Formulation and Evaluation of Fast Disintegrating Tablet of Solid Dispersion of Irbesartan

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Abstract- *Irbesartan is an angiotensin receptor blocker used to treat hypertension and diabetic nephropathy. In present study, the attempts have been made to increase the dissolution of BCS class II drug Irbesartan using hydrophilic polymers HPMC and Polyethylene glycol 6000 by Kneading Method and Microwave Induced fusion method of solid dispersion. The drug polymer complex was prepared. The solid dispersion of Irbesartan were evaluated for number of parameters like physical appearance, percentage practical yield, solubility study, invitro dissolution study and compatibility study. The percentage drug release of pure drug was calculated. The dissolution profile of solid dispersions prepared by Kneading Method and Microwave Induced fusion method of solid dispersion were studied. Out of eight formulations of solid dispersion, S8 showed maximum drug release i.e. 95.61%. After that among all the formulations, solid dispersion prepared by Microwave Induced Fusion Method was selected for further preparation of fast disintegrating tablet formulations. Nine formulations (F1 to F9) were developed by using various concentrations of superdisintegrants like croscarmellose, Sodium starch glycolate, crosspovidone. The F9 batch with disintegration time 41 sec and dissolution 94.96 % was selected as optimized formulation.*

Keywords- Irbesartan, Fast Disintegrating Tablet, Solid Dispersions, Kneading Method, Microwave Induced fusion method, Superdisintegrants.

I. INTRODUCTION

Nowadays, vehicles are important in daily life and for industrial use as well. Sufficient effort is being done to withdraw the combustion Engines By Electric MOTORS. Due To Increase In Carbon Dioxide (CO2) Caused By Industries And Transportation, The Kyoto Treaty Was Signed. THIS Treaty Was Aimed To Reduce The Level Of Co2. As A Finding Electric Vehicle Is A Solution To Reduce Co2 Emissions. Electric Vehicles Are Increasing Everyday Across The World. When The Number Of Electric Vehicles Is Increasing, There Is A Need To Implement Electric Vehicles Charging Stations. Previous Battery Monitoring System Only Monitor And Detect The Condition Of Battery And Notify The User Via Battery Indicator Inside The Vehicle. Due To The Advanced Design Of Notification systems, Internet Of Things (IoT)Technology Can Be Used To Notify The Manufacturer And Users Regarding The Battery Status Of Ev. In Ev's, it is important to monitor the battery's state of charge (SoC) although this is not always easy because of the properties themselves. The boom of the world wide web has sharpened interest in e-money that can be transferred over the internet. SO, IT is essential to do the transaction for the charging of the vehicle with an e-wallet or with e-money. For, an e-wallet SOME FORM of digital payment system is developed for faster and ease of transaction.

USP & BP Solubility Criteria

Descriptive Term	Part of Solvent Required Per Part of Solute
Very Soluble	Less than 1
Freely Soluble	1 to 10
Sparingly Soluble	30 to 100
Slightly Soluble	10,000 and over
Very Slightly Soluble	1000 to 10,000
Practically Insoluble	10,000 and over

Biopharmaceutical Classification System (B.C.S.)

Class	Solubility	Permeability	Examples
I	High	High	Metoprolol, Diltiazem
II	Low	High	Glibenclamide, Phenytoin, Danazol, Mefenamic acid, Irbesartan
III	High	Low	Ranitidine, Acyclovir, Neomycin B, Atenolol, and Captopril.
IV	Low	Low	Hydrochlorothiazide, Taxol

II. MATERIALS AND METHODS:

1. Irbesartan (AR) API Arati Pharma, Mumbai 2 .PEG 6000(AR) Polymer Research lab Fine chem. Industry, Mumbai 3. Sodium Lauryl Sulphate (AR) Surfactant Research lab Fine chem. Industry, Mumbai 4. Sodium Starch Glycolate

(AR) Superdisintegrant Research lab Fine chem. Industry, Mumbai 5. Crosspovidone (AR) Superdisintegrant Research lab Fine chem. Industry, Mumbai. 6.Croscarmellose Sodium (AR) Superdisintegrant Research lab Fine chem. Industry, Mumbai 7. Microcrystalline Cellulose (LR) Superdisintegrant Research lab Fine chem. Industry, Mumbai 8. Magnesium Stearate (LR) Lubricant Research lab Fine chem. Industry, Mumbai 9. Talc (LR) Glidant Research lab Fine chem. Industry, Mumbai.

III. PREPARATION OF SOLID DISPERSIONS

The solid dispersions of drug and polymer were prepared by Kneading method and Microwave induced fusion method in various ratios such as Irbesartan + HPMC (1:1), (1:2); Irbesartan+ PEG 6000 (1:1), (1:2). Solid dispersions prepared by Kneading method were S1, S2, S3, S4 and solid dispersions prepared by microwave induced fusion method wereS5, S6, S7, S8 respectively.

Preparation of Solid Dispersions of Irbesartan by Kneading Method.

In this method, Irbesartan and Polymers were taken in a glass beaker 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.

Preparation of Solid Dispersions of Irbesartan by Microwave Induced Fusion Method

In this method microwave energy was used to prepare solid dispersion.The drug and hydrophilic polymer will get fused together to form solid dispersion. Solid dispersions were prepared by placing the mixture of drug and polymer in porcelain dish and subjected to microwave radiation. Only one sample was placed at a time inside the microwave oven, then porcelain dish was placed in room temperature to solidify molten mass.After that the solid dispersion was placed in desiccators for 24 hr and then product was pulverized using a porcelain mortar and pestle. The pulverizedpowder was passed through 100# sieve.

IV. PREFORMULATION STUDY

Organoleptic Properties

The drug sample of Irbesartan was evaluated for its Organoleptic Properties and it was found that , the drug sample of Irbesartan complies with the standards of IP. The results are as follows

Organoleptic Properties of Irbesartan

Test	Specification/ Limit	Observation
Appearance	Fine Powder	Complies with IP
Color	White	Complies with IP
Odour	Odourless	Complies with IP

Solubility Study of Drug

The solubility study of Irbesartan was performed and it was found to be **practically insoluble** in water

Determination of Melting Point

The Melting point of received drug sample of Irbesartan was determined and it was found to be in range 180-181^{0C} which complies with standard , indicating purity of dr

Loss on Drying

The percentage loss on drying after 4 hours was found to be 0.3%. The sample passes test for loss on drying as per the limits specified in I.P.(N.M.T. 0.5%).

Percentage loss on drying for Irbesartan

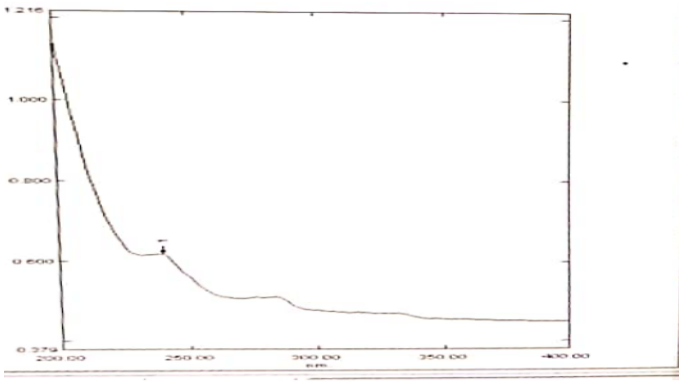
Sr.No.	Percentage LOD	Average Percentage LOD
1	0.3	0.3±0.1
2	0.2	
3	0.4	

V. SPECTROPHOTOMETRIC ANALYSIS OF IRBESARTAN

Scanning of Irbesartan

In UV spectroscopy study, the maximum wavelength(λmax) of Irbesartan in 0.1N HCL was found to be 244 nm. The reported λmax value of Irbesartan in 0.1N HCL

was also 244 nm respectively, so the values similar with the reported values indicates that the given sample of Irbesartan was in pure form**.**



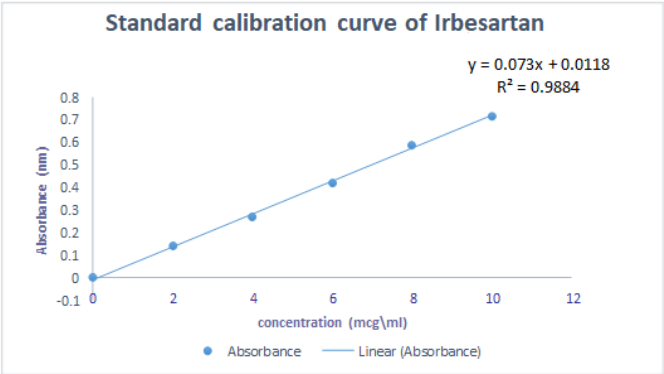
UV spectra of Irbesartan in 0.1N HCl at 244 nm

Preparation of Standard Calibration Curve of Irbesartan in 0.1N HCl

The Standard curve of Irbesartan was determined by plotting absorbance Vs concentration at 244nm. Using solution prepared in 0.1N HCl and water at 244 nm; It was found that there was linear relationship between concentration and absorbance with R^2 value 0.996 and R^2 value 0.995 respectively, which reveals that , the drug Irbesartan obeys the Beers lamberts law.

Standard Calibration Curve of Irbesartan in 0.1 N HCl

Sr.no.	Concentration (µg/ml)	Absorbance
1	0	0
2	2	0.157
3	4	0.226
4	6	0.419
5	8	0.599
6	10	0.718

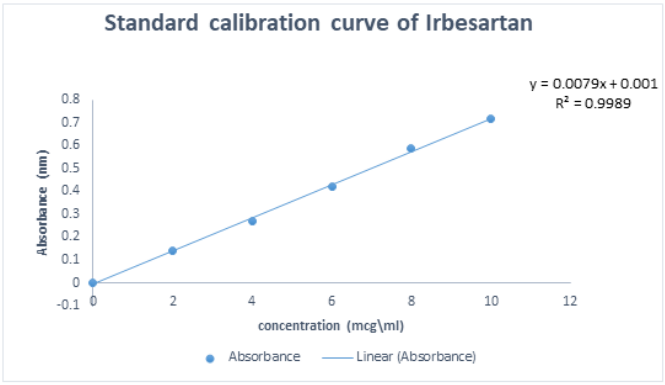


Standard Calibration Curve Graph of Irbesartan in 0.1N HCL

Standard Calibration Curve of Irbesartan in water

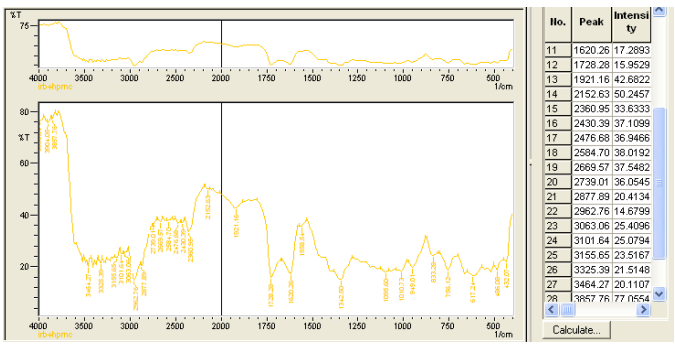
Sr.no.	Concentration (µg/ml)	Absorbance
1	0	0
2	2	0.015
3	4	0.029
4	6	0.046
5	8	0.062
6	10	0.079

Standard Calibration Curve Graph of Irbesartan in 0.1N HCL



VI. DRUG EXCIPIENT COMPATABILITY STUDY

Fourier Transform Infra-Red Spectroscopy (FTIR) Interpretation Major functional groups present in Irbesartan show characteristic peaks in IR spectrum shows peaks observed at different wave numbers and the functional group associated with these peaks. The major peaks are identical to functional group of Irbesartan. Hence, the sample was confirmed as Irbesartan.

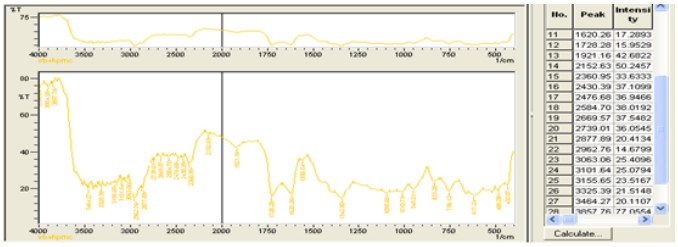


FTIR Studies of Irbesartan

Interpretation of FTIR Spectrum of Irbesartan

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2962.76	C-H Stretching
2	1650-1780	1728.28	C=O Stretching of carbonyl group
3	1620-1680	1620.26	C=C Stretching
4	1340 - 1250	1342.50	C-N stretching of tertiary amine
5	3100 - 3000	2368.66	N=N Stretching
6	3300-3700	3634.01	N-H Stretching amide

Fourier Transform Infra-red Spectroscopy (FTIR) Interpretation of Irbesartan +HPMC



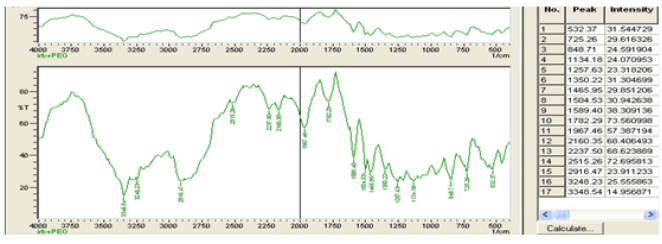
FTIR Studies of Irbesartan +HPMC

Interpretation of FTIR Spectrum of Irbesartan +HPMC

Fourier Transform Infra-red Spectroscopy (FTIR)Fourier Transform Infra-red

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2962.76	C-H Stretching
2	1650-1780	1728.28	C=O Stretching of carbonyl group
3	1620-1680	1620.26	C=C Stretching
4	3300 – 3700	3464.27	N-H stretching of amide

Spectroscopy (FTIR) Interpretation of Irbesartan + PEG 6000

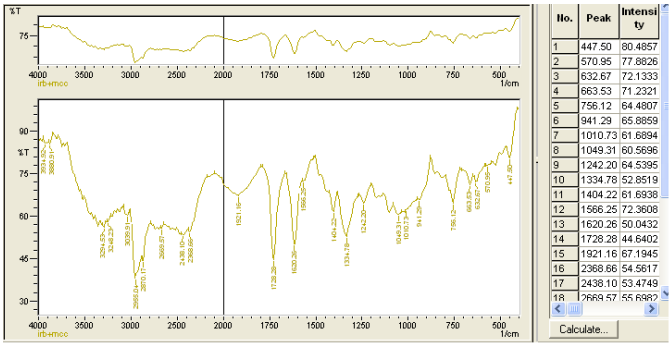


FTIR Studies of Irbesartan + PEG 6000

Interpretation of FTIR Spectrum of Irbesartan + PEG 6000

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2916.47	C-H Stretching
2	1650-1780	1789.29	C=O Stretching of carbonyl group
3	1620-1680	1569.40	C=C Stretching
4	3300 – 3700	3348.54	N-H stretching of amide

Interpretation of Irbesartan + Microcrystalline cellulose

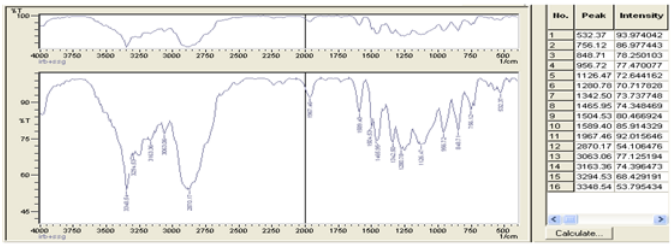


FTIR Studies of Irbesartan + Microcrystalline cellulose

Interpretation of FTIR Spectrum of Irbesartan + Microcrystalline cellulose

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2931.90	C-H Stretching
2	1550-1780	1566.27	C=O Stretching of carbonyl group
3	1620-1680	1643.47	C=C Stretching
4	3300 - 3700	3379.40	N-H stretching of amide

Fourier Transform Infra-red Spectroscopy (FTIR) Interpretation of Irbesartan + Sodium starch glycolate



FTIR Studies of Irbesartan + sodium starch glycolat

Interpretation of FTIR Spectrum of Irbesartan + sodium starch glycolate

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2870.17	C-H Stretching
2	1650-1780	1967.46	C=O Stretching of carbonyl group
3	1620-1680	1589.40	C=C Stretching
4	3300 - 3700	3348.54	N-H stretching of amide

Fourier Transform Infra-red Spectroscopy (FTIR) Interpretation of Irbesartan + Crosspovidone

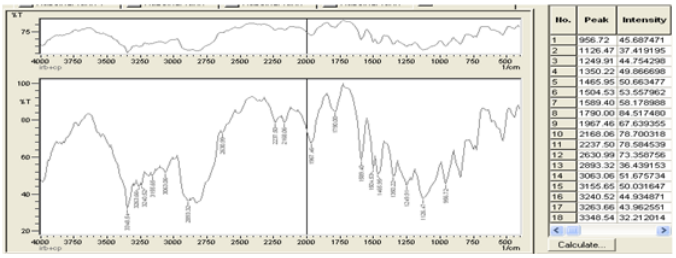
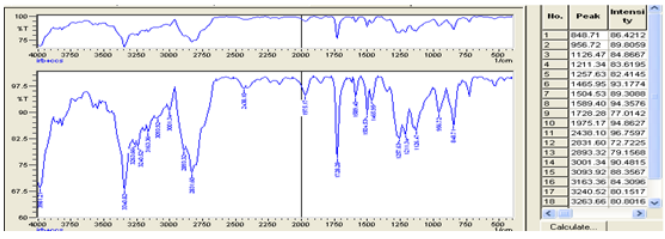


Figure 10.10 : FTIR Studies of Irbesartan + Crosspovidone

Table 10.11 : Interpretation of FTIR Spectrum of Irbesartan + Crosspovidone

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2893.32	C-H Stretching
2	1650-1780	1790.00	C=O Stretching of carbonyl group
3	1620-1680	1589.40	C=C Stretching
4	3300 - 3700	3348.54	N-H stretching of amide

Fourier Transform Infra-red Spectroscopy (FTIR) Interpretation of Irbesartan + Crosscarmellose sodium



FTIR Studies of Irbesartan + Crosscarmellose sodium

Interpretation of FTIR Spectrum of Irbesartan + Crosscarmellose sodium

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2893.32	C-H Stretching
2	1650-1780	1728.28	C=O Stretching of carbonyl group
3	1620-1680	1589.40	C=C Stretching
4	3300 - 3700	3340.82	N-H stretching of amide

VII. EVALUATION OF IRBESARTAN SOLID DISPERSION

The solid dispersion of Irbesartan were evaluated for no. of parameter like physical appearance, % practical yield, solubility study, in-vitro dissolution study, compatibility study

Physical Appearance

All batches of Irbesartan solid dispersion were evaluated for color and appearance. The physical appearance of each formulation is shown below

Physical appearance of Irbesartan Solid Dispersion

Formulations	Physical Appearance	
	Color	Appearance
S1	White	Powder (Amorphous)
S2	White	Powder (Amorphous)
S3	White	Powder (Amorphous)
S4	White	Powder (Amorphous)
S5	White	Powder (Amorphous)
S6	White	Powder (Amorphous)
S7	White	Powder (Amorphous)
S8	White	Powder (Amorphous)

Solubility Study of Solid Dispersion

Formulations	Drug : Carrier	Solubility(µg/ml)
Pure drug	Pure drug	1.95
S1	Irbesartan + HPMC (1:1)	14.81
S2	Irbesartan + HPMC (1:2)	29.68
S3	Irbesartan +	36.81

	PEG6000 (1:1)	
S4	Irbesartan + PEG6000 (1:2)	44.46
S5	Irbesartan + HPMC (1:1)	21.21
S6	Irbesartan + HPMC (1:2)	32.39
S7	Irbesartan + PEG6000 (1:1)	43.97
S8	Irbesartan + PEG6000 (1:2)	51.78

Solubility study of various solid dispersion trial batches was performed. Solid dispersion prepared by microwave induced fusion method improved solubility of Irbesartan as compared to pure drug and solid dispersion prepared by Kneading method. The batch S8 was more soluble than pure drug and other formulation batches.

10.5.3 Percentage Practical Yield Study of Solid Dispersion

Percentage practical yield was calculated to know about % yield or efficiency of any method which will help in selection of appropriate method. The practical yield for each batch is reported below.

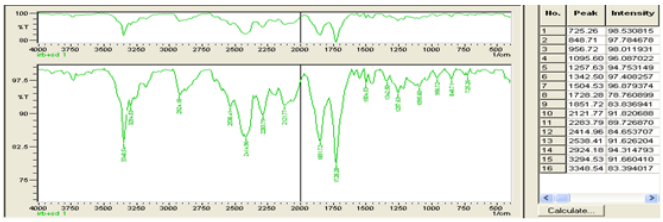
Percentage Practical Yield Study of Solid Dispersion

Formulation	Ratio	Initial weight	Final Weight	% Practical Yield
S1	1:1	0.318	0.276	86.79
S2	1:2	0.468	0.439	93.80
S3	1:1	0.325	0.273	84.00
S4	1:2	0.598	0.568	94.98
S5	1:1	0.384	0.336	87.50
S6	1:2	0.458	0.437	95.41
S7	1:1	0.410	0.382	93.17
S8	1:2	0.578	0.568	98.96

Different trial batches of solid dispersion show % practical yield from range 86.79 to 98.96%. Batch S8 Showed 98.96 % practical yield.

Drug Excipient Compatibility Studies of Solid Dispersion of Irbesartan

Fourier Transform Infra-red Spectroscopy (FTIR) Interpretation of Solid Dispersion Irbesartan + PEG6000 (1:2) (S4) By Kneading Method

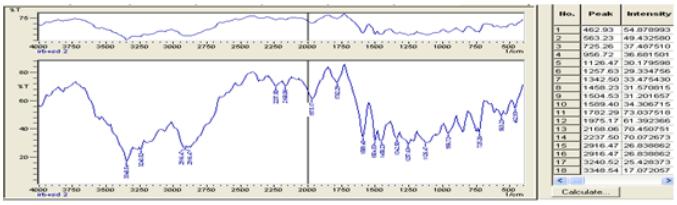


FTIR Studies of Solid Dispersion Irbesartan + PEG6000 (1:2) (S4) By Kneading Method

Interpretation of FTIR Spectrum of Solid Dispersion Irbesartan + PEG6000 (1:2) (S4) By Kneading Method

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2924.18	C-H Stretching
2	1650-1780	1728.28	C=O Stretching of carbonyl group
3	1620-1680	1504.53	C=C Stretching
4	3300 – 3700	3348.54	N-H stretching of amide

Fourier Transform Infra-red Spectroscopy (FTIR) Interpretation of Solid Dispersion Irbesartan + PEG6000 (1:2) (S8) By Microwave induce fusion method



FTIR Studies of Solid Dispersion Irbesartan + PEG6000 (1:2) (S8) By Microwave induce fusion method

Interpretation of FTIR Spectrum of Solid Dispersion Irbesartan + PEG6000 (1:2) (S8) By Microwave induce fusion method

Sr.no.	Reference Peak Wavenumber(cm^{-1})	Observed Peak Wavenumber(cm^{-1})	Functional Group
1	2850-2960	2916.47	C-H Stretching
2	1650-1780	1782.29	C=O Stretching of carbonyl group
3	1620-1680	1589.40	C=C Stretching
4	3300 – 3700	3348.54	N-H stretching of amide

In spectrum of solid dispersion is showed in figures. In above IR spectra the peak of solid dispersions are showed in Tables. All these peaks have appeared in formulation and physical mixture indicating no chemical interaction between Irbesartan and polymers in solid dispersion.

10.5.5 In vitro Dissolution Study and Observation

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

Dissolution study of pure drug

Dissolution study of pure drug in 0.1 N HCL was carried out and absorbance was taken in UV spectrophotometer which is reported below

Dissolution profile of Irbesartan pure drug

Time (min.)	Cumulative % drug release
0	0.00
5	11.61±1.84
10	12.21±0.44
15	16.65±0.91
20	17.38±1.76
30	18.32±1.14
45	22.59±0.42
60	24.75±0.31

Result are mean of three determinations

The cumulative % drug release of pure drug after 60 min was 23.75% each reading is taken was triplicate and then mean values were calculated.

Dissolution Profile of Solid Dispersion Prepared by Kneading Method

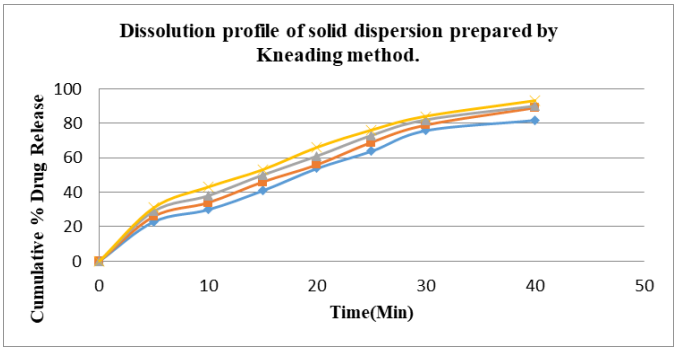
Dissolution study of formulations prepared by Kneading method S1, S2, S3, S4 was carried out in 0.1N HCL and analysed spectrophotometrically at 244nm. Each preparation was tested in triplicate and then mean values were calculated. The table 10.21 indicates the % drug release of each formulation at the end of 60 min. And graph was plotted to show % drug release which was represented in figure below.

Dissolution profile of solid dispersions prepared by Kneading method

Time (min)	Cumulative % Drug Release			
	S1	**S2**	**S3**	**S4**
0	00	00	00	00
5	23.34±0.21	26.87±0.25	29.14±0.22	31.27±0.57
10	30.23±0.25	34.51±0.14	38.23±0.32	43.83±0.42
15	41.42±0.13	46.67±0.46	50.94±0.71	53.24±.0.35
20	54.22±0.18	56.47±0.51	61.12±0.64	63.42±0.18
30	61.20±0.94	68.34±0.15	73.53±0.24	74.61±0.78
45	76.31±0.34	77.12±0.42	79.82±0.82	85.92±0.46
60	82.86±0.21	84.52±0.81	87.51±0.37	92.83±0.63

Result are mean of three determinations

Out of four formulations S4 shown maximum drug release i.e. 92.83%. Solid dispersion (S4) of Irbesartan with PEG 6000 (1:2) prepared by Kneading method significantly improved its solubility and dissolution rate. Increased wetting and solubilizing effect of PEG 6000 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 Irbesartan from solid dispersion compared to pure Irbesartan.



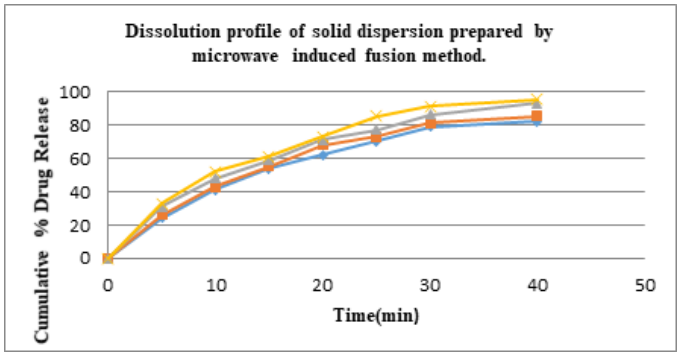
Dissolution profile of solid dispersions prepared by Microwave Induced Fusion Method

Dissolution study of formulations prepared by Microwave induced fusion method (S5, S6, S7, S8) was carried out in 0.1N HCL and analyzed spectrophotometrically at 244nm. Each preparation was tested in triplicate and then mean values were calculated. The table 10.22. indicates the % drug release of each formulation at the end of 60 min. and graph was plotted to show % drug release which was represented in figure below

Dissolution profile of solid dispersion prepared by microwave induced fusion method.

Time (min.)	Cumulative % Drug Release			
	S5	S6	S7	S8
0	00	00	00	00
5	24.21±0.55	26.56±0.36	31.84±0.38	33.74±0.19
10	41.32±0.81	43.01±0.27	48.65±0.43	52.51±0.64
15	54.23±0.24	55.40±0.64	59.27±0.21	61.42±0.28
20	62.74±0.62	68.21±0.19	71.61±0.81	73.07±0.74
30	70.28±0.73	73.57±0.85	77.83±0.62	85.72±0.94
45	79.64±0.51	81.30±0.77	86.42±0.70	91.28±0.57
60	82.19±0.69	85.94±0.30	93.57±0.55	95.61±0.83

Out of four formulations S8 showed maximum drug release i.e. 98.61%. Solid dispersion (S8) of Irbesartan with polymer PEG 6000 (1:2) prepared by microwave induced fusion method significantly improved its solubility and its dissolution rate. Increased wetting and solubilizing effect of PEG 6000 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 Irbesartan from solid dispersion compared to pure Irbesartan and other formulations.



Dissolution Profile of Solid Dispersions Prepared by Microwave Induced Fusion Method

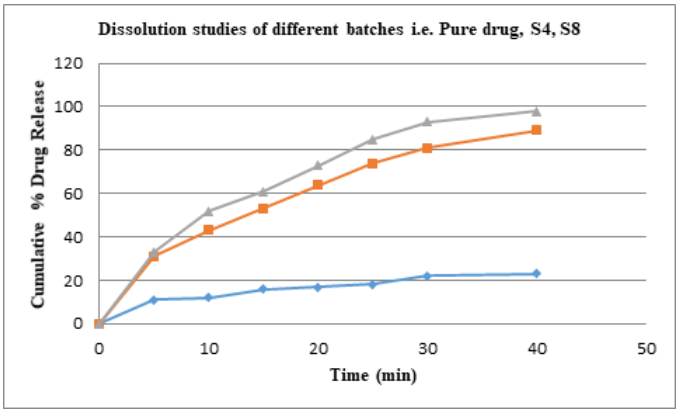
Comparative Dissolution Study

For the selection of best solid dispersion method the dissolution of pure was compared with solid dispersion by Kneading method (S4) and microwave induced fusion method (S8) which is shown And graph was plotted to show % drug release which was represented

Percent drug release of pure drug Irbesartan and solid dispersion by Kneading method (S4) and microwave induced fusion method (S8)

Time (Min)	Cumulative % Drug Release		
	Pure Drug	S4	S8
0	00	00	00
5	11.61±1.84	31.27±0.57	33.74±0.19
10	12.21±0.44	43.83±0.42	52.51±0.64
15	16.65±0.91	53.24±.0.35	61.42±0.28
20	17.38±1.76	64.42±0.18	73.07±0.74
30	18.32±1.14	74.61±0.78	85.72±0.94
45	22.59±0.42	85.92±0.46	93.28±0.57
60	24.75±0.31	92.83±0.63	95.61±0.83

Result are mean of three determinations



Dissolution studies of different batches i.e. Pure drug, S4, S8

According to graph 10.18. It was concluded that the S8 formulation gives highest drug release i.e 95.61% in 60 min, in 0.1N HCL whereas the S4 formulation and pure drug was found to be 23.75% and 92.83% drug release in 0.1N HCL in 60 min. In that comparative study 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 Irbesartan with significant enhancement of the *in-vitro* dissolution rate, hence batch S8 was selected for the further factorial design

VIII.FORMULATION OF FAST DISINTEGRATING TABLET OF IRBESARTAN

According to comparative dissolution study showed in graph10.18. It is concluded that the solid dispersion prepared by microwave induced fusion method in that

containing Irbesartan+ PEG 6000 (1:2) was shown maximum percent drug release as compared to other solid dispersion. Hence the solid dispersion S8 is selected for further tablet formulations. Total 8 formulations were developed by using various concentration of superdisintrgrants like crosprovidone, croscarmellose sodium, sodium starch glycolate

IX. EVALUATION OF TABLET BLEND OF FAST DISINTEGRATING TABLETS OF SOLID DISPERSION OF IRBESARTAN

The characterization of mixed blend was done for determination of mass-volume relationship parameter. The evaluated parameter angle of repose, bulk density, tapped density, hausner's ratio and compressibility index was reported in table below

Evaluation of tablet blend for fast disintegrating tablets

Formulations	Angle of repose (Θ)	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Hausner's Ratio (H_R)	Carr's Compressibility index (%)
F1	21.78±1.88	0.45±0.12	0.50±0.23	1.18±0.10	10.00±0.20
F2	20.67±0.95	0.43±0.16	0.49±0.09	1.13±0.21	12.24±0.33
F3	24.53±1.78	0.45±0.40	0.50±0.06	1.11±0.11	10.00±0.52
F4	28.42±1.27	0.41±0.10	0.47±0.20	1.14±0.42	12.76±0.63
F5	23.78±1.45	0.45±0.90	0.52±0.21	1.15±0.36	13.46±0.39
F6	29.04±1.14	0.47±0.12	0.54±0.21	1.14±0.51	14.81±0.91
F7	23.65±0.54	0.46±0.10	0.50±0.10	1.08±0.40	8.00±0.12
F8	28.66±1.67	0.48±0.13	0.56±0.21	1.16±0.10	14.28±0.10
F9	23.59±0.47	0.43±0.17	0.48±0.26	1.11±0.20	10.41±0.10

Result are mean of three dimentions

X. EVALUATION OF FAST DISINTEGRATING TABLETS

The FDT of solid dispersion of Irbesartan were prepared & subjected to postcompression parameters like 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 parameter which was reported in Table below

Evaluation of Fast Disintgrating Tablets

Formulations	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Drug Content (%)	Weight variations (mg)	Disintegration time (sec)
F1	2.90±0.10	3.26±0.05	0.8±0.05	98.50±0.11	302± 0.93	45±3.28
F2	2.9±0.17	3.36± 0.11	0.8±0.15	98.75±0.01	301±0.32	49±1.41
F3	2.76±0.25	3.26± 0.15	0.9±0.1	98.25±0.15	304±0.51	45±1.41
F4	2.80±0.10	3.36± 0.15	0.9±0.13	98.25±0.13	298±0.47	50±1.89
F5	2.70±0.17	3.33± 0.25	0.8±0.07	98.50±0.06	300± 0.85	42±1.41
F6	2.0±0.10	3.43± 0.10	0.8±0.09	98.70±0.23	299±0.56	48±1.91
F7	2.86±0.11	3.42± 0.10	0.8±0.06	98.75±0.14	303±0.67	50±2.0
F8	2.96±0.05	3.43± 0.10	0.9±0.10	98.75±0.17	301±0.16	45±1.41
F9	2.8±0.10	3.0± 0.10	0.9±0.11	98.75±0.01	301±0.70	41±1.19

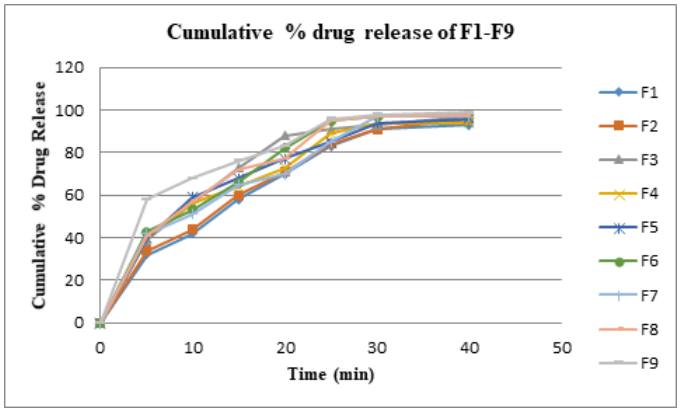
Results are mean of three determinations.

In vitro % Drug Release of Drug from Tablet

All the nine tablet batches of fast disintegrating tablet of solid dispersion of Irbesartan were subjected for the in vitro dissolution studies using tablet dissolution apparatus (USP). 0.1N HCl was used as dissolution medium.

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	00	00	00	00	00	00	00	00	00
5	32.89±0.97	34.65±1.76	29.38±1.06	30.88±1.46	30.75±1.92	33.38±0.88	32.47±1.06	31.10±2.11	33.34±1.06
10	42.18±155	44.89±1.23	46.41±1.88	46.76±1.65	49.98±1.54	43.14±1.17	41.13±1.89	47.74±0.94	51.34±1.89
15	58.62±1.89	50.43±0.76	53.87±1.46	54.35±2.45	53.24±1.98	56.91±1.98	55.06±2.35	52.20±1.56	61.37±2.35
20	65.94±2.63	61.25±1.89	68.85±2.23	63.98±1.33	57.61±1.17	62.68±1.05	60.29±0.78	67.14±2.35	72.15±0.51
30	73.64±1.30	74.13±1.27	74.15±1.45	79.54±1.34	75.52±1.43	75.86±2.07	75.14±1.20	75.33±1.34	84.21±1.76
45	81.69±1.44	81.35±1.09	83.24±2.67	83.67±1.43	83.29±2.78	83.30±1.93	83.09±1.88	83.94±1.17	91.06±1.27
60	92.32±1.93	91.43±1.78	92.84±1.98	91.45±1.22	91.37±3.12	90.03±2.33	92.46±2.07	93.96±1.89	94.96±2.94

The rapid dissolution was observed in formulation F9 releases 94.96% at the end of 60 minutes. Formulations F1-F8 released 92.32±1.93 to 93.96±1.89 at the end of 60 min. Rapid dissolution might be due to fast breakdown of particles and rapid absorption of drugs. The drug release was completely achieve in shorter duration of time. In all the formulations the drug release within 60 minutes. High dissolution may occur due to faster breakdown.



In comparative study F9 formulation gives higher percent drug release compare to other remaining eight formulations at the end of 60 minutes and graphical representation is shown in Figure . 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 60 min among all the formulations. Because it containing Sodium starch glycolate superdisintegrant with fast wetting time and highest swelling property.

XI. CONCLUSION

Overall, the results concluded that suitable formulated solid dispersion F8 of Irbesartan with PEG 6000 prepared by microwave induced fusion method improved its solubility and dissolution rate. Alteration of surface property of drug particles may be responsible for enhanced dissolution rate of Irbesartan from solid dispersion compared to pure Irbesartan. It was decided to prepare fast dissolving tablets of solid dispersion of Irbesartan by direct compression method. In the formulation of tablets, sodium starch glycolate, and croscarmellose, crosspovidone were used as superdisintegrants Prior to compression, the granules were evaluated for angle of repose, bulk density, tapped density, compressibility index, Hausner's ratio. The compressed tablets were also evaluated for weight variation, hardness, friability, drug content, disintegration time, wetting time, in vitro drug release and stability studies. In the above studies, F9 formulation showed promising results. It was further supported by FTIR analysis which showed that F9 had no interaction with excipient. The stability studies were carried out for the optimized batch F9 for 90days and it showed acceptable results. So F9 formulation was considered as the optimized formulation.Among all the prepared solid dispersions S8 was found to be optimized. The study shows that the dissolution rate of Irbesartan can be enhanced to a great extent by solid

dispersion technique using microwave induced fusion method. Hence, Irbesartan SSG croscarmellose & crospovidine systems could be considered for formulations of fast dissolving tablets of Irbesartan. The fast dissolving tablets of Irbesartan (F9) was shown higher drug release when compared to other formulations. From above results it can be concluded that the Solid dispersion technique can be used to enhance the solubility, Dissolution rate and oral bioavailability of water insoluble drugs.

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