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Original Research Article

Formulation, modification and evaluation of fast dissolving tablet of irbesartan for hypertension management

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ABSTRACT

To prepare fast dissolving tablet of Irbesartan an Angiotensin Receptor Blocker (ARB), direct compression method was utilised, and it comprised several steps. The main focus was to improve the disintergation time as well as the dissolution rate of the drug as it comes into contact with water. Lactose and Microcrystalline sodium (MCC) were used as diluents and fillers, Aspartame and Magnesium Stearate were used as lubricants, Crospovidone, Croscarmellose sodium (CCS), Sodium Starch Glycolate (SSG) were used as superdisintergrants as they increase the hydraulic pressure when the come into contact with water. The post compression properties of the tablet; disintergration time, wetting time and the drug release profile of the prepared table were investigated. The drug release of the prepared formulation was compared to the marketed formulation. 5 formulations were prepared using different ratios of the excipients and the optimized formulations were subjected to characterization. Hardness of the tablet was controlled by compression during the manufacturing process. Following FTIR studies, it was found that there were no interaction between the drug and the excipients and that the drug release depended on the type of the excipients used in the formulation. Direct compression was found to be a suitable, easy and efficient technique for designing fast dissolving tablet (FDT) for oral use.

1. Introduction

Oral drug delivery is the delivery of a drug formulation through the mouth into the systemic circulation for its intended action. The drug is used to treat various chronic disorders that require long term use of the drug. Its primary goal is to deliver the active medicaments of the drug to its site of action through the systemc circulation. Several formulations are seen to be used in the oral route of delivery such as tablets, capsules, solutions and elixirs.

For efficient delivery of this therapeutic agents, oral administration is the preferred as it is considered easy to use, affordable and patient compliant. Obtaining a maximum concentration of a specific drug at the required duration is important for designing a therapeutic system, to achieve this is quite challenging thus creating the attention in the past few years. However, factors like gastro intestinal absorption and irritation create drawbacks in the administration of the drugs thereby making the oral drug delivery systems to suffer. To achieve success in the oral delivery of drugs, the avoidance of GIT should be a priority. [1,2]

Intended for oral administration and are obtained by compressing uniform volumes of ingredients. The objective of the design and manufacture of the compressed tablet is to deliver orally the correct amount of drug in the desired location and to have its chemical properties protected to the point.

Tablets may vary in size, shape, weight, hardness, thickness, and disintegration characteristics and in other aspects, depending upon the intended use of the tablets and

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their method of manufacture.[3]

According to CDER and FDA a fast dissolving tablet is a solid dosage form containing medicinal substances that disintegrate rapidly, usually within a matter of seconds, when placed on the tongue.

The basic approach used in development of FDDTS is incorporating the use of Superdisintegrants like cross linked carboxymethylcellulose (croscarmilose), sodium starch Glycolate (primogel, Explotab). Polyvinylpyrrolidone (polyplasdone) etc. which provide instantaneous disintegration of tablet after putting on tongue, thereby releasing the drug in saliva. The bioavailability of some drug may be increased due to absorption of drugs in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down into the stomach. Moreover, the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablets.[4,5]

1.1. Requirements of fast dissolving tablets

A perfect fast dissolving tablets should dissolve/disperse/disintegrate in mouth in a matter of seconds without the need of water.[6]

1. Have an acceptable taste masking property
2. Have a pleasing feel in the mouth
3. Leave minimal or no residual in mouth after administration
4. Be harder and less friable
5. They should not be affected by environmental conditions (temperature and humidity)

1.2. Advantages of mouth dissolving tablets

1. Beneficial in case such as motion sickness, sudden dose allergic attack or coughing, when an ultra rapid on set of action required.
2. Some drugs are absorbed from mouth, pharynx and oesophagus as the saliva pass down in to the stomach.
3. An increased bioavailabilty, particularly in case of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
4. Improved patient compliance
5. Rapid onset of action and may offer an improved bioavailability
6. Patient having difficulty in swallowing tablets can easily administer this type of dosage form
7. New business opportunity like product promotion, patent extension and life cycle management[7,8]

2. Objectives

To develop and evaluate the Fast Dissolving Tablet of Irbesartan.

To increase the drug release, thereby achieving better therapeutic effect for the longer half life of Irbesartan.

To Formulate FDTs of Irbesartan by using superdisintegrants as croscarmellose sodium and Sodium Starch Glycolate.

Analysing the various parameters of the Fast Dissolving Tablets.

To carry out the stability studies in different temperatures like room temperature and accelerated temperature on FDTs.

3. Materials and Methods

3.1. Materials

Lactose Monohydrate which was used as a filler and a diluent was obtained from (Loba chemical, Hyderabad, India). Croscarmellose Sodium that was used as a superdisintergrant was procured from (Loba chemical, Hyderabad, India). Microcrystalline Cellulose (MCC Ph103) was purchase from (Cadila healthcare, Hyderabad, India). Sodium Starch Glycolate used as a super disintergrant was from (Signet chemical, Hyderabad, India). Aspartame a lubricant was a gift from (Cadila healthcare, Hyderabad, India), Magnesium Stearate which was used as a lubricant was obtained from (Loba chemical, Hyderabad, India) and Talc an anti-caking agent was purchased from (Signet chemical, Hyderabad, India). The Active pharmaceutical ingredient Irbesartan was obtained from (Arabintho Pharmaceutical Ltd, Hyderabad, India). The other chemicals were used as received.

This research was conducted at Vinayaka Missions College of Pharmacy, Salem, Tamilnadu.

3.2. Preparation of fast dissolving tablet

3.2.1. Method: Direct compression technique

All the ingredients were weighed accurately as given in the table. The drug, Crosspovidone and Sodium starch glycolate were swifted through sieve no 60 and the mixture was mixed in a poly bag for 15 minutes. Simultaneously talc and magnesium stearate were passsed through sieve no 60. It was then added to the previous mixture of the drug for lubrication and was blend for 20 minutes untill it was ready for compression. The blend was then compressed using multiple tolling twenty station single rotary with single puch (8mm), on labpress machine to produce round shaped tablets weighing 200mg each. The compression force is adjusted to obtain tablets with hardness 3-5kg/cm^2.[9,10]

3.3. Solubility studies

Solubility studies were performed in distilled water, Ethanol, Methanol, Acetonitrile, Phosphate Buffer pH 7.4 phosphate buffer by water bath shaker method. To each of these Medias an excess amount of drug was added. Then these solutions were kept in the shaker for 24 hours. After 24

Table 1: Composition of fast dissolving tablets

Ingredients (mg)	F1	F2	F3	F4	F5
Irbesartan	50	50	50	50	50
Lactose Monohydrate	60	60	60	60	60
Microcrystalline Cellulose (MCC Ph103)	75	72.5	75	72.5	70
Croscarmellose Sodium	5	7.5	-	-	5
Sodium Starch Glycolate	-	-	5	7.5	5
Aspartame	6	6	6	6	6
Magnesium Stearate	2	2	2	2	2
Talc	2	2	2	2	2
Total Tablet Weight			200mg		

All quantities are in mg

hours samples were centrifuged the supernatant was suitably diluted and estimated for Irbesartan concentration using UV spectrometer at 224 nm.

3.4. UV spectrophotometer analysis

Drug was dissolved in 10 ml of Acetonitrile & Phosphate Buffer pH 7.4. It's stirred for 15mm, sonicated and then filtered through membrane filter paper. Samples were taken from stock solution and serial dilutions were made and UV absorbance was analyzed for l max.

3.5. FTIR studies of irbesartan and excipients

The pellets were made by mixing 1gm of drug or excipients and 100gm of dried potassium bromide powder. The mixture was then compressed under 10-ton pressure in a hydraulic press to form a transparent pellet. The thin pellet was put on pellet disc to get IR spectra.[11]

3.6. Bulk density

The term bulk density refers to a measure used to describe the packing of particles. It is given in (gm/ml) and was determined using balance and measuring cylinder. Initially the weight of the measuring cylinder was taken. Then, 4 gm pre sieved bulk drug was poured into the measuring cylinder using a funnel. Then volume of the powder was taken. Bulk density of the granules was calculated using following formula.[12]

Bulk density = weight of powder / volume of powder.

3.7. Tapped density

Tapped density is determined by placing a graduated cylinder containing same mass of powder used for B.D on a mechanical tapper apparatus which is operated for a fixed number of taps (approximately 500) until powder bed volume has reached a minimum volume.

Tapped density = Weight of powder / Min volume of powder

3.8. Angle of repose

Angle of repose in the tan inverse of angle between height (h) of pile of powder and the radius of the base of conical pile. It can be obtained between the free standing surface of the powder heap and the horizontal pale. The fixed funnel that is secured with its tip at a given height h above the graph paper, placed on the flat horizontal surface. Powder is carefully poured through funnel until the apex of conical pile just touches the tip of the funnel.[13]

Tan q = h/r

3.9. Hardness test

The hardness of tablets for fast dissolving tablets is usually kept low for easy disintegration in the mouth. The hardness of the prepared Irbesartan tablet was measured using shulinger hardness tester.[14]

3.10. Thickness

The thickness of tablets was determined using a Vernier callipers. 6 tablets from each batch were used and average values were calculated.[15]

3.11. Friability test

The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%)

10 tablets were initially weighed and revolved at 25 rpm for 4 min. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated.

The % friability was then calculated by,

$$(Friability = (W\ initial - w\ final / W\ initial) \times 100)$$

Acceptance criteria for % friability, % weight loss should be less than 1%

3.12. Weight variation test

Twenty tablets were selected randomly from each batch and weighed individually on electronic balance. The individual tablet is weighed and then compared with average weight for the weight variations.

3.13. Disintegration time testing

It was determined using tablet disintegration test apparatus, using 900 ml of distilled water without disk at room temperature. Test was performed on 6 tablets. Limit set for the disintegration should not be more than 30 seconds.[16]

3.14. Wetting time of tablet

Wetting time is used to show the porosity, compressibility as well as absorption capacity of the tablets. Since the dissolution process of a tablet depends upon the wetting followed by disintegration of the tablet, the measurement of wetting time may be used as another confirmative test for the evaluation of tablets.

3.15. Procedure

For determination of wetting time, a piece of tissue paper folded twice was placed in a small petri dish (internal diameter of 5 cm) containing 6 ml of water. A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of tablets was noted as wetting time. The test was repeated on three other tablets of the same batch in same petridish and average of the three readings gives the mean wetting time of the tablets.

3.16. Water absorption ratio

Test as done with the same procedure as that of wetting time. In this test, initial weight of tablet was taken before placing on petridish. After complete, wetting, the wetter tablet was then weighed water absorption ratio, R was determined using the equation.

$R=100\ (w_b - w_a)/w_a$

Where w_a is weight of tablet before water absorption w_b is weight of tablet after water absorption.

3.17. In vitro dispersion time

For determination of in vitro dispersion time, one tablet was placed in a beaker containing 10ml of Phosphate Buffer pH7.4 at 37^0C $\pm 0.5^0$C and the time required for complete dispersion was determined. The test was repeated on three other tablets of same batch, the average gives *in vitro* dispersion time.

3.18. In vitro drug release study

The release rate of drug from FDT was determined using USP dissolution testing apparatus. (II paddle method). The dissolution modern was maintained at 37^oC ± 0.5^oC the rotation speed was 50 rpm. A sample (5ml) of the solution was withdrawn from the dissolution apparatus at 5, 10, 15, 30, 45 minute, and the samples were replaced with fresh dissolution medium to maintain the sink condition. The samples were filtered through a membrane filter and absorbance of there solutions was measured at 224 nm using a UV – visible double beam spectrophotometer. Cumulative percentage drug release was calculated using linear equation obtained from a standard curve. [17]

3.19. Stability studies

In any design and evaluation of dosage forms for drugs, the stability of the active component must be a major criteria in determining their acceptance or rejection.

Table 2: ICH guidelines for stability study

Study	Storage condition	Time period
Long term	25^oC ± 2^oC/60^o % RH ± 5RH Or 30^oC ±2^oC/65%RH ±5%RH	12 months
Intermediate	30^oC ±2^oC/65% RH ± 5% RH	6 months
Accelerated	40^oC ± 2^oC/75%RH ±5% RH	3 months

In the present work, stability study was carried out for the optimized formulation at 40^oC/75% RM for 1 month.

4. Results and discussion

4.1. Solubility studies

The solubility studies were conducted in different solvents and the results are shown in Table 5.

Table 3: Solubility of Irbesartan in different solvents

Solvent	Solubility (mg/mL)
Water	0.0098
Ethanol	0.0128
Methanol	0.0143
Acetonitrile	0.0162
Phosphate Buffer pH 7.4	0.0282

4.2. FTIR studies

4.2.1. Identification of drug (Irbesartan) sample

The drug was identified and confirmed by FTIR spectrum. FT-IR spectrum of Irbesartan. The characteristic absorption peaks of Irbesartan are within the pharmacopeial limits. [18]

4.3. Drug excipients compatibility study

Compatibility of the drug with recipients was determined by FT-IR spectral analysis, this study was carried out to detect any changes on chemical constitution of the drug after combined it with the recipients. The samples were taken for FT-IR study.

The principle peaks were observed at 2956.50 $cm^{-3}$for (N-H stretching), 1760.36 cm^{-3} for (C=O stretching), 1557.38 $cm^{-3}$for (C=C stretching) and 1615.03 $cm^{-3}$for (C-N stretching)

The absorption peaks of both the drug and excipients were observed indicating there was no interaction.

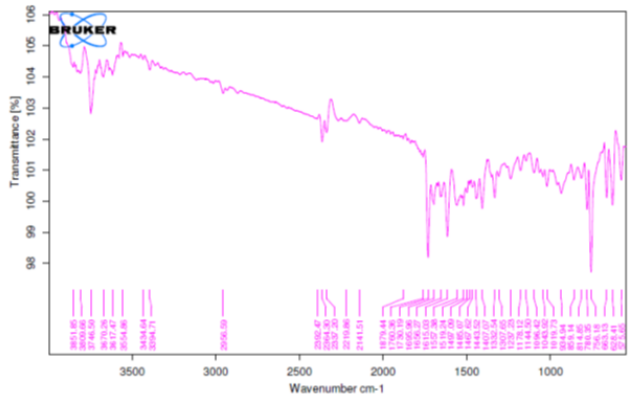

Figure 1: FTIR spectrum of irbesartan pure drug

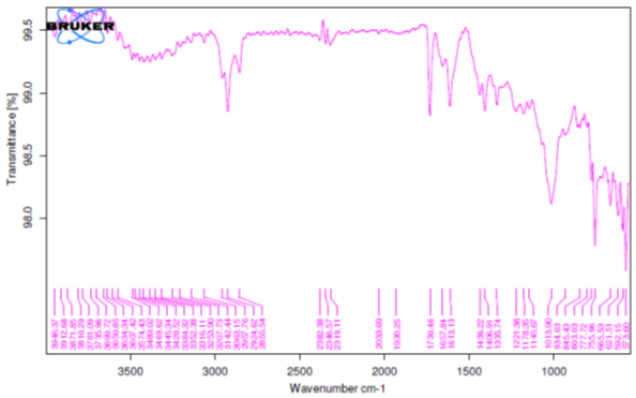

Figure 2: FT IR spectrum of irbesartan optimized formulation F5

4.4. Preformulation studies

The flow properties of the pure drug of Irbesartan and irbesartan granules were carried out and the results are shown in tables

The physical parameters of drug as well as excipients concluded that these were considerably good to formulate the Fast Dissolving Tablets using direct compression technique.

4.5. Evaluation parameters of the prepared formulation

The evaluation parameters were carried out and the results are shown in Table 6.

5. Discussion

The tablets were compressed at the average weight of 200mg. The maximum weight variation of the tablets was 199.7 to 203.4 %. Hardness for tablets of all batches was in the range of 3.37 to 3.67 kg/cm^2. The thickness of the tablets of all the batches was found in the range of 3.25 to 3.36 mm. The friability of the tablets of all batches was found in the range of 0.31 to 0.28 %. All the parameters are indicated that the, physical parameters of formulated tablets were within the Pharmacopeial specifications.

5.1. Comparative study of disintegration time of formulations F1 to F5

Disintegration time is the main parameter to be evaluated in fast dissolving tablets. The effect of two different superdisintegrants and their functional differences is graphically represented in the below figure. Among all the formulations, tablets containing sodium starch glycolate in 5% concentration were found to show the least disintegration time, it was due to the rapid intake of water within second without formation of lumps and produces a burst effect. It was observed that as the concentration of superdisintegant increased the disintegration time also increased. With the reference to the type of superdisntegrant, the disintegration time to the following flow order.

Crosspovidone < Sodium Starch Glycolate

5.2. Comparative study of wetting time of formulations of F1-F5

Wetting time of the formulation is the important criteria of fast dissolving tablet. The time taken for the water to reach the surface of tablets indicates the wetting time of concerned tablets. It indicates the hydrophilicity of the drug as well as the effect of superdisintegrant. The less time taken for completer wetting indicates the rapid uptake of water through capillary action mainly in the case of wicking type of superdisintegrant like sodium starch glycolate. In the present investigation of wetting time of different superdisintegrants, sodium starch glycolate as showed the least time 14.5sec. It is also depicted in the below figure through graphically by comparing the formulation from F1-F2. In this study as the ratio of superdisintegrant is increased the wetting time is decreased in the case of all the batches. The wetting time of all formulation is in the following order.

Crosspovidone < Sodium Starch Glycolate

5.3. In vitro dissolution studies

5.4. Stability studies

The Stability studies were undertaken in the investigation of stability of solid oral dosage forms to support post formulation strategies as per ICH guidelines. The accelerated stability studies data of selected formulation (F5) shown in Table 10. The drug content, weight variation, thickness, friability, hardness and in vitro drug release were closely monitored and analyzed at regular intervals (1month). There were no significant changes observed in the drug content thickness, weight variation, hardness, friability and in vitro drug release during and period of stability studies.[19]

Table 4: Flow properties of pure drug

Drug	Bulk density (gm/ml) *	Tapped density (gm/ml) *	Compressibility index (%) *	Hausners ratio *	Angle of repose *
Irbesartan	0.250	0.310	24.01	1.32	24º.41’

*Mean±SD, (n=6)

Table 5: Physical characteristics ofIrbesartan granules

Formulation Code	F1	F2	F3	F4	F5
Bulk Density (g/ml)*	0.252	0.248	0.247	0.221	0.242
Tapped Density (g/ml) *	0.335	0.321	0.309	0.328	0.325
Carr’s Index %	24.77	24.62	24.71	24.06	24.07
Hausner Ratio	1.32	1.30	1.28	1.30	1.28
Angle of Repose (0)	25º.41’	25º.31’	25º.01’	25º.21’	24º.41’

*Mean±SD, (n=6)

Table 6: Physical characteristics of FDT’S of Irbesartan

Specification	F1	F2	F3	F4	F5
Weight Variation (mg)	202.7±0.08	200.9±1.25	203.4±1.18	201.8±1.17	199.7±1.25
Hardness(kg/cm2)	3.45±0.21	3.51±0.20	3.45±0.14	3.37±0.13	3.67±0.12
Thickness(mm)	3.23±0.04	3.34±0.04	3.25±0.05	3.28±0.05	3.36±0.04
Friability (%)	0.29%	0.28%	0.31%	0.28%	0.31%
Disintegration Time (sec)	18	16	21	20	12
Wetting Time (sec)	11	9	17	14	6
Dispersion Time (sec)	7	6	11	8	5
Assay (%)	98.5	98.7	98.1	98.3	99.1
Water absorbance ratio (%)	75.30	77.92	65.72	68.96	87.83

*Mean±SD, (n=6) **Mean±SD, (n=20)

Table 7: Disintegration time of formulations F1 to F5

Superdisintegrant	Formulations	Disintegration time (sec)
Sodium Starch Glycolate	F1	24
	F2	23
Crosspovidone	F3	22
	F4	24
SSG + CP	F5	16

Table 8: Wetting time of formulations F1 to F5

Superdisintegrant	Formulations	Wetting time (sec)
Sodium Starch Glycolate	F1	09
	F2	08
Cross Povidone	F3	07
	F4	08
SSG + CP	F5	06

Table 9: In vitro % dissolution studies of FDT of irbesartan and marketed formulation

Time (Minutes)	F1	F2	F3	F4	F5	Marketed Formulation
0	0	0	0	0	0	0
5	12.55	19.33	16.22	21.22	29.88	11.24
10	19.37	28.99	29.33	32.33	60.21	19.58
15	29.06	41.22	49.55	49.33	78.88	31.22
30	38.74	58.55	63.55	71.55	87.88	41.22
45	58.11	72.55	81.22	82.36	99.87	58.99

(Mean±SD, n=3)

Table 10: Stabilityparameters of optimized formulation F5

Parameters	1st Month	
	RT	40°C/75%RH
Weight variation test**	199.7±1.25	199.21±1.25
Thickness*	3.67±0.12	3.45±0.12
Hardness*	3.36±0.04	3.28±0.03
Friability*	0.31%	0.30%
Disintegration Time (sec) *	12	11
Wetting Time (sec) *	6	6
Dispersion Time (sec)*	5	5
Assay (%) **	99.1	99.0
Water absorbance ratio (%) *	87.83	87.33
% of Drug Release *	99.87	99.17

*Mean±SD, (n=6) & **Mean±SD, (n=20)

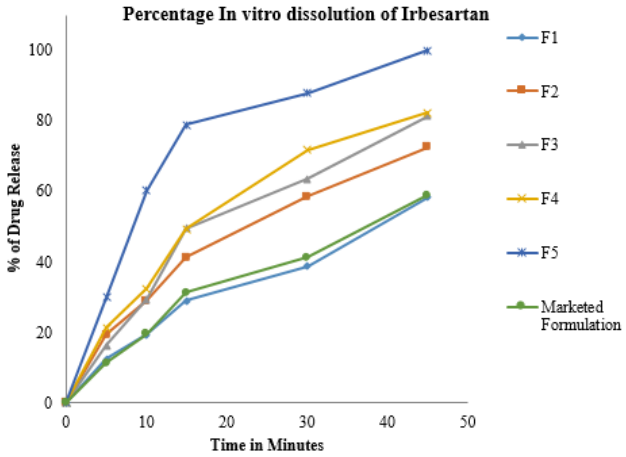

Figure 3: *In vitro* percentage dissolution studies of FDT of irbesartan and marketed formulation

6. Conclusion

From the above results a conclusion can be drawn that the formulated tablet dissolved rapidily with the modifiactions and the drug release was found to be higher as compared to the formulated tablet.

7. Source of Funding

None.

8. Declaration of Interest

We authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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