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Formulation and Evaluation of Immediate Release Tablets of Imeglimin Hydrochloride

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Abstract: Immediate release tablets are those tablets which disintegrate and release the drug Rapidly once it enters GIT. Recently immediate release tablets have started gaining popularity and acceptance as a drug delivery system, mainly because they are easy to administer and lead to better patient compliance. The aim is to formulate various formulations of immediate release tablet of Imeglimin Hydrochloride using different Super disintegrants (Sodium starch glycolate, PolyplasdoneXL10 and Ac- Di- Sol), Mannitol, Talc, Magnesium stearate and Lactose by direct compression method. The drug-excipients interaction was investigated by FTIR. The granules and tablets of Imeglimin Hydrochloride were evaluated for various pre and post compression parameters like angle of repose, compressibility index, hausners ratio, tablet hardness, friability and *in vitro* disintegration and dissolution studies and their results were found to be satisfactory. These results suggest that maximum *in vitro* dissolution profile of formulation F6 were found to have equivalent percentage of drug release and concluded that F6 is better and similar to innovator product.

Key words: Imeglimin Hydrochloride, Sodium starch glycolate, Polyplasdone XL10 and Ac- Di- Sol and Immediate release tablets.

1. INTRODUCTION

Immediate release drug formulation is a novel type of drug delivery system which disintegrates rapidly and get dissolved to release the medicaments after administration. Recently, several newer agents were developed known as “Super0 disintegrants” such as sodium starch glycolate, croscarmellose sodium, and crospovidone. These newer substances shows good effectiveness at lower concentrations with greater disintegrating power and mechanical strength. Conventional immediate release drugs include fast disintegrating tablets and granules that are used in effervescent mixture, such as tartaric acid, sodium bicarbonate, etc. Recently immediate release tablets have started gaining popularity and acceptance as a drug delivery system because it has several benefits of easy administration, quick onset of action, economical available and lead to better patient compliance. These are also a tool for expanding markets, generating opportunities and extending product life cycles.

In that present study and research novel drug delivery systems are developed for expanding indications, extending product life cycles and generating opportunities. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly patient compliance. The development of enhanced oral protein delivery technology by immediate release tablets which may release the drugs at an enhanced rate are very promising for the delivery of poorly soluble drugs high molecular weight protein and peptide.^{1,2}

The oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy, manufacturing and ease of administration lead to high levels of patient compliance. Many patients require quick onset of action in particular therapeutic condition and consequently immediate release of medicament is required. It is estimated that 50% of the population is affected by this problem, which results in a high incidence of ineffective therapy. Immediate release tablets are those which disintegrate rapidly and get dissolved to release the medicaments. Immediate release may be provided for by way of an appropriate pharmaceutically acceptable diluent or carrier, which diluent or carrier does not prolong, to an appreciable extent, the rate of drug release and/or absorption.^{2,3}

This term excludes formulations which are adapted to provide for “modified”, “controlled”, “sustained”, “prolonged”, “extended” or “delayed” release of drug. Release term includes the provision (or presentation) of drug from the formulation to the gastrointestinal tract, to body tissues and/or into systemic circulation.

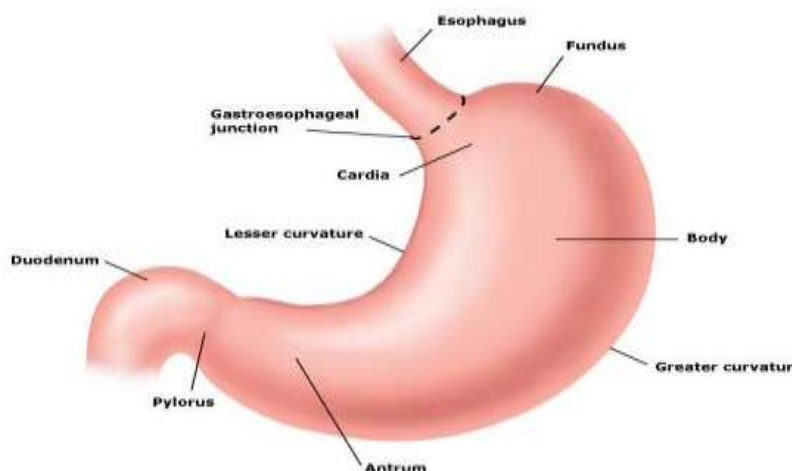


Fig 1.1: Anatomy of stomach

The stomach is part of the digestive system and is connected to the:

- Esophagus – a tube-like organ that connects the mouth and throat to the stomach. The area where the esophagus joins the stomach is called the gastroesophageal (GE) junction.
 - Small intestine (small bowel) – a long tube-like organ that extends from the stomach to the colon (large intestine or large bowel). The first part of the small intestine is called the duodenum, and it is this part that is connected to the stomach.
 - The stomach is divided into 5 regions: The cardia is the first part of the stomach below the esophagus. It contains the cardiac sphincter, which is a thin ring of muscle that helps to prevent stomach contents from going back up into the esophagus.
 - The fundus is the rounded area that lies to the left of the cardia and below the diaphragm.
 - The body is the largest and main part of the stomach. This is where food is mixed and starts to break down.
 - The antrum is the lower part of the stomach. The antrum holds the broken-down food until it is ready to be released into the small intestine. It is sometimes called the pyloric antrum.
 - The pylorus is the part of the stomach that connects to the small intestine. This region includes the pyloric sphincter, which is a thick ring of muscle that acts as a valve to control the emptying of stomach contents (chyme) into the duodenum (first part of the small intestine). The pyloric sphincter also prevents the contents of the duodenum from going back into the stomach.
- 2 Pharmacokinetics It is the study of absorption, distribution, metabolism and excretion. After absorption, drug attains therapeutic level and therefore elicits pharmacological effect, so both rate and extend of absorption is important. In conventional dosage form there is delay in disintegration and therefore dissolution is fast. Drug distribution depends on many factors like tissue permeability, perfusion rate, binding of drug to tissue, disease state, drug interaction etc. Duration and intensity of action depends upon rate of drug removal from the body or site of action i.e. biotransformation. Decrease in liver volume, regional blood flow to liver reduces the biotransformation of drug through oxidation, reduction and hydrolysis. Excretion by renal clearance is slowed, thus half-life of renal excreted drugs increase.

- Pharmacodynamics Drug reception interaction impaired in elderly as well as in young adult due to undue development of organ. Decreased ability of the body to respond reflexive stimuli, cardiac output, and orthostatic hypotension may see in taking antihypertensive like prazosin. Decreased sensitivity of the CVS to α -adrenergic agonist and antagonist. Immunity is less and taken into consideration while administered antibiotics.
- Altered response to drug therapy-elderly show diminished bronchodilator effect of theophylline shows increased sensitivity to barbiturates. Concomitant illnesses are often present in elderly, which is also taken into consideration, while multiple drug therapy prescribed. Research workers have clinically evaluated drug combination for various classes' cardiovascular agents, diuretics, anti-hypertensive etc. for immediate release dosage forms. The combination choice depends on disease state of the patient.

Desired Criteria for Immediate Release Drug Delivery System:

- Immediate release dosage form should
- It should not leave minimal or no residue in the mouth after oral administration.
- Exhibit low sensitivity to environmental condition as humidity and temperature.
- Be manufactured using conventional processing and packaging equipment at low cost.
- Rapid dissolution and absorption of drug, which may produce rapid onset of action
- In the case of solid dosage it should dissolve or disintegrate in the stomach within a short period.
- In the case of liquid dosage form it should be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasing mouth feel. Merits of Immediate Release Drug Delivery System: Adaptable and amenable to existing processing and packaging machinery⁵
- Cost- effective
- Improved solubility of the pharmaceutical composition; Decreased disintegration and dissolution times for immediate release oral dosage forms.
- Improved compliance/added convenience
- Improved stability, bioavailability
- Suitable for controlled/sustained release actives
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation.

General excipients used in immediate release tablets

Ideal characteristics of excipients

- They must be free of any unacceptable microbiological load.
- They must be color compatible, should not change shade of color in the formulation.
- If product is classified as food, the diluents and other excipients must be approved food additives.
- They must not have an adverse effect on the bioavailability of the products. They must be nontoxic with no pharmacological activity and acceptable to the regulatory agencies in the countries where the product is to be marketed.
- They must be commercially available in an acceptable grade in countries where the product is to be manufacture.
- Cost effective.
- They must be physiologically inert.
- They must be physically and chemically stable by themselves and in combination with other drugs and tablet components.⁶

METHODOLOGY

Buffer Preparation:

Preparation of 0.2M Potassium dihydrogen orthophosphate solution: Accurately weighed 27.218 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000mL of distilled water and mixed.

Preparation of 0.2M sodium hydroxide solution: Accurately weighed 8 gm sodium hydroxide pellets were dissolved 1000ml of distilled water and mixed.

Preparation of pH 6.8 Phosphate buffer: Accurately measured 250ml of 0.2M potassium Dihydrogen orthophosphate and 112.5 ml 0.2M NaOH was taken into the 1000ml volumetric flask. Volume was made up to 1000ml with distilled water.

Pre formulation Studies

Pre formulation involves the application of biopharmaceutical principles to the physicochemical parameters of drug substance are characterized with the goal of designing optimum drug delivery system.

Analytical method development for Imeglimin Hydrochloride:

a) Determination of absorption maxima

A spectrum of the working standards was obtained by scanning from 200-400nm against the reagent blank to fix absorption maxima. The $\lambda_{\max}$ was found to be 240 nm. Hence all further investigation was carried out at the same wavelength.

b) Preparation of Standard graph in pH 6.8 phosphate buffer

100 mg of Imeglimin Hydrochloride was dissolved in 100 mL of pH 6.8 phosphate buffer to give a concentration in 1mg/mL (1000 μ g/mL) 1 ml was taken and diluted to 100 ml with pH 6.8 phosphate buffer to give a concentration of 0.01 mg/ml (10 μ g/ml). From this stock solution aliquots of 0.2 ml, 0.4 ml, 0.6 ml, 0.8 ml, 1 ml, were pipette out in 10 ml volumetric flask and volume was made up to the mark with pH 6.8 phosphate buffer to produce concentration of 2, 4, 6, 8 and 10 μ g/ml respectively. The absorbance of each concentration was measured at respective ($\lambda_{\max}$) i.e., 240nm.

Formulation Development:

- Drug and different concentrations for super Disintegrates and required ingredients were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass mortar for 15 minutes.
- The obtained blend was lubricated with Magnesium stearate and glidant (Talc) was added and mixing was continued for further 5 minutes.
- The resultant mixture was directly compressed into tablets by using puch of rotary tablet compression machine. Compression force was kept constant for all formulations.

Table 7.1: Formulation of Immediate Release tablets

INGREDIENTS (MG)	FORMULATIONS								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Imeglimin Hydrochloride	500	500	500	500	500	500	500	500	500
Sodium starch glycolate	100	200	300	-	-	-	-	-	-
Polyplasdone XL10	-	-	-	100	200	300	-	-	-
Ac- Di- Sol	-	-	-	-	-	-	100	200	300
Talc	10	10	10	10	10	10	10	10	10
Mg. Stearate	8	8	8	8	8	8	8	8	8
Mannitol	15	15	15	15	15	15	15	15	15
Lactose	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Total weight (mg)	1000	1000	1000	1000	1000	1000	1000	1000	1000

Total weight of tablets = 1000mg

Evaluation parameters:**Pre compression parameters:**

Measurement of Micromeritic Properties of Powders

1. Angle of repose

The angle of repose of API powder is determined by the funnel method. The accurately weight powder blend are taken in the funnel. The height of the funnel is adjusted in way that, the tip of the funnel just touched the apex of the powder blend. The powder blend is allowed to flow through the funnel freely on the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation.

$$\tan \theta = h/r$$

(1)

where, h and r are the height and radius of the powder cone.

Table 7.2: Flow Properties and Corresponding Angle of Repose

Flow Property	Angle of Repose (°)
Excellent	25-30
Good	31-35
Fair- aid not needed	36-40
Passable-may hang up	41-45
Poor-must agitate, Vibrate	46-55
Very Poor	56-65
Very, very Poor	>66

2. Bulk density

The powder sample under test is screened through sieve No.18 and the sample equivalent to 25 gm is weighed and filled in a 100 ml graduated cylinder and the power is leveled and the unsettled volume, V_0 is noted. The bulk density is calculated in g/cm^3 by the formula.

$$\text{Bulk density} = M/V_0$$

(2)

M= Powder mass

V_0 = apparent unstirred volume

3. Tapped density

The powder sample under test is screened through sieve No.18 and the weight of the sample equivalent to 25 gm filled in 100 ml granulated cylinder. The mechanical tapping of cylinder is carried out using tapped density tester at a nominal rate for 500 times initially and the tapped volume V_0 is noted. Tapping's are proceeded further for an additional tapping 750 times and tapped volume, V_b is noted. The difference between two tapping volume is less than 2%, V_b is considered as a tapped volume V_f . the tapped density is calculated in g/cm^3 by the formula.

$$\text{Tapped density} = M/V_f$$

(3)

M= weight of sample power taken

V_f = Tapped volume

4. Compressibility Index

The Compressibility Index of the power blend is determined by Carr's compressibility index to know the flow character of a powder. The formula for Carr's Index is an below:

$$\text{Carr's Index (\%)} = [(TD-BD)/TD] \times 100$$

(4)

5. Hauser's ratio

The Hauser's ratio is a number that is correlated to the flowability of a powder or granular material. The ratio of tapped density to bulk density of the powders is called the Hauser's ratio. It is calculated by the following equation.

$$H = \rho_T / \rho_B \quad (5)$$

Where ρ_T = tapped density, ρ_B = bulk density

Table 7.3: Scale of Flowability

Compressibility Index (%)	Flow Character	Hausner Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Post compression parameters:

a) Thickness

The thickness of tablets was determined by using Digital micrometer. Ten individual tablets from each batch were used and the results averaged.

b) Weight variation

Twenty tablets randomly selected from each batch and individually weighed. The average weight and standard deviation three batches were calculated. It passes the test weight variation test if not more than two of the individual tablet's weights deviate from the average weight by more than the allowed percentage deviation and more deviate by more than twice the percentage shown. It was calculated on an electronic weighing balance.

c) Friability

The friability values of the tablets were determined using a Roche-type friabilator. Accurately weighed six tablets were placed in Roche friabilator and rotated at 25rpm for 4 min. Percentage friability was calculated using the following equation.

$$\text{Friability} = \left(\frac{w_0 - w}{w_0} \right) \times 100$$

d) Assay

The content of drug was carried out by five randomly selected tablets of each formulation. The five tablets were grinded in mortar to get powder; this powder was dissolved in pH 6.8 phosphate buffer by sonication for 30 min and filtered through filter paper. The drug content was analyzed spectrophotometrically at 240 nm using UV spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

e) Disintegration test

Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 minutes and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

f) Dissolution test of Imeglimin Hydrochloride tablets

Drug release from Imeglimin Hydrochloride tablets was determined by using dissolution test United States Pharmacopoeia (USP) 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8

Phosphate Buffer as the dissolution medium of quantity 500ml. the whole study is being carried out at a temperature of 37°C and at speed of 50 rpm.

5 ml aliquots of dissolution media were withdrawn each time at suitable time intervals (5, 10, 15, 20, 25 and 30 minutes) and replaced with fresh medium. After withdrawing, samples were filtered and analyzed after appropriate dilution by UV Spectrophotometer. The concentration was calculated using standard calibration curve.

Drug-Excipients compatibility studies:

Drug Excipients compatibility studies were carried out by mixing the drug with various excipients in different proportions (In 1:1 ratio were prepared to have maximum likelihood interaction between them) was placed in a vial, and closed with rubber stopper and sealed properly.

RESULTS AND DISCUSSION

Determination of $\lambda_{\max}$:

The prepared stock solution was scanned between 200-400 nm to determine the absorption maxima. It was found to be 240nm.

Calibration curve of Imeglimin Hydrochloride

The standard curve of Imeglimin Hydrochloride was obtained and good correlation was obtained with R^2 value of 0.998 the medium selected was pH 6.8 phosphate buffer.

Table 8.1: Standard graph values of Imeglimin Hydrochloride at 240nm in pH 6.8 phosphate buffer

Concentration ($\mu\text{g/ml}$)	Absorbance
0	0
2	0.136
4	0.258
6	0.367
8	0.476
10	0.588

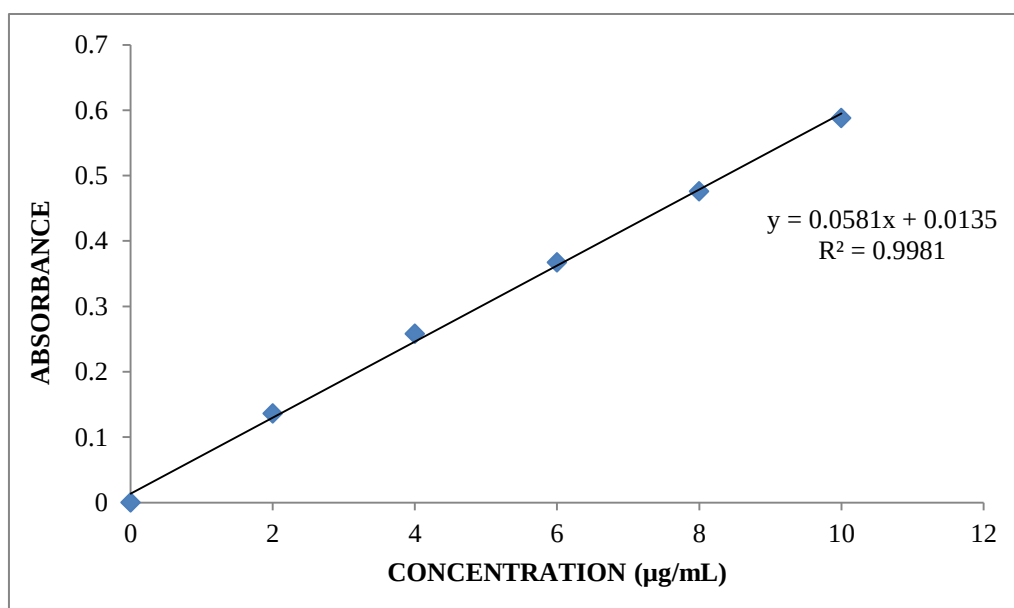


Fig 8.1: Standard curve of Imeglimin Hydrochloride

Evaluation:**Characterization of precompression blend:**

The precompression blend of Imeglimin Hydrochloride were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. Angle of repose was less than $28.3 \pm 0.4^\circ$, Carr's index values were less than 25.00 for the precompression blend of all the batches indicating good to fair flowability and compressibility. Hausner's ratio was less than 1.333 for all batches indicating good flow properties.

Table 8.2: Physical properties of precompression blend

Formulation code	Angle of repose (Θ)	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Carr's index (%)	Hausner's ratio
F1	23.2 ± 0.2	0.434 ± 0.2	0.476 ± 0.3	8.695	1.095
F2	25.2 ± 0.1	0.277 ± 0.2	0.312 ± 0.2	11.11	1.333
F3	27.1 ± 0.1	0.588 ± 0.3	0.666 ± 0.4	11.76	1.333
F4	24.4 ± 0.4	0.521 ± 0.3	0.631 ± 0.3	17.39	1.121
F5	28.3 ± 0.4	0.625 ± 0.1	0.833 ± 0.1	25.00	1.333
F6	25.1 ± 0.1	0.476 ± 0.3	0.526 ± 0.2	9.52	1.105
F7	26.7 ± 0.4	0.416 ± 0.2	0.476 ± 0.3	12.50	1.142
F8	26.0 ± 0.3	0.384 ± 0.4	0.434 ± 0.3	11.53	1.130
F9	26.6 ± 0.2	0.555 ± 0.1	0.714 ± 0.1	22.22	1.285

All the values represent n=3

Evaluation of tablets:**Physical evaluation of Imeglimin Hydrochloride Immediate release tablets:**

The results of the weight variation, Hardness, Thickness, Friability, and Drug content of tablets are given in table 8.3. All the tablets of different batches complied with the official requirement of weight variation as their weight variation passes the limit. The hardness of the tablets ranged from $3.15 - 3.95 \text{ kg/cm}^2$ and the friability values were $< 0.69\%$ indicating that the tablets were compact and hard. The thickness of the tablets ranged from $5.11 - 5.98$. All the formulations satisfied the content of the drug as they contained 96.12-99.35 % of Imeglimin Hydrochloride and good uniformity in drug content was observed. Thus, all physical attributes of the prepared tablets were found to be practically within control limits.

Table 8.3: Evaluation of Imeglimin Hydrochloride Immediate release tablets

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Content uniformity (%)	In Vitro Disintegration time (seconds)
F1	998.62	6.96	3.68	0.18	98.68	54
F2	997.56	6.62	3.95	0.25	97.45	45
F3	998.25	6.85	3.27	0.69	99.35	30
F4	999.36	6.71	3.15	0.54	96.12	51
F5	998.25	6.11	3.78	0.29	98.41	32
F6	997.86	6.98	3.89	0.47	99.21	20
F7	998.92	6.76	3.52	0.35	98.40	60
F8	997.38	6.69	3.17	0.62	97.53	39
F9	1000.02	6.57	3.28	0.38	96.74	25

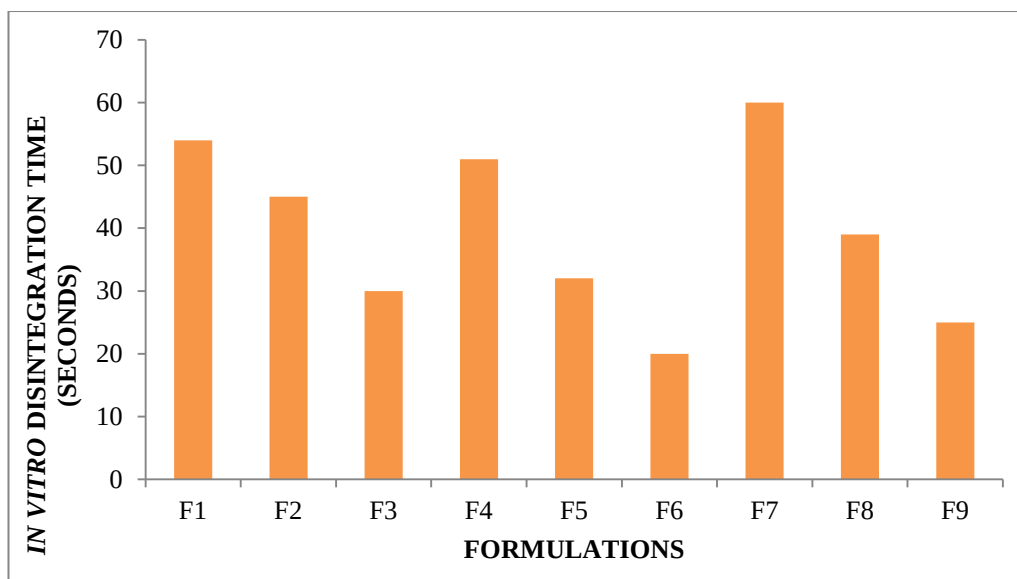


Fig 8.2: *In vitro* disintegration time graph

***In vitro* Dissolution:** The drug release rate from tablets was studied using the USP type II dissolution test apparatus. The dissolution medium was 500 ml of pH 6.8 phosphate buffer at 50 rpm at a temperature of 37 ± 0.5 °C. Samples of 5 ml were collected at different time intervals up to 30min and has analyzed after appropriate dilution by using UV spectrophotometer at 240nm

Table 8.4: *In vitro* data for formulation F1- 12

TIME (Minutes)	IN VITRO DRUG RELEASE								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	15.75	26.20	30.96	19.42	25.71	19.58	17.99	20.14	35.73
10	32.18	43.71	47.14	29.95	32.96	30.74	26.57	32.61	49.92
15	40.62	56.17	60.27	35.15	45.35	51.93	45.52	41.39	56.70
20	56.10	65.92	73.58	46.50	61.82	63.46	51.78	56.27	64.21
25	65.73	77.80	84.16	61.89	75.96	80.33	65.44	67.98	86.64
30	73.14	89.42	97.10	76.32	86.28	98.92	76.12	85.71	96.83

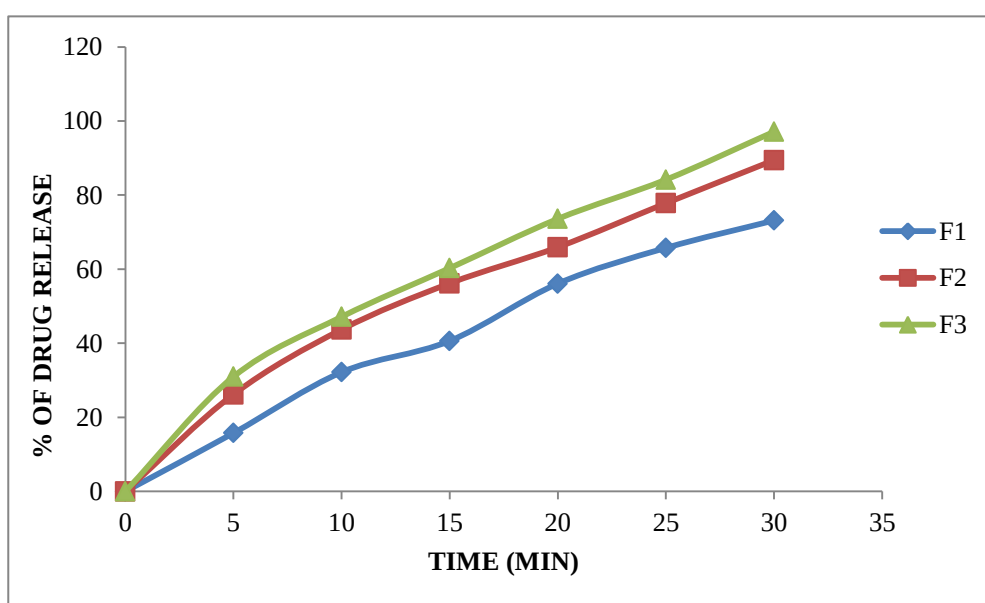


Fig 8.3: *In vitro* dissolution data for formulation F1-F3

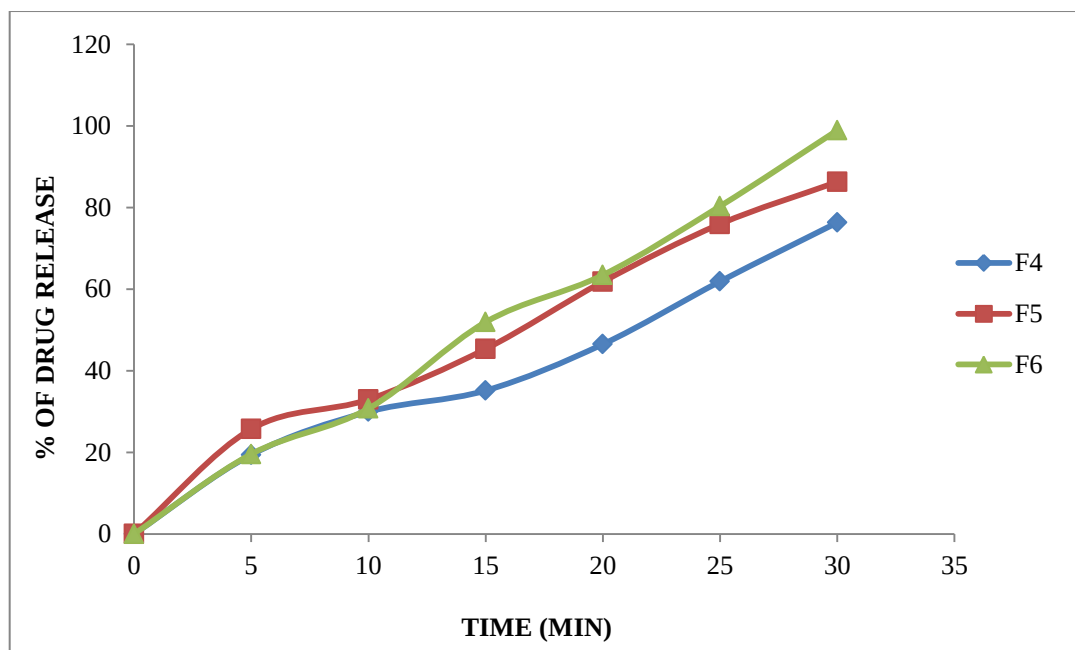


Fig 8.4: *In vitro* dissolution data for formulations F4-F6

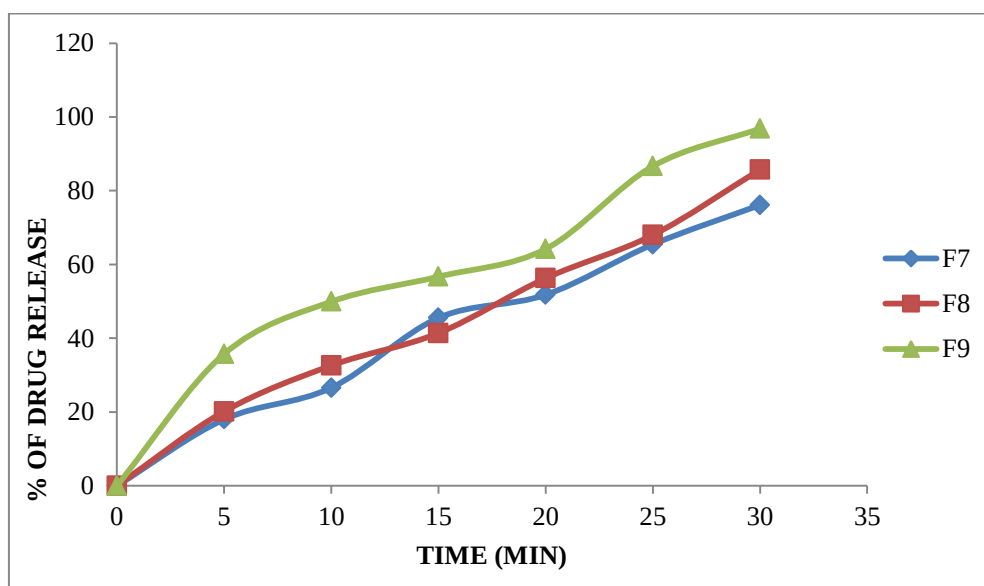


Fig 8.5: *In vitro* dissolution data for formulations F7-F9

From the table it was evident that the formulation prepared with Sodium starch glycolate were showed good drug release i.e., F3 formulation (97.10 %) in higher concentration of blend i.e 150 mg. Formulations prepared with Polyplasdone XL10 showed good drug release i.e., 98.92 % (F6 formulation) in 150 mg concentration. When increase in the concentration of PolyplasdoneXL10 drug able to retarded. Formulations prepared with Ac- Di- Sol showed maximum drug release i.e., 96.83 % (F9 formulation) at 30 min in 150 mg of blend. Among all formulations F6 considered as optimized formulation which showed maximum drug release at 30 min i.e., 98.92 %. Finally concluded that F6 formulation contains Polyplasdone XL10 was optimized formulation.

Drug-Excipient compatibility studies by FTIR studies:

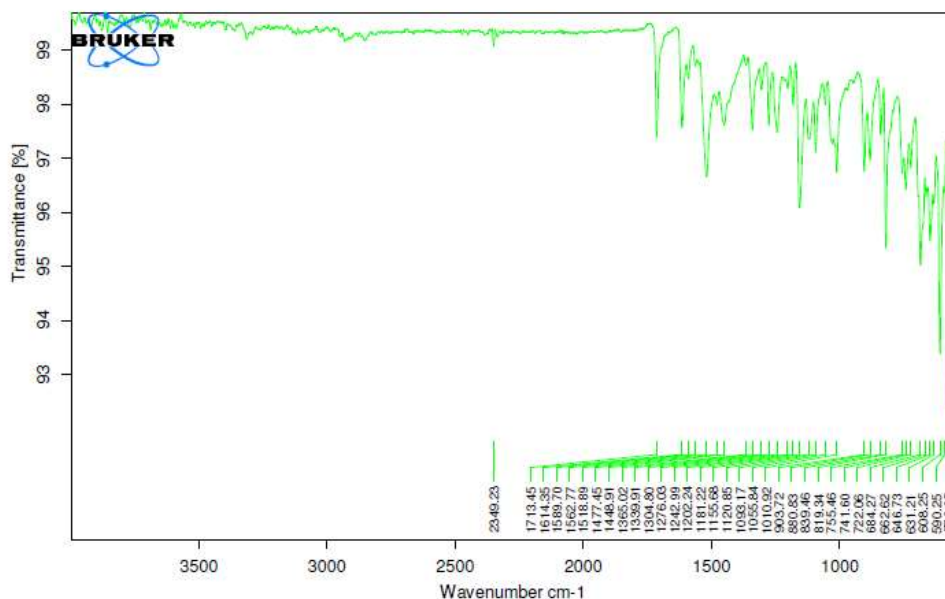


Fig 8.6: FTIR spectra of pure drug

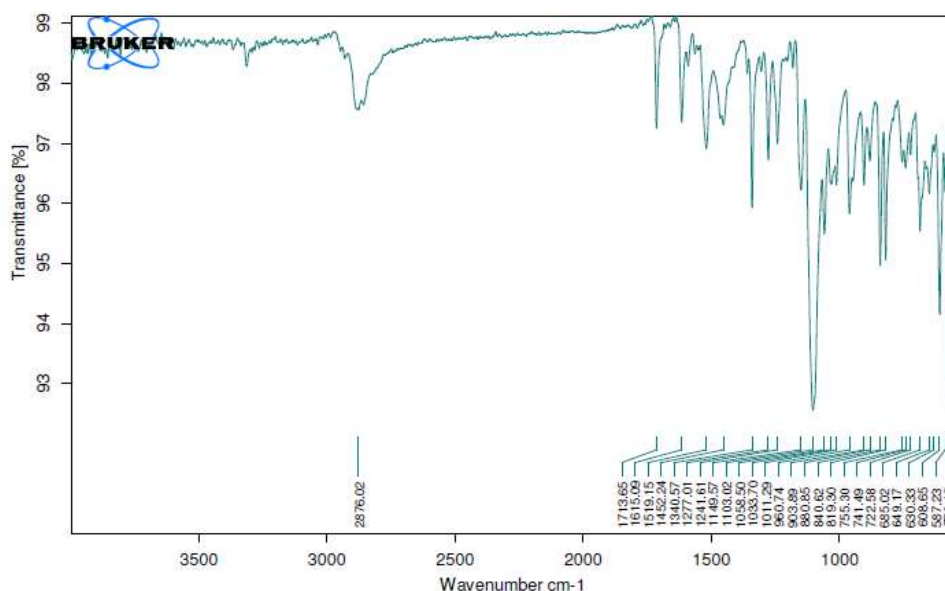


Fig 8.7: FTIR spectra of optimized formulation

Imeglimin Hydrochloride was mixed with various proportions of excipients showed no Colour change at the end of two months, providing no drug –excipient interactions.

SUMMARY AND CONCLUSION

The present study deals with the formulation and evaluation of immediate release tablets of Imeglimin Hydrochloride is a chemotherapy medication used to treat diabetic

The drug powders were subjected to Preformulation studies. The drug and excipients compatibility were carried out by FT-IR studies. The FT-IR studies it was found that following API and their granules for compression match with reference standard of the API. From this result it can be concluded that API is pure no incompatibility was found, which no changes its properties. The drug and excipients compatibility studies it can be seen the Imeglimin Hydrochloride is compatible with all the excipients used. No physical changes in Colour and appearance.

The precompression blend of Imeglimin Hydrochloride was characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio was indicating good flow properties.

The post compression results of the weight variation, hardness, thickness, friability, drug content and *In vitro* disintegration time of tablets. Thus, all physical attributes of the prepared tablets were found to be practically within control limits.

For Imeglimin Hydrochloride tablets direct compression method was selected. Optimization was found that based on the *in-vitro* drug release profile. Here three super disintegrants i.e. Sodium starch glycolate, Polyplasdone XL10 and Ac-Di-Sol different concentrations. From this result it can be indicated that the, optimized formulated tablet (F6) were within the Pharmacopoeial specifications. From this result it can be indicated that the, optimized formulated tablet (F6) assay were within the Pharmacopoeial specifications. A part from all formulations F6 formulation showed maximum drug release 98.92 % at end of 30 min.

It was also observed that direct compression was the best suitable method used for producing immediate release tablets Imeglimin Hydrochloride tablets.

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