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Formulation Design of Metformin Hydrochloride Mouth Dissolving Tablet by Melt Granulation Technique

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ABSTRACT

The most popular solid dosage forms are being tablets and capsules; one important drawback of these dosage form for some patients, is the difficulty to swallow. Drinking water plays an important role in swallowing of oral dosage forms. For these reasons tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Mouth dissolving tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. The concept of formulating Mouth dissolving tablets containing Metformin Hydrochloride offer a suitable and practical approach in serving the desired objective of faster disintegration and dissolution characteristic with increase bioavailability.

Keywords: Metformin Hydrochloride, Antidiabetic activity, Melt Granulation Technique, Superdisintegrant, Mouth Dissolving Tablet.

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INTRODUCTION

Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms. The reason that the oral route achieved such popularity may be in part attributed to its ease of administration as well as traditional belief that by oral administration the drug is as well absorbed as the food stuffs that are ingested daily. In fact, the development of pharmaceutical products for oral delivery, irrespective of physical form involves varying extents of optimization of dosage form characteristics within the inherent constraints of gastrointestinal physiology. A fundamental understanding of various disciplines, including GI physiology, Pharmacokinetics, Pharmacodynamics and formulation design are essential to achieve a systemic approach to the successful development of an oral pharmaceutical dosage form. In any case, the scientific frame work required for the successful development of an oral drug delivery system consists of a basic understanding of the following three aspects:

- Physiochemical, pharmacokinetic and pharmacodynamics characteristics of the drug,
- The anatomic and physiologic characteristics of the GIT, and
- Physiochemical characteristics and the drug delivery mode of the dosage form to be designed.

Tablets and hard gelatin capsules constitute a major portion of drug delivery systems that are currently available. However, many patient groups such as the elderly, children and patients who are mentally retarded, uncooperative, nauseated or on reduced liquid-intake/diets have difficulties swallowing these dosage forms. Those who are travelling or have little access to water are similarly affected. For these reasons; tablets which can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Rapidly dissolving or disintegrating tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people.[1, 2]

MATERIALS AND METHOD

Materials:

Metformin Hydrochloride purchased (Glenmark Research Centre Sinnar, Nashik), roscarmellose Sodium (Maxheal Pharmaceuticals (india) Ltd, Satpur, Nashik), Hydroxy Propyl Methyl Cellulose, Stearic Acid, Colloidal Silicon Dioxide (Aerosil), Magnesium Sterate, Starlac, Peppermint, purchased from (Maxheal Pharmaceuticals (india) Ltd)

Methodology:

Mouth dissolving tablet of metformin HCL were prepared by Melt granulation technique according.

All the ingredient were passed through 60 Mesh Sieve separately. The drug and Stearic acid was mixed by small portion of each time & blending it to get a uniform mixture. Then the other ingredients were weighed & mixed in geometrical order to form blend. Then this blend pass through 16 mesh sieve to form uniform granules & tablets were compressed of 8mm sizes flat round punch to get tablet using multi station rotary punch tablet compression machine.

Table 1: Formulation of Metformin Hydrochloride Mouth Dissolving Tablet Prepared by Melt Granulation Technique.

Ingredients	**Formulation Code**					
	F1	**F2**	**F3**	**F4**	**F5**	**F6**
Metformin HCL	500	500	500	500	500	500
AC-Di-Sol	40	40	40	40	40	40
Hydroxy propyl methyl cellulose	99.25	100	99.75	-	-	-
Starlac	-	-	-	99.25	100	99.75
Stearic	40	39.25	39.50	40	39.25	39.50
Aerosil (colloidal silicon dioxide)	10	10	10	10	10	10
Mg. Stearate	10	10	10	10	10	10
Peppermint	0.75	0.75	0.75	0.75	0.75	0.75
Total weight (mg)	700	700	700	700	700	700

Evaluation of Tablet

Pre-compression parameters[38, 46]:

1 Angle of repose (θ):

Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane. The frictional force in a loose powder or granules can be measured by the angle of repose.

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

$$\theta = \tan^{-1} (h/r)$$

Where, θis the angle of repose

h is height of pile

r is radius of the base of the pile

Different ranges of flow ability in terms of angle of repose are given below.

Table 2: Relationship between angle of repose (θ) and flow properties[38].

Angle of Repose (θ)	Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Method:

A funnel was filled to the brim and the test sample was allowed to flow smoothly through the orifice under gravity. From the cone formed on a graph sheet was taken to measure the area of pile, thereby evaluating the flow ability of the granules. Height of the pile was also measured.

2. Bulk density:

Bulk density is defined as the mass of a powder, divided by the bulk volume. The bulk density of a powder depends primarily on particle size distribution, particle shape, and the tendency of the particles to adhere to one another.

Method:

Both loose bulk density (LBD) and tapped bulk density (TBD) were determined. A quantity of accurately weighed powder (bulk) from each formula, previously shaken to break any agglomerates formed was introduced into a 25 ml measuring cylinder. After the initial volume was observed, the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5 cm at 2 Sec intervals. The taping was continued until no further change in volume was noted. BD and BD were calculated using following formula

$$\text{LBD} = \frac{\text{Weight of the powder}}{\text{Volume of the packing}}$$

$$\text{TBD} = \frac{\text{Weight of the powder}}{\text{Tapped volume of packing}}$$

3. Tapped Density

The measuring cylinder containing a known mass of blend was tapped for a fixed time. The minimum volume (Vt) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density (pt) was calculated using the following formula

$$\rho t = \frac{M}{Vt}$$

4. Hausner's ratio:

Hausner ratio is an indirect index of ease of power flow. It is calculated by the following formula.

$$\text{Hausner's ratio} = \frac{\rho_t}{\rho_d}$$

Where ρ_t is tapped density and ρ_d is bulk density. Lower Hausner ratio (<1.25) indicates better flow properties than higher ones. (>1.25) indicates poor flow.

5. Carr's Compressibility index:

The compressibility index of the granules was determined by the Carr's compressibility index. (%) Carr's Index can be calculated by using the following formula

$$\text{Carr's Index (\%)} = \frac{\text{TBD - LBD}}{\text{TBD}} \text{ x } 100$$

Table 3: Grading of the powders for their flow properties according to Carr's Index

Compressibility index	Flow
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair to passable
23 – 35	Poor
33 – 38	Very poor
>40	Very, very poor

Post-Compression Parameters

1. Hardness test:

Tablets require a certain amount of strength, or hardness and resistance to friability, to withstand mechanical shocks of handling during manufacture, packaging and shipping. The hardness of the tablets was determined using Monsanto Hardness tester. It is expressed in Kg/cm. Three tablets were randomly picked from each formulation and the mean and standard deviation values were calculated.

2. Friability test:

It is the phenomenon whereby tablet surfaces are damaged and/or show evidence of lamination or breakage when subjected to mechanical shock or attrition.

The friability of tablets was determined by using Electro lab, USP EF 2 friabilator. It is expressed in percentage (%). Ten tablets were initially weighed ($W_{initial}$) and transferred into friabilator. The friabilator was operated at 25 RPM for 4 minutes or run up to 100 revolutions. The tablets were weighed again (W_{final}). The percentage friability was then calculated by,

$$F = \frac{W_{initial} - W_{final}}{W_{initial}} x100$$

% Friability of tablets less than 1% is considered acceptable.

3. Weight variation test:

The tablets were selected randomly from each formulation and weighed individually to check for weight variation. The U.S Pharmacopoeia allows a little variation in the weight of a tablet. The following percentage deviation in weight variation is allowed.

Table 4: Percentage Deviation in Weight Variation

Average weight of a tablet	Percentage deviation
130 mg or less	10
More than 130 mg and less than 324 mg	7.5
324 mg or more	5

In all the formulations the tablet weight was more than 324 mg or more, hence 5% maximum difference allowed.

4. Uniformity of thickness:

The crown thickness of individual tablet may be measured with a digital vernier calliper, which permits accurate measurements and provides information on the variation between tablets.

5. Drug content Uniformity:

Four tablets weighted and crushed in a mortar then weighed powder contain equivalent to 10 mg of drug was taken and dissolved in 100 ml 0.1M HCL from this solution 1 ml of solution was diluted to 10Ml 0.1 M HCL again 1 ml solution from this diluted up to 10 ml with 0.1 M HCL and assayed for drug content at 237.5nm.

6. Wetting Time:

The method was applied to measure tablet wetting time. A piece of tissue paper folded twice was placed in a small Petri dish (I. D. = 6.5cm) containing 10 ml of water, a tablet was placed on the paper and the time for complete wetting was measured. Three trials for each batch were performed and standard deviation was also determined.

7. Water Absorption Ratio:

A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. A tablet was put on the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R was determined using following equation.

$$R = \frac{(Wa - Wb)}{Wb} \times 100$$

Where, Wb- weight of tablet before absorption

Wa – weight of tablet after absorption

Three tablets from each formulation were performed and standard deviation was also determined.

8.*In vitro* Disintegration Time:

The process of breakdown of a tablet into smaller particles is called as disintegration. The in-vitro disintegration time of a tablet was determined using disintegrating taste apparatus as per I P Specification.*

Figure 1: Disintegration test apparatus

IP Specifications:

Place one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using pH 6.8 maintained at $37^0 \pm 2^0$C as the immersion liquid. The assembly should be raised and lowered between 30 cycles per minute in the pH 6.8 maintained at $37^0 \pm 2^0$C. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

***9. In vitro* dissolution studies:**

The drug release studies were performed by USP Type II dissolution test apparatus pH 6.8 phosphate buffer solution was used as dissolution medium. The temperature and speed of the apparatus were maintained at 37±0.5ºC and 50 rpm respectively. The samples were withdrawn at predetermined time interval and analyzed for drug concentration at 225 nm by UV-visible spectrophotometer (LABINDIA 3000+) after filtration.

Figure 2: Dissolution test apparatus

***In vitro* drug release studies details:**

Apparatus used : USP apparatus type- II

Dissolution medium : 6.8 pH phosphate buffer solution.

Dissolution medium volume : 900 ml

Temperature : 37±0.5°C

Speed of basket paddle : 50 rpm

Sampling intervals : 5 min

Sample withdraw : 5 ml

Absorbance measured : 225 nm

10. Stability Studies:

Stability of a drug has been defined as the ability of a particular formulation, in a specific container, to remain within its physical, chemical, therapeutic and toxicological specifications.

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light. The ability of a pharmaceutical product to retain its chemical, physical, microbiological and biopharmaceutical properties within specified limits throughout its shelf life and recommended storage conditions:

Table 5: Stability testing as per ICH guidelines

Sr. No.	Description	Storage Conditions
1	Long term testing	$25^0C \pm 2^0C$ / 60%RH±5% for 12 months
2	Accelerated testing	$40^0C \pm 2^0C$ / 75%RH±5% for 6 months
3	In the present study, stability studies were carried out at	40^0C / 75%RH for a specific time period up to one month for the selected formulations.

RESULTS AND DISCUSSION

Results of Pre-Compression Parameter for Prepared Tablet by Melt Granulation Technique.

Powder ready for compression containing drug and various excipients were subjected for pre-compression parameter to study flow property of granules to achieve uniformity of tablet weight. Results of all the pre-formulation parameter are given in Table 6.

Table 6: Pre-Compression Parameters for Prepared Tablet by Melt Granulation Technique

Formulation Code	Parameters				
	Bulk Density* (g/CC)	**Tapped Density* (g/CC)**	**Angle of Repose* (Degree)**	**Carr's Index (Percent)**	**Hausner's Ratio**
F1	0.36±0.028	0.6454±0.004	28.70±0.014	15.44±0.170	1.10±0.025
F2	0.38±0.025	0.6439±0.005	28.16±0.03	14.44±0.115	1.18±0.020
F3	0.36±0.013	0.6413±0.004	29.98±0.156	15.55±0.308	1.13±0.013
F4	0.37±0.015	0.6514±0.003	28.16±0.025	09.54±0.025	1.18±0.012
F5	0.42±0.012	0.6321±0.006	29.03±0.035	11.12±0.145	1.14±0.013
F6	0.41±0.021	0.6604±0.004	28.17±0.045	14.04±0.111	1.12±0.015

*Mean ± S.D., n=3 (All the values are the average of three determination)

CONCLUSION:

Angle of Repose (ɵ)

The data obtained from angle of repose for all the formulations werefound to be in the range of 28.70±0.014 to 29.98±0.1562. All the formulations prepared by both the methods showed the angle of repose less than 30^0, which reveals good flow property (Table 6).

Bulk Density

Loose bulk density (LBD) & for all formulations varied from 0.36±0.028 gm/cm3 to 0.42±0.012 gm/cm3. Tapped bulk density (TBD) of entire formulation 0.6413±0.004gm/cm3 to 0.6604±0.004gm/cm3 (Table 6).

Hausner's Ratio

Hausner's Ratio of entire formulation showed between 1.10±0.025 to 1.18±0.020 which indicates better flow properties (Table 6).

Carr's Consolidation Index

The result of Carr's Consolidation Index or compressility index (%) of the entire formulation blend ranged from 9.54±0.0255% to 15.55±0.308 (Table 6)

Results of Post Compression Tablets prepared by Melt Granulation Technique

Hardness:

The hardness of all the tablets prepared by both methods was maintained within the 2.5 ± 0.264 kg/cm^{2}to 4.0 ± 0.251 kg/cm^2. The mean harness test results are tabulated in **Table 7.**

Friability test:

The friability was found in all designed formulations in the range 0.20 ± 0.065 to 0.90 ± 0.072 to be well within the approved range (<1 %). The friability study results were tabulated in **Table 7.**

Thickness:

The mean thickness was (n=3) almost uniform in all the formulations and values ranges from 3.28 ± 0.155 mm to 3.47 ± 0.265 mm. The results of thickness for tablets were shown in the **Table 7.**

***In vitro* dispersion time:**

The *in vitro* dispersion time is measured by the time taken to undergo uniform dispersion. Rapid dispersion within several minutes was observed in all the formulations. The *in-vitro* dispersion data is tabulated in the **Table 7.**

Table 7: Evaluation of Metformin HCL MDT Formulations

Formulation Code	Parameters			
	Hardness* (kg/cm^2)	Friability* (%)	Thickness* (mm)	In vitro Dispersion time* (sec)
F1	3.0±0.254	0.50±0.05	3.36±0.030	20±1.00
F2	3.0±0.285	0.40±0.084	3.35±0.055	23±1.627
F3	3.5±0.136	0.20±0.065	3.43±0.015	17±1.610
F4	2.5±0.264	0.90±0.072	3.47±0.265	36±3.516
F5	4.0±0.251	0.30±0.076	3.28±0.15	30±1.023
F6	3.5±0.201	0.50±0.076	3.38±0.065	45±1.081

Mean ± S. D. , n=3 (All the values are the average of three determination)

Weight variation test:

The weight variation was found in all designed formulation in the range 700.13 ±0.486 to 700.28±475 mg. The mean weight variation test results are tabulated in **Table 8.**

Wetting time:

The results of wetting time are shown in **Table 8**. The wetting time of Metformin HCL tablets prepared by Melt Granulation Technique was found in the range of 41.59±0.675 and 69.10±0.369 sec respectively, which facilate the faster dispersion.

Water absorption ratio:

The values of water absorption ratio shown in **Table 8.**

Drug Content:

The drug content uniformity was performed for all the 6 formulations and results are tabulated in Table 8. Three trials from each batch were analyzed spectrophotometrically. The average value and standard deviations of all the formulations were calculated.

Table 8: Evaluation of Metformin HCL MDT Formulations

Formulation Code	Parameters			
	Wetting Time* (sec)	Water Absorption Ratio* (%)	Percentage Drug Content*	Weight Variation*
F1	69.10±0.369	52.95±1.571	698±0.582	700.28±0.475
F2	51.79±0.503	45.36±1.023	699±0.612	700.18±0.440
F3	59.71±0.518	49.33±0.675	700.4±0.632	700.28±0.447

F4	55.72±0.475	58.16±0.944	698.2±0.290	700.12±0.405
F5	51.89±0.320	64.86±0.490	600.3±0.205	700.18±0.472
F6	41.59±0.675	72.42±1.156	700.2±0.405	700.13±0.486

* Mean ± S.D., n=3 (all the values are the average of three determination)

CONCLUSION:

Hardness

Tablet crushing strength, the critical parameter was controlled as the resistance of tablets to capping, abrasion or breakage under condition of storage, transportation and handling before usage, depends on its hardness. Hence, hardness for all formulation batches prepared by melt granulation technique was found to be between pharmacopoeia limits. This finding was observed due to constant tablet press setting across all batches, irrespective of weight variation.

Friability

To achieve % friability within limits for fast dispersible tablet is a challenge to the formulator since all methods of manufacturing of fast dispersible tablet are responsible for increasing the % friability values. The % friability values for all formulation batches prepared by direct compression method were found to be between pharmacopoeia limits.

Average Weight

As material was free-flowing, tablets were obtained of uniform weight due to uniform die fill with acceptable variation as per I.P. Standards. The weight variation was found in all designed formulations in the range 700.12±0.405 to 700.28±0.475 mg. All the tablets passed weight variation test as the average percentage weight variation was within 7.5% i.e. in the pharmacopoeia limits.

Thickness

Thickness for all formulation batches prepared by both methods was found to be between pharmacopoeia limits. This finding was observed again due to constant tablet press setting across all batches, irrespective of weight variation. The standard deviation values indicated that all the formulations were within the range.

***In vitro* Disintegration Time[4, 47]**

Disintegration is first important step for drug absorption from a solid dosage form after oral administration was preliminarily focused. Disintegration time were determined for all the formulations and it was found that by increasing concentration of superdisintegrants, the disintegration time decreases; but increase concentration above 6% hardness value decreases. An important factor affecting the disintegration is the tablet hardness and/or the compaction force used

in making the tablet hardness. The hardness of the tablet has an influence on the disintegration time as it affects the porosity of the matrix and, accordingly, the ability of water to percentage through the matrix. All tablets disintegrated rapidly without disc in the IP test.

The in-vitro dispersion time of Metformin HCL prepared by direct compression method were found to be in the range of 17±1.610 to 45±1.081 sec. fulfilling the official requirements. Based on the in vitro disintegration time, formulation F3 and F6 were found to be promising and showed a dispersion time of 17±1.610 and 45±1.081 sec respectively.

Wetting Time[4, 47]

Wetting time is another important related inner structure of tablet & parameter to water absorption ratio, which needs to be assessed to give an insight into the disintegration properties of the tablets. Wetting time for all formulation batches showed wide variation in the range of 41.59±0.675 and 69.10±0.369 seconds.

Water Absorption Ratio[4, 47]

The formulation shows water absorption ratio in the range of 45.36±1.023 to 72.42±1.156%. By increase in concentration of superdisintegrants the water absorption ratio increases, that might be due to the increase in the porosity of the formulation with increase in Superdisintegrant concentration.

Uniformity of Dug Content

The low values of standard deviation indicates uniform drug content in tablets the percent drug content of all tablets was found to be in the range of 698±0.582 to 700.4±0.632%.

DISSOLUTION STUDY

The dissolution of Metformin HCL from tablets is tabulated in Table 9.

Release profile of Metformin HCL

Table 9: Release profile of Metformin HCL Mouth dissolving tablets by Melt Granulation Technique

Time Interval (Minutes)	F1*	F2*	F	F4	F5*	F6*
5	59.42%±0.01	60.05%±0.18	59.52%±0.02	54.57%±0.27	58.99%±0.12	64.99%±0.42
10	67.65%±0.35	68.56%±0.28	68.01%±0.49	62.78%±0.31	66.92%±0.42	74.00%±0.15
15	71.15%±0.26	72.73%±0.37	72.46%±0.19	66.22%±0.51	71.88%±0.30	77.19%±0.16
20	78.66%±0.33	80.25%±0.10	79.60%±0.28	73.40%±0.28	78.26%±0.25	84.47%±0.25
25	84.96%±0.48	87.07%±0.37	86.65%±0.10	79.78%±0.28	84.94%±0.35	92.19%±0.28
30	89.64%±0.20	91.53%±0.49	90.95%±0.31	89.17%±0.27	91.38%±0.31	97.52%±0.21
35	93.41%±0.33	95.67%±0.12	96.26%±0.24	92.03%±0.49	94.14%±0.51	99.17%±0.12

* Mean ± S.D., n=3 (all the values are the average of three determination)

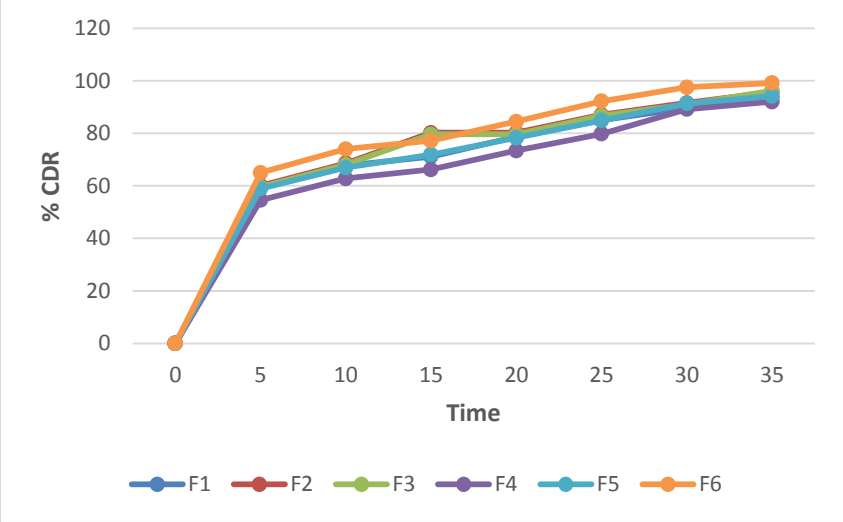

Figure 3: Release profile of Metformin HCL MDT by Melt granulation technique

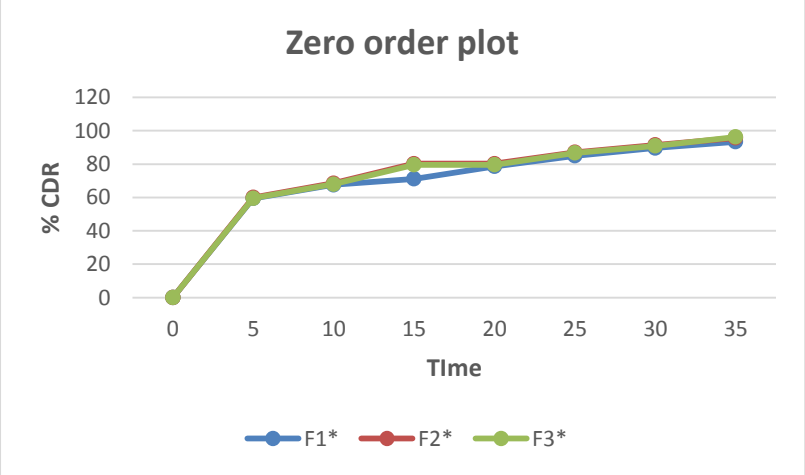

Figure 4: Comparative zero order plots for formulation F1 to F3

Figure 5: Comparative zero order plots for Formulations F4 to F6

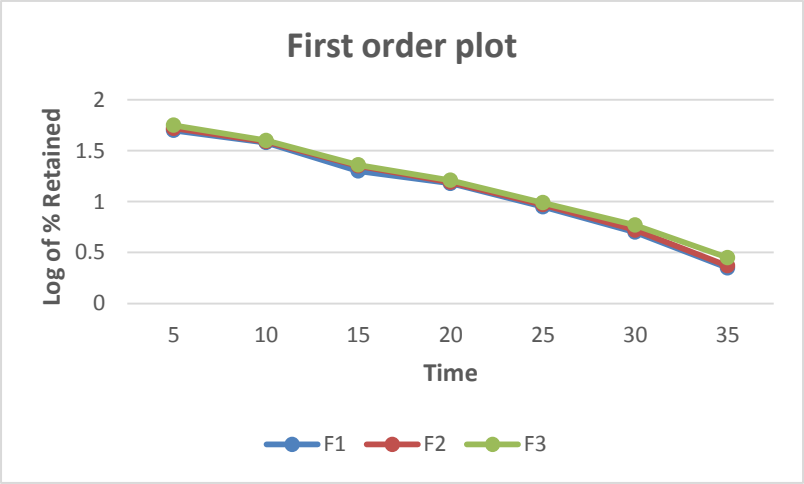

Figure 6: Comparative first order plots for formulations F1 to F3

Figure 7: Comparative first order plots for formulations F4 to F6

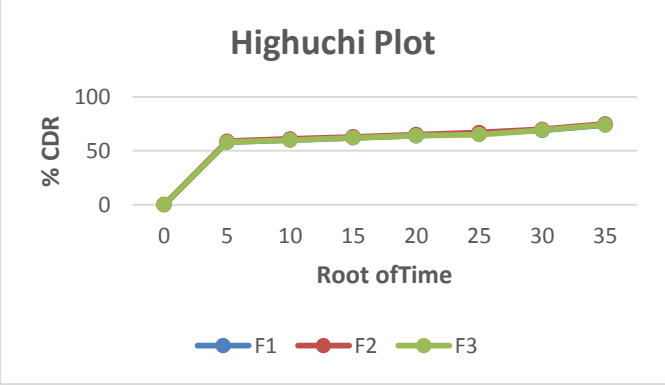

Figure 8: Comparative Highuchi's plots for Formulations F1 to F3

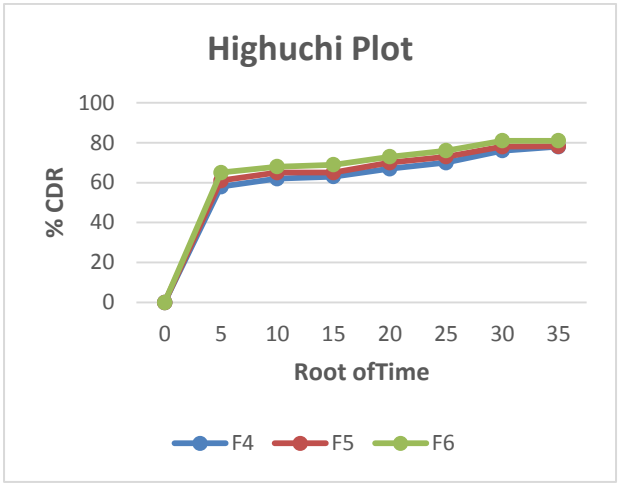

Figure 9: Comparative Highuchi's plots for Formulations F4 to F6

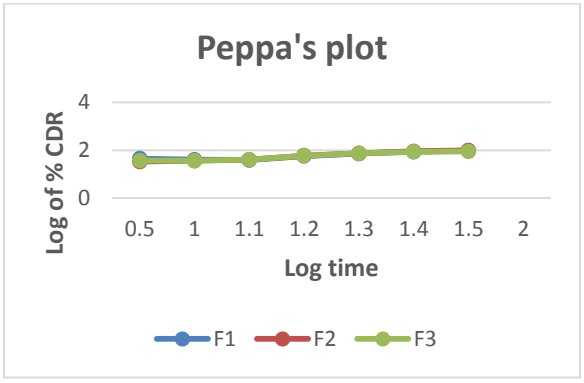

Figure 10: Comparative Peppa's plots for formulations F1 to F3

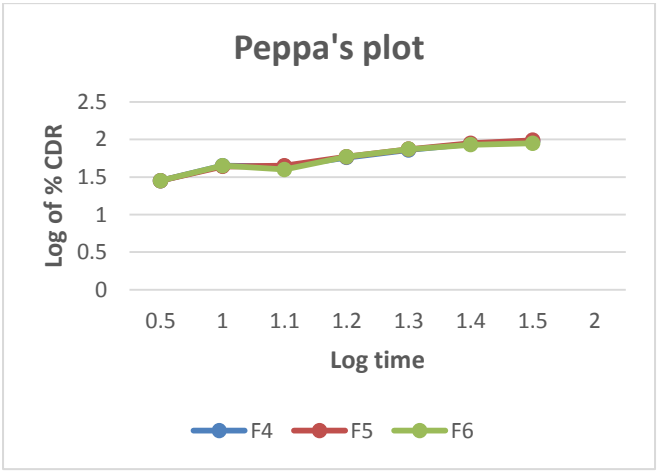

Figure 11: Comparative Peppa's plots for formulations F4 to F6

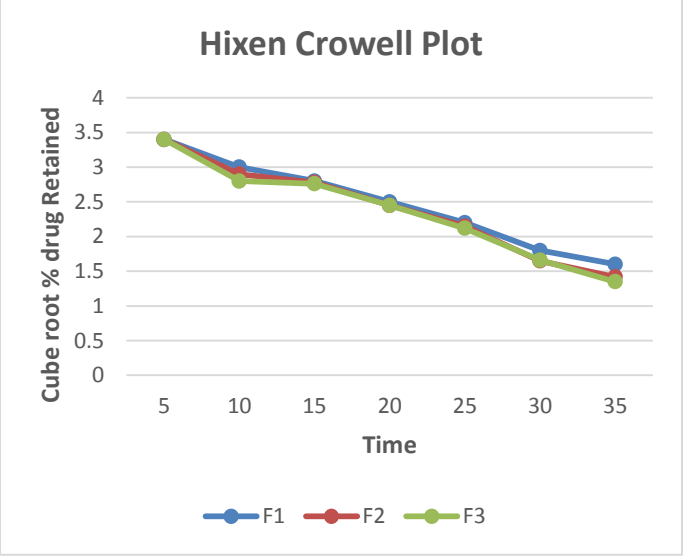

Figure 12: Comparative Hixen crowell plots for formulations F1 to F3

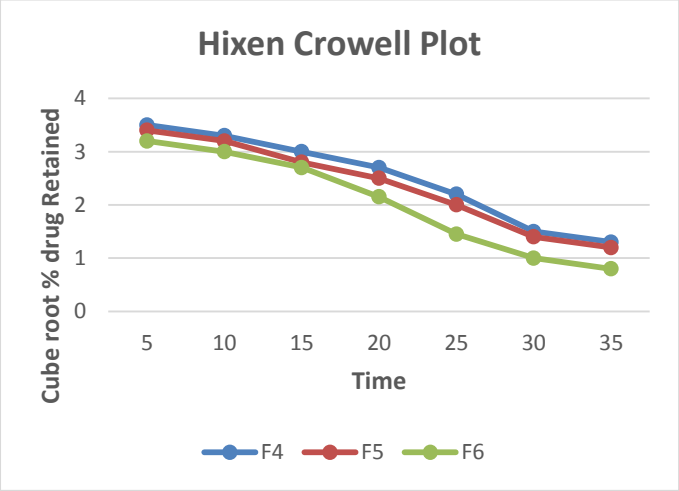

Figure 13: Comparative Hixen crowell plots for formulations F4 to F6

***In-vitro* Dissolution Study**[4, 47]

Effect of Ac-Di-Sol on drug release:

The cross linking in the structure of Ac-Di-Sol serves to greatly reduce water solubility, while allowing the material to swell and absorb many times weight of water. It does this without the losing integrity of individual fibers. It was observed that combination of Ac-Di-Sol and starlac cause decrease in disintegration time and gives effective drug release up to 99.17% at 35 min.

Effect of Starlac on drug release:

Starlac ensures uniformity of weight, greater capacity of pick particle, greater rank of speed of compression.

Effect of Magnesium stearate on drug release:

It was observed that, use of Magnesium stearate as lubricant does not affect release time of Zolmitriptan from prepared tablets.

Stability Studies

The promising formulations were subjected to short term stability by storing the formulations at 40 ^{0}C /75 % RH up to one month. The formulations were selected. After one month the tablets were again analyzed for the hardness, friability, and drug release and dispersion time. No increase in the disintegration time was observed in tablets prepared by Melt granulation technique. There were no changes observed after storage period.

Table 10: Result of stability study of optimized formulation (F_6)

Sr. No.	Evaluation Parameters	Initial stage	1st month	2nd month
1	Color	No change	No change	No change
2	Odor	No change	No change	No change
3	Hardness	4.5±0.201	4.5±0.201	4.5±0.201
4	Friability	0.60±0.076	0.60±0.076	0.60±0.076
5	Disintegration Time	45±1.081	45±1.081	45±1.081
6	% drug release	99.17%±0.12	99.17%±0.12	99.15%±0.10

CONCLUSION

In the present work mouth dissolving tablets of Metformin Hydrochloride were prepared by Melt Granulation Technique using superdisintegrants and binder such as starlac hydroxypropyl methylcellulose and stearic acid. All the tablets of Metformin Hydrochloride were subjected to weight variation, hardness, friability, *in vitro* dispersion, drug polymer interaction, drug content uniformity, water absorption ratio, wetting time and *in vitro* drug release. Based on the above studies following conclusions can be drawn: Super disintegrants and binder are used in various concentrations. In pre-compression evaluation of physical mixture of Superdisintegrant shows better result. Bulk Density, Angle of Repose, Hausner's Ratio and Tapped Density results are good. The tablets prepared by direct compression method were found to be good and free from chipping and capping. Post compression parameter (hardness, friability, thickness and drug content) was within the acceptable limit. IR spectroscopic studies indicated that the drug is compatible with all the excipients. DSC Studies indicated that the drug compatible with all excipients. Based on disintegration time, formulation (F6) co processed mixtures of starlac & stearic acid was found to be promising and showed a dispersion time of 45 sec, wetting time of 41.59 sec.

The in-vitro drug release form fast dissolving tablets of metformin HCL prepared by Melt Granulation Technique were found to be 99.17% within 35 minute. The stability study shows that no significant changes in drug content after one month study.

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