. Along-with these properties it is equally important to have good %practical yield of the solid dispersions. We have observed 95.0 % practical yield in these solid dispersions.

Drug Content

Drug content of the solid dispersions was found to be 98.28%. The mixture of solid dispersions showed the presence of high drug content and low standard deviations of the results. It indicates that the drug is uniformly dispersed in the powder formulation. Therefore, the method used in this study appears to be reproducible for preparation of solid dispersion.

Drug Carrier compatibility IR

Spectroscopic studies conducted for possible drug: carrier interactions are FTIR spectra of pure drug and carrier F 108 as only these combination gave better



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solubility and better drug content and which shows all the characteristic peaks of drug and carrier thus indicating no significant evidence of chemical interaction between drug and carrier, which confirms the stability of drug with its solid dispersion.

DSC

The occurrence of any interaction between a drug and polymers in the formulation can be predicted by conducting the differential scanning calorimetry studies. The thermograms of solid dispersions display the characteristic features of the drug. This indicates no possible interaction between the polymer and Irbesartan. DSC thermograms of Irbesartan & F 108 as well as their solid dispersions prepared by hot melt method and physical mixture . Irbesartan exhibits a characteristic, sharp exothermic peak at their respective melting points, which is associated with the decomposition of drug and associated with melting point of the drug and indicatesthe crystalline nature of the drug.

SEM

Micrographs of drug/polymer and SDI 3 (1:3) are shown in Figure 8. The particles of F 108 as received from the supplier were rather irregular in size and shape. The spray drying process resulted in generally spherical particles. Compared to the starting material, the particle sizes of the SDI are much smaller. This reduction in particle size facilitates the dissolution process.

In-vitro Dissolution Studies of solid dispersions

The study reveals that there is marked increase in the dissolution rate of Irbesartan from all the solid dispersions when compared to pure Irbesartan itself. From the in vitro drug release profile, it can be seen that formulation SDI 3, containing F 108 (1:3 ratio of drug: F 108) shows higher dissolution rate compared with other formulations. This may be attributed to the increase in drug wettability, conversion to amorphous form and solubilization of the drug due to hydrophilic carrier.

Preparation of Tablets from Solid Dispersion

Direct compression is the easiest way to develop rapidly dissolving tablets. Solid dispersions were found not to be amenable to wet granulation method. The combined use of disintegrants and water soluble excipients has been useful in preparation of rapidly disintegrating tablets. The disintegration and solubilization depend on the combined action of disintegrants and water-soluble excipients. Disintegrant in the formulation was Crospovidone, which proved to be a better superdisintegrant compared to other superdisintegrants for this experiment

The disintegration time of the tablets in case of all the formulations prepared from solid dispersions were found to be very short. The disintegration time of the tablets increased with the increase in the concentration of the F 108. This may be due to the waxy nature of the F 108, which during compression, could plasticize, soften or melt and then fill the pores within tablets. The other parameters of friability, hardness and drug content were well within the pharmacopoeial limits (Table 6). Tablet characteristics of optimized tablet (A7) are tabulated in Table5. In vitro dissolution studies for 7 (A7) confirmed the results obtained with solid binary mixtures. A7 tablets showed good dissolution efficiency.

As the amount of Crospovidone and pearlitol was increased, the wetting period of the tablets decreased. That increasingthe means that concentration of superdisintegrant agent or poreforming agent decreases the wetting time. Croscarmellose sodium 4% (wt/wt) and pearlitol (wt/wt) were selected as the optimum 10% concentrations that showed a minimal wetting time of 65 sec with 98.45% drug release in 45 min. Rudnic et al.¹⁵ postulated that wicking and capillary action are major factors in the ability of superdisintegrants to function.



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To select the amounts of superdisintegrant and poreforming agent, preliminary trials were conducted as shown in Table 5. All the prepared tablets were characterized by weight, uniform thickness, diameter, hardness, friability, disintegration time, and wetting. As a result, the tablet containing Crospovidone showed the longest time for wetting, because the major mechanism of disintegration for crospovidone is swelling, whereas tablets containing pearlitol showed a quicker water uptake rate and less time for wetting . Thus we have selected a formulation which contained both Crospovidone and pearlitol, that exhibited faster disintegration and wetting. All the tablets passed weight variation test as the percent weight variation was within the pharmacopoeial limits. Hardness was shown within the range in all the formulations.

The hardness of all tablets was kept within the above mentioned range to compare the disintegration time between the formulations prepared using different disintegrants and their varying concentrations. The friability of all formulations was determined. The friability values of none of the formulations exceeded 1%. The results of friability indicate that the tablets were mechanically stable and can withstand rigors of transportation and handling. The results of disintegration of all the tablets were found to be within prescribed limits and satisfied the criteria of Fast Dissolving tablets.

Drug content

The drug content of the prepared FDT was found to be in the range of 90-99 %. Maximum % drug content was found in the formulation A7 (1:3). Percent drug content decreased as the amount of drug added to each formulation increased (1:5 and 1:7 ratio of drug: carrier). The release data obtained for all 8 formulations are tabulated in Table 8, shows the cumulative percent drug released as a function of time for all formulations.

In-vitro Dissolution Studies

All the tablets prepared were subjected for release profile. The tablets prepared from Crospovidone i.e. F1 to F8 showed good drug release Among 8 batches, batch A7 which contain both poreforming agent and Crospovidone were selected as optimized batch because of its lowest disintegration time and highest drug release.

CONCLUSION

The present study concluded that F 108 is suitable carrier for the preparation of Irbesartan solid demonstratedby dispersions. As DSC. the amorphization of Irbesartan offered an explanation of better dissolution rate from its solid dispersion. In the FTIR spectra, most of the characteristic polymer peaks were present, but the characteristic peaks of Irbesartan were absent. This indicates that Irbesartan was trapped inside the polymer matrix. Experimental design provided a better understanding of the effect of formulation variables on the quality of fastdissolve tablets containing a solid dispersion of a hydrophobic drug. The optimal batch exhibited a disintegration time of 110 sec, a percentage friability of 0.22%, a wettability of 65 sec, and a Q20 of 86.565%.

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