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FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF IMIPRAMINE HCl

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ABSTRACT

This study focused on the formulation and evaluation of mouth dissolving tablets (MDTs) of Imipramine HCl to enhance patient compliance and improve drug bioavailability in the treatment of depression and nocturnal enuresis. Imipramine HCl, a tricyclic antidepressant with moderate bioavailability, was selected due to its suitability for rapid release through oral mucosal absorption, thereby reducing first-pass metabolism. The MDTs were prepared using the direct compression method incorporating natural superdisintegrants such as Plantago ovata mucilage, Moringa gum, and Fenugreek seed mucilage in varying concentrations. The powder blends exhibited good flow properties, as indicated by acceptable values of precompression parameters. The compressed tablets were evaluated for post-compression parameters including thickness, weight variation, hardness, friability, wetting time, disintegration time, and drug content, all of which complied with pharmacopeial limits. Among all nine formulations, batch IM8 showed the fastest disintegration (18.71 sec.) and highest drug release (99.56%), indicating its superiority as an optimized formulation. Stability studies under accelerated conditions showed no significant changes in physicochemical properties or drug release profile. Overall, the study concludes that natural polymer-based mouth dissolving tablets of Imipramine HCl can provide rapid onset of action, improved bioavailability, and enhanced patient compliance.

KEYWORDS: Mouth dissolving tablets, Imipramine HCl, Plantago ovata mucilage, Moringa gum, Fenugreek seed mucilage.

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INTRODUCTION

Tricyclic antidepressants like Imipramine are used to treat nocturnal enuresis in addition to depression because they shorten the delta wave stage of sleep, which is when bedwetting happens. According to WHO data, depression is the most common mental illness, affecting an estimated 3.8% of the global population, or 280 million individuals.[1] Depression escalates into a dangerous illness that has the potential to be fatal. One of the tricyclic antidepressants that is frequently used to treat depression is imipramine, which has a mean half-life of roughly 10 to 16 hours and a low oral bioavailability of just 27 - 97%. Because of its extended half-life, Mouth Dissolving Tablet formulation won't be limited by dosage dumping. Because of their mood swings and transient emotional responses, patients with depression often ignore their treatment regimens. Mouth Dissolving Tablets have higher bioavailability in comparison to other traditional dosage forms. This could be described as the drug's immediate absorption into the systemic circulation through the mouth cavity, thereby circumventing the liver.[2] Additionally, once the medication is absorbed from the oral cavity, the first pass metabolism will be decreased. Because it is so simple to use, this type of formulation is ideal for individuals who are depressed or mentally unstable. Moreover, Mouth Dissolving Tablets dissolve quickly in the mouth, requiring no water to be taken this improves patient compliance, offers a quick start of action, and eventually increases bioavailability. Additionally, because the medication is in BCS Class I, it will readily dissolve and have a high permeability from the oral cavity. In order to help patients stick to their treatment plan, efforts are being undertaken to create a formulation that is simple to use and doesn't cause discomfort.[3,4].

MATERIALS AND METHOD

MATERIALS: Plantagoovata seeds mucilage, Fenugreek seeds mucilage, Moringa gum mucilage, and all other excipients were obtained from Chemdyes Corporation, Rajkot.

METHOD[5-6]: Mouth Dissolving Tablet of Imipramine HCl were prepared by Direct Compression Method. Required amount of ingredients were weighed and mixed in mortar and pestle. Then the blend was passed through a 40 number mesh size aperture and collected. Finally, the mixture was compressed using Rotary Punch Machine. The Mouth dissolving tablets were prepared by using ingredients with concentrations as mentioned in table 1.

Table 1: Formulation Design of Mouth Dissolving Tablets of Imipramine HCl by Direct Compression Method

Ingredients (mg)	Formulation batch								
	IM1	IM2	IM3	IM4	IM5	IM6	IM7	IM8	IM9
Imipramine HCl	10	10	10	10	10	10	10	10	10
Avicel PH 102	50	50	50	50	50	50	50	50	50
Plantago ovata seeds mucilage	3	6	9	-	-	-	-	-	-
Moringa gum mucilage	-	-	-	3	6	9	-	-	-
Fenugreek seed mucilage	-	-	-	-	-	-	3	6	9
D- Mannitol	39.6	36.6	33.6	39.6	36.6	33.6	39.6	36.6	33.6
Magnesium stearate	5	5	5	5	5	5	5	5	5
Aspartame	10	10	10	10	10	10	10	10	10
Talc	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Total weight	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**

Determination of Melting Point of Imipramine HCl

The melting point of Imipramine HCl was determined using a digital melting point apparatus. A small quantity of the drug was filled into a thin-walled capillary tube sealed at one end. The capillary tube was then placed in the melting point apparatus alongside a calibrated thermometer. The temperature range at which the drug sample melted was recorded. All measurements were performed in triplicate to ensure accuracy and reproducibility, and the average value was reported.[7,8]

Estimation of Imipramine HCl by UV–Visible Spectrophotometry

A standard stock solution of Imipramine HCl was prepared using phosphate buffer (pH 6.8) as the solvent system. Accurately weighed 10 mg of Imipramine HCl was transferred into a 100 mL volumetric flask and dissolved in phosphate buffer (pH 6.8) to prepare stock solution having a concentration of 100 µg/mL. Working standard solutions were prepared from the stock solution by appropriate dilution. Aliquots of 0.5, 1.0, 1.5, 2.0, and 2.5 mL were withdrawn from the stock solution (100 µg/mL) and transferred into separate 10 mL volumetric flasks. Each flask was then diluted to the mark with phosphate buffer (pH 6.8) to obtain solutions with concentrations of 5, 10, 15, 20, and 25 µg/mL, respectively. The absorbance of the prepared working solutions was measured at the maximum wavelength (λmax) of 252 nm using a UV–Visible spectrophotometer. Phosphate buffer (pH 6.8) was used as the blank. All measurements were performed in triplicate to ensure reproducibility, and the mean absorbance values were recorded for further analysis.[7,8]

Pre-Compression Parameters[9,10]

Pre-compression parameters of the powder blend were evaluated to assess the flow characteristics and compressibility of the formulation prior to tablet compression.

Bulk Density: Bulk density was determined by gently transferring a known mass of the powder blend into a graduated measuring cylinder without compacting the material. The volume occupied by the powder was recorded, and bulk density was calculated using the following equation:

$$\text{Bulk Density} = \frac{\text{Mass of powder (gm)}}{\text{Bulk volume of powder (ml)}}$$

Tapped Density: Tapped density was measured using a mechanical tapping apparatus. A graduated cylinder containing a known quantity of powder blend was tapped repeatedly until a constant volume was obtained. The tapped density was then calculated using the following formula:

$$\text{Tapped Density} = \frac{\text{Mass of powder (gm)}}{\text{Tapped volume of powder (ml)}}$$

Compressibility Index (Carr's Index): The compressibility index indicates the flow properties of a powder blend and was calculated from the bulk and tapped densities using the following equation:

$$\text{Carr's index} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} X\ 100$$

Hausner's Ratio: Hausner's ratio was calculated as the ratio of tapped density to bulk density and provides an indication of powder flowability. A Hausner's ratio value of ≤ 1.25 indicates good flow properties, whereas values greater than 1.25 indicate poor flow characteristics.

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Tapped Density}}$$

Angle of Repose: The angle of repose was determined using the funnel method to evaluate the flowability of the powder blend. The powder was allowed to flow through a funnel positioned at a fixed height to form a conical heap on a flat surface. The height (h) and radius (r) of the powder cone were measured, and the angle of repose (θ) was calculated using the following equation:

$$\text{Tan } \theta = \frac{\text{Height of pile (h)}}{\text{radius of pile (r)}}$$

Post-Compression Evaluation of Tablets

Tablet Thickness (mm)[11]: The thickness of the prepared tablets was determined using a digital Vernier caliper. six tablets were randomly selected from each formulation batch, and their thickness was measured by placing the tablets between the two jaws of the caliper. The mean thickness value was calculated and reported.

Weight Variation (mg)[11]: The weight variation test was performed according to pharmacopeial guidelines. Twenty tablets were randomly selected from each batch and individually weighed using an electronic analytical balance. The average tablet weight was calculated, and the percentage deviation of individual tablet weights from the mean value was determined. The acceptable limits for weight variation are presented in Table 2.

Table 2: Weight variation limit

Average weight of tablet	%Deviation
≤ 80 mg	±10
80 – 250 mg	±7.5
≥ 250 mg	±5

Hardness (kg/cm^2)[12]: Tablet hardness was evaluated to determine the mechanical strength of the compressed tablets. The crushing strength required to break the tablet under diametrical compression was measured using a Monsanto hardness tester. The results were expressed in terms of force required to break the tablet.

Friability Test[12]: The friability of tablets was determined using a Roche friabilator to evaluate their resistance to mechanical stress during handling and transportation. Twenty tablets were accurately weighed and placed in the friabilator, which was operated at 25 rpm for 4 minutes (100 revolutions). After completion of the test, the tablets were dedusted and reweighed. The percentage friability was calculated using the following equation:

$$\% \textbf{ Friability} = \frac{\textbf{Initial weight} - \textbf{Final weight}}{\textbf{Initial weight}} \times \textbf{100}$$

Drug Content (%)[13]: Drug content was determined to ensure uniform distribution of Imipramine HCl in the tablets. Ten tablets were weighed and finely powdered. A quantity of powder equivalent to 10 mg of Imipramine HCl was accurately weighed and transferred to a 100 mL volumetric flask containing phosphate buffer (pH 6.8). The solution was filtered, and 1 mL of the filtrate was further diluted to 10 mL with the same buffer. The absorbance of the resulting solution was measured at 252 nm using a UV–Visible spectrophotometer, and the drug content was calculated.

Wetting Time (Sec.)[14]: Wetting time was determined to evaluate the hydrophilicity and water absorption capacity of the mouth dissolving tablets. A Petri dish containing six layers of tissue paper (10 cm diameter) was prepared, and 10 mL of phosphate buffer (pH 6.8) containing amaranth dye was added. A tablet was carefully placed on the surface of the tissue paper, and the time required for the liquid to reach the upper surface of the tablet was recorded as the wetting time.

In-Vitro Disintegration time (Sec.)[14]: The disintegration time of the tablets was determined using a digital tablet disintegration test apparatus. Six tablets were tested using phosphate buffer (pH 6.8) maintained as the disintegration medium. The time required for the complete disintegration of each tablet without leaving any residue on the screen was recorded in seconds.

***In Vitro* Drug Release Study (%)[15]:** The in-vitro drug release profile of Imipramine mouth dissolving tablets was evaluated using a USP Type II (paddle type) dissolution apparatus. The study was conducted using 900 mL of phosphate buffer (pH 6.8) as the dissolution medium maintained at 37 ± 0.5°C with a paddle rotation speed of 50 rpm. At predetermined time intervals, 5 mL samples were withdrawn from the dissolution medium and replaced with an equal volume of fresh medium to maintain sink conditions. The samples were filtered through a 0.45 µm membrane filter, and the absorbance was measured at 252 nm using a UV–Visible spectrophotometer.

Stability Study of Optimized Batch[16]: Stability studies of the optimized tablet formulation were conducted to evaluate the effect of storage conditions on the physical and chemical stability of the drug product. The optimized batch of Imipramine HCl tablets was subjected to accelerated stability testing according to ICH guidelines. The samples were stored at 40 ± 2°C and 75 ± 5% relative humidity for a period of 1 month. After the storage period, the tablets were evaluated for critical quality parameters including hardness, drug content, and in-vitro drug release, and the results were compared with those obtained immediately after formulation.

RESULTS AND DISSCUSSION:

Melting point of Imipramine HCl: One common method for identifying drugs is melting point determination, which involves utilizing a melting point instrument. Imipramine HCl's melting point was discovered to be between 170 - 174 °C. The melting point of Imipramine HCl is reported to be between 170 - 175 °C, indicating a comparable melting point.

Estimation of drug by UV overlay spectra

The overlay spectra of drug were obtained by scanning different concentrations of solutions viz. 5, 10, 15, 20 and 25 ppm showed maximum absorption at 252 nm. The absorbance of different concentration of Imipramine HCl in phosphate buffer at pH 6.8 are shown in Table 3 and figure 1.

Table 3: Absorbance of different concentrations of Imipramine HCl in phosphate buffer pH 6.8

Sr. No.	Concentration (ppm)	Absorbance			Mean Absorbance ±SD
		I	II	III	
1	5	0.15	0.151	0.153	0.151 ± 0.002
2	10	0.286	0.282	0.285	0.284 ± 0.002
3	15	0.397	0.392	0.395	0.395 ± 0.003
4	20	0.516	0.511	0.518	0.515 ± 0.004
5	25	0.649	0.648	0.649	0.649 ± 0.001

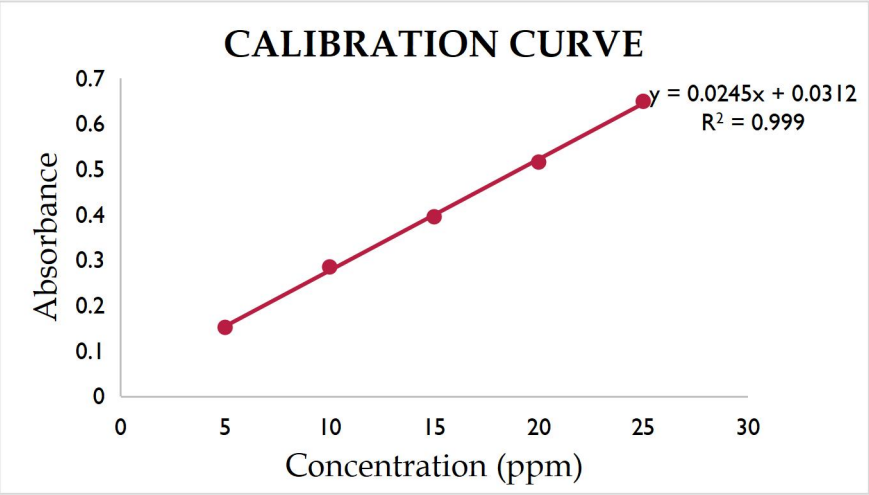

Figure 1: Calibration curve of Imipramine HCl in phosphate buffer at PH 6.8

Pre compression Parameters

The micromeritic properties of the powder blends (IM1–IM9) were evaluated to assess their suitability for compression into tablets. The bulk density of the formulations ranged from 0.50 ± 0.01 to 0.94 ± 0.07 g/mL, while the tapped density varied between 0.54 ± 0.00 and 1.23 ± 0.09 g/mL, indicating acceptable packing characteristics of the blends.

The Carr's index values were found in the range of 4.29 ± 0.05% to 23.19 ± 11.24%, suggesting fair to good compressibility of most formulations. Similarly, the Hausner's ratio ranged from 1.04 ± 0.00 to 1.32 ± 0.20, indicating that the majority of the powder blends exhibited good flow properties, although some batches showed relatively higher values indicating slightly reduced flowability.

The angle of repose values ranged from 26.76 ± 0.34° to 32.84 ± 0.84°, which falls within the acceptable range for good flow behavior. Overall, the micromeritic evaluation confirmed that the prepared powder blends possessed adequate flowability and compressibility, making them suitable for further processing into tablet dosage forms (Table 4)

Table 4: Bulk density, Tapped density, Carr's index, Hausner's ratio and Angle of Repose data

Batch	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio	Angle of repose(°θ)
IM1	0.87 ± 0.02	1.06 ± 0.05	17.45 ± 3.47	1.21 ± 0.05	29.28 ± 0.40
IM2	0.84 ± 0.02	0.98 ± 0.04	13.41 ± 5.64	1.16 ± 0.07	28.18 ± 0.37
IM3	0.55 ± 0.01	0.58 ± 0.01	4.40 ± 2.15	1.05 ± 0.02	28.18 ± 0.37
IM4	0.52 ± 0.00	0.56 ± 0.00	6.25 ± 0.00	1.07 ± 0.00	27.35 ± 0.35
IM5	0.54 ± 0.01	0.56 ± 0.01	4.29 ± 0.05	1.04 ± 0.00	27.36 ± 0.69
IM6	0.84 ± 0.02	0.88 ± 0.04	4.52 ± 2.06	1.05 ± 0.02	28.39 ± 0.00
IM7	0.50 ± 0.01	0.54 ± 0.00	8.58 ± 2.13	1.09 ± 0.03	26.76 ± 0.34
IM8	0.94 ± 0.07	1.23 ± 0.09	23.19 ± 1.24	1.32 ± 0.20	32.84 ± 0.84
IM9	0.84 ± 0.02	0.94 ± 0.09	10.08 ± 8.78	1.12 ± 0.11	27.78 ± 1.06

n = 3

Post-Compression Evaluation of Tablets

The prepared tablet formulations (IM1–IM9) were evaluated for post-compression parameters to ensure their quality and suitability for further studies. The tablet thickness ranged from 2.83 ± 0.06 to 3.50 ± 0.10 mm, indicating uniform die filling and consistent compression. The weight variation of all batches was found between 119.10 ± 1.17 mg and 121.10 ± 1.17 mg, which complies with pharmacopeial limits, confirming uniformity in tablet weight.

The hardness of the tablets ranged from 2.17 ± 0.29 to 3.67 ± 0.76 kg/cm², indicating adequate mechanical strength for handling, while still allowing rapid disintegration. The friability values were observed between 0.42 ± 0.15% and 0.80 ± 0.10%, which are within the acceptable limit of less than 1%, indicating good resistance to abrasion.

Furthermore, the wetting time ranged from 17.38 ± 0.87 to 49.94 ± 0.40 seconds, and the in vitro disintegration time varied between 18.71 ± 0.84 and 51.10 ± 0.27 seconds, demonstrating rapid disintegration characteristics of the formulations. The drug content was found within 98.63 ± 0.50% to 99.45 ± 0.39%, indicating uniform drug distribution across all batches (Table 5 and Table 6).

Overall, the results confirm that all formulations exhibited acceptable mechanical properties, rapid disintegration behavior, and uniform drug content, making them suitable for immediate release tablet formulations.

Table 5: Weight variation, Thickness, Hardness and Friability data

Batch	Thickness (mm ± S.D.)	Weight variation (mg ± S.D.)	Hardness (kg/cm² ± S.D.)	Friability
IM1	3.50 ± 0.10	120.25 ± 1.37	3.67 ± 0.76	0.42 ± 0.15
IM2	3.40 ± 0.17	120.70 ± 1.53	3.33 ± 0.58	0.50 ± 0.20
IM3	2.83 ± 0.06	119.30 ± 1.45	3.00 ± 0.50	0.58 ± 0.20
IM4	2.87 ± 0.06	120.20 ± 1.32	3.17 ± 0.76	0.55 ± 0.22
IM5	3.33 ± 0.46	121.10 ± 1.17	2.67 ± 0.76	0.71 ± 0.19
IM6	3.30 ± 0.35	119.20 ± 1.44	2.50 ± 0.50	0.74 ± 0.13
IM7	3.27 ± 0.21	119.90 ± 1.33	2.83 ± 0.76	0.64 ± 0.24
IM8	3.43 ± 0.31	120.21 ± 1.27	2.17 ± 0.29	0.80 ± 0.10
IM9	3.07 ± 0.38	120.35 ± 1.50	2.33 ± 0.58	0.78 ± 0.14

n = 6

Table 6: Wetting time, *In Vitro* disintegration time and Drug Content

Batch	Wetting time (sec. ± S.D.)	*In Vitro* disintegration time (sec. ± S.D.)	Drug content (% ± S.D.)
IM1	49.94 ± 0.40	51.10 ± 0.27	99.45 ± 0.39
IM2	45.24 ± 0.70	49.46 ± 0.69	98.67 ± 0.49
IM3	36.07 ± 0.51	37.37 ± 0.85	98.80 ± 0.47
IM4	39.11 ± 0.75	42.96 ± 0.46	98.95 ± 0.34
IM5	26.52 ± 0.59	29.86 ± 0.60	99.00 ± 0.42
IM6	22.17 ± 0.94	23.65 ± 0.69	98.86 ± 0.34
IM7	31.29 ± 0.76	33.04 ± 0.52	98.63 ± 0.50
IM8	17.38 ± 0.87	18.71 ± 0.84	99.21 ± 0.80
IM9	19.13 ± 0.59	21.17 ± 0.40	99.29 ± 0.62

n = 6

***In Vitro* Drug Release Profile of Mouth Dissolving Tablets:**

The in vitro drug release profiles of mouth dissolving tablet formulations (IM1–IM9) were evaluated over a period of 12 minutes to assess their rapid release characteristics. All formulations exhibited a fast and progressive increase in drug release, indicating efficient disintegration and dissolution behaviour.

At 2 minutes, the initial drug release ranged from 17.15 ± 0.64% (IM1) to 49.41 ± 0.79% (IM8), demonstrating variation in the onset of drug release among formulations. A significant increase in drug release was observed at 6 minutes, where formulations released between 46.26 ± 0.83% and 75.26 ± 0.19% of the drug.

By 10 minutes, most formulations showed substantial drug release in the range of 84.36 ± 0.66% to 96.59 ± 0.48%, indicating rapid drug availability. At the end of 12 minutes, the cumulative drug release ranged from 86.72 ± 0.66% (IM1) to 99.56 ± 0.95% (IM8), confirming the immediate release nature of the prepared tablets as mentioned in figure 2.

Among all batches, IM8 demonstrated the fastest and highest drug release, while IM1 showed comparatively slower release. Overall, the results indicate that all formulations exhibited rapid drug release within a short time frame, making them suitable candidates for mouth dissolving tablet systems with quick onset of action.

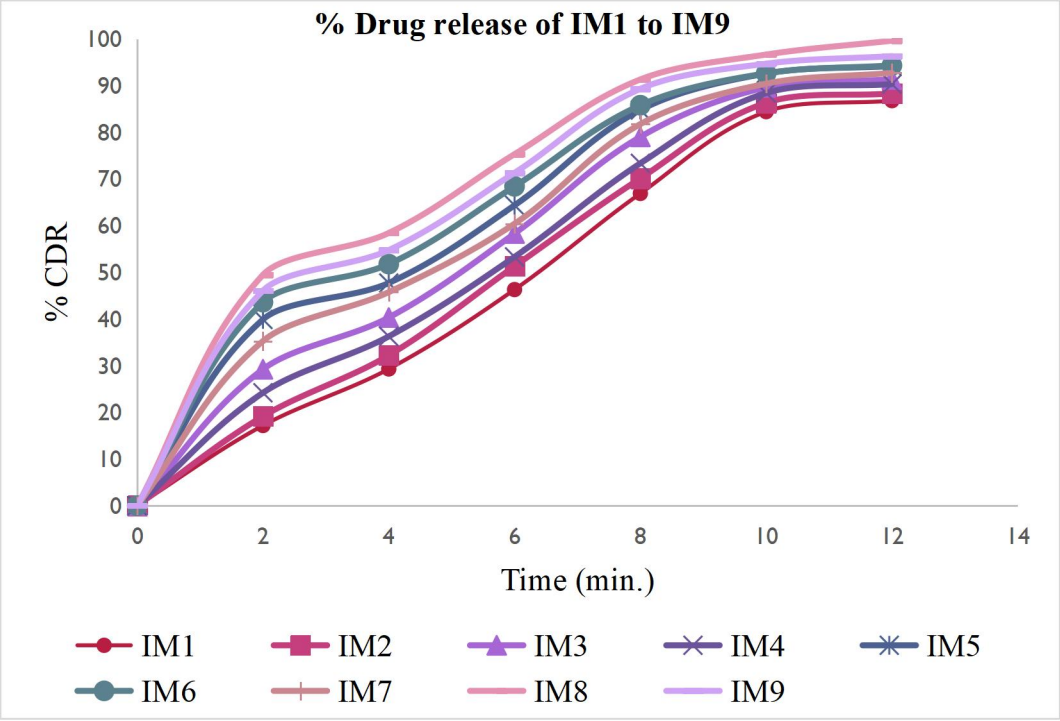

Figure 2: In Vitro Drug Release of Batches IM1 to IM9

In Vitro Drug Release Study of Mouth Dissolving Tablets

STABILITY STUDY

Based on all above parameters it was concluded that the batch IM8 was an optimized batch, as it had Mechanical strength and Drug Content. A stability study carried out at 40° ± 2 °C and 75 ± 5% RH. After period of stability study Hardness, Wetting time, *In vitro* Disintegration time and *In vitro* Drug release study was carried out. Results of stability study shows that there is no significant difference in the all performed parameters. So, it was concluded that selected formulation is

stable for longer period of time (Table 7 and figure 3).

Table 7: Result of the Stability study

Sr. No.	Evaluation parameter	Results of optimized batch IM8	Result after 1 month at 40°±2°C and 75 ± 5%RH
1	Thickness	3.43 ± 0.31	3.40 ± 0.17
2	Hardness	2.17 ± 0.29	2.17 ± 0.29
3	Wetting Time	17.38 ± 0.87	18.96 ± 0.61
4	*In Vitro* Disintegration Time	18.71 ± 0.84	20.92 ± 0.58
5	Drug Content	99.21 ± 0.80	98.65 ± 0.65

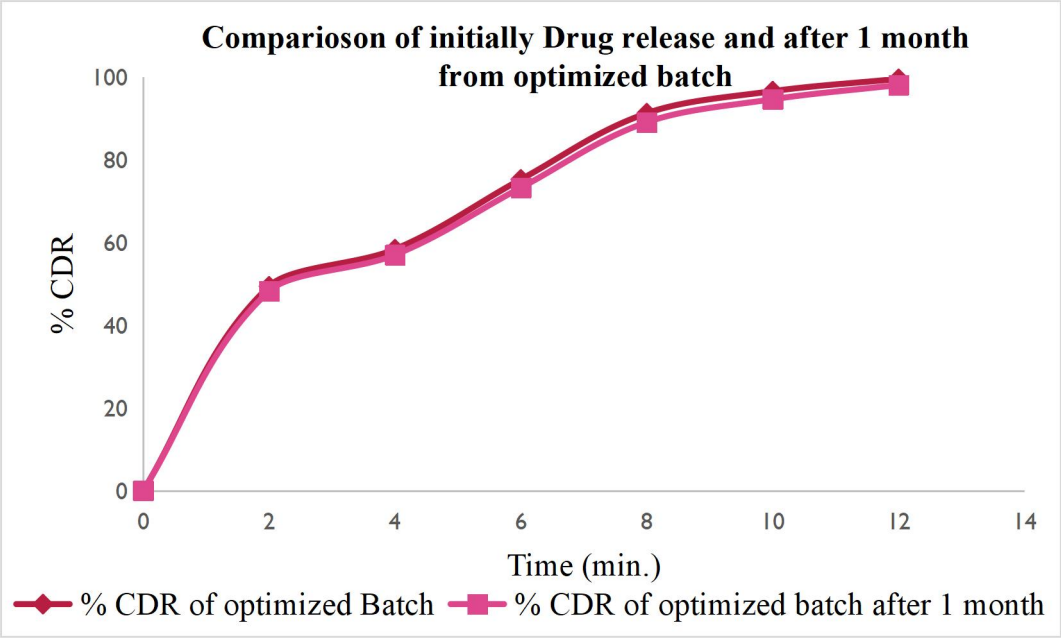

Figure 3: Comparison of In Vitro Drug Release Study of Optimized batch and stability batch

CONCLUSION

The present study was undertaken to formulate and evaluate mouth dissolving tablets (MDTs) of Imipramine HCl using natural superdisintegrants to enhance patient compliance and improve drug performance. Tablets were prepared by the direct compression method employing Plantago ovata mucilage, Moringa gum mucilage, and Fenugreek seed mucilage in varying concentrations. Pre-compression studies revealed that all powder blends exhibited good flowability. Post-compression evaluation confirmed that all formulations complied with pharmacopeial standards, showing uniform thickness, acceptable weight variation, sufficient hardness, and low friability (<1%). The IM8 batch demonstrated rapid wetting and disintegration of optimized batch IM8 with wetting time 17.38 sec. and disintegration time between 18.71 sec. was noted. *In vitro* drug release studies showed fast and efficient drug release, As IM8 batch showed best performance, with the shortest disintegration time and maximum drug 99.56%. Stability studies of the optimized batch confirmed no significant changes in tablet properties or drug release behavior under accelerated conditions.

The findings indicate that the use of natural polymers is an effective approach for designing MDTs with enhanced dissolution and better patient compliance, particularly for patients with swallowing difficulties or psychiatric conditions. Thus, the developed formulation represents a promising alternative to conventional oral dosage forms for the effective management of depression.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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