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PHARMACEUTICAL EQUIVALENCE AND IN VITRO DISSOLUTION SIMILARITY STUDIES OF COMMERCIALLY AVAILABLE METOCLOPRAMIDE HYDROCHLORIDE TABLETS

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Abstract:

The present study aimed to develop and characterize Metoclopramide Hydrochloride Mouth Dissolving Tablets (MDTs) to provide rapid drug release, quick onset of action, and improved patient compliance, particularly for paediatric, geriatric, and dysphagic patients. Mouth dissolving tablets were prepared by the direct compression method using croscarmellose sodium and sodium starch glycolate as super disintegrants at different concentrations. A total of eight formulations (F1–F8) were developed and evaluated. All formulations exhibited acceptable physical characteristics with friability values below 1%, indicating adequate mechanical strength. Among all formulations, F8, containing 40 mg of sodium starch glycolate, exhibited the best performance with 83.33% drug content, 23 seconds wetting time, 25 seconds disintegration time, and 98.75% cumulative drug release within 30 minutes. Drug release kinetic analysis revealed that the optimized formulation best fitted the Zero-order kinetic model (R^2 = 0.963), indicating a nearly constant drug release pattern. Accelerated stability studies conducted at 25°C/60% RH, 30°C/75% RH, and 40°C/75% RH for three months demonstrated no significant changes in the dissolution profile, with cumulative drug release remaining above 95%, confirming the stability of the optimized formulation. The study concludes that Metoclopramide Hydrochloride mouth dissolving tablets prepared by the direct compression method provide rapid disintegration, excellent drug release, satisfactory physicochemical properties, and good stability. The optimized formulation has the potential to improve patient compliance and therapeutic efficacy by providing a convenient and effective oral dosage form for the management of nausea, vomiting, and related gastrointestinal disorders.

Keywords: *Metoclopramide Hydrochloride, Direct compression method, FTIR Studies, In vitro drug release studies*

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INTRODUCTION: Mouth Dissolving Tablets (MDTs), also known as Oro dispersible Tablets (ODTs), Fast Dissolving Tablets (FDTs), or Fast Melt Tablets, are innovative solid oral dosage forms that disintegrate and dissolve rapidly in the saliva, usually within 30–60 seconds, without the need for water. These dosage forms were developed to improve patient compliance, particularly among paediatric, geriatric, and dysphagic patients who experience difficulty swallowing conventional tablets and capsules.

The oral route remains the most preferred and convenient method for drug administration because of its ease of use, cost-effectiveness, and high patient acceptance. However, conventional tablets may present challenges for patients with swallowing disorders, unconscious individuals, or patients who are traveling without access to water. Mouth dissolving tablets overcome these limitations by rapidly disintegrating in the oral cavity, releasing the drug for swallowing or partial absorption through the oral mucosa. This results in improved convenience, better patient adherence, and, in some cases, a faster onset of therapeutic action.

The rapid disintegration of MDTs is achieved through the incorporation of super disintegrants such as crospovidone, croscarmellose sodium, and sodium starch glycolate. Other excipients including fillers, sweeteners, flavouring agents, lubricants, and saliva-stimulating agents are incorporated to enhance tablet performance, palatability, and patient acceptability. Various manufacturing techniques such as direct compression, lyophilization, spray drying, sublimation, and molding are employed depending on the physicochemical properties of the drug and the desired tablet characteristics.

Advantages

1. **Rapid disintegration and dissolution:** MDTs disintegrate quickly in the oral cavity, usually within 30–60 seconds, resulting in faster drug release.
2. **Improved patient compliance:** They are particularly beneficial for pediatric, geriatric, bedridden, and dysphagic patients who have difficulty swallowing conventional tablets.
3. **No need for water:** MDTs can be administered without water, making them convenient during travel and in emergency situations.
4. **Quick onset of action:** Rapid disintegration may lead to faster absorption and an earlier therapeutic effect for suitable drugs.
5. **Enhanced bioavailability:** Some drugs may undergo partial absorption through the oral mucosa, thereby reducing first-pass hepatic metabolism and improving bioavailability.

Disadvantages

1. **Mechanical fragility:** Many MDTs are less robust than conventional tablets and require careful handling during packaging and transportation.
2. **Limited drug loading:** High-dose drugs are generally difficult to formulate as MDTs due to tablet size and patient acceptability.
3. **Taste masking challenges:** Drugs with an unpleasant or bitter taste require effective taste-masking techniques, increasing formulation complexity.
4. **Packaging requirements:** MDTs often require blister packs or specialized packaging to protect them from humidity and physical damage.
5. **Reduced suitability for hygroscopic drugs:** Moisture-sensitive or highly hygroscopic drugs may exhibit poor stability in MDT formulations.

MATERIAL AND EQUIPMENTS:

MATERIALS

Metoclopramide HCL were obtained as pure sample from Hetero Labs, HYD.., as gift samples along with their analytical reports. Croscarmellose sodium, Sodium starch glycolate was obtained from SD Fine Chemicals, Mumbai, All other chemical were purchased from Hi Media, Mumbai. Double distilled water was prepared freshly and used whenever required. All other chemicals used in this study including those stated were of analytical reagent (A.R.) grade.

METHODOLOGY:

Preformulation study:

1.Physical Appearance

The physical appearance of Metoclopramide Hydrochloride was evaluated by visual inspection. A small quantity of the drug was observed under normal daylight for its color, odor, texture, and physical state. The appearance was compared with the specifications reported in the official pharmacopeia or manufacturer's certificate of analysis. The observations were recorded to confirm the identity and purity of the drug sample.

2. Determination of Melting Point

The melting point of Metoclopramide Hydrochloride was determined by the capillary tube method. A small quantity of the finely powdered drug was filled into a sealed capillary tube to a height of about 2–3 mm. The capillary tube was placed in a digital melting point apparatus, and the temperature was gradually increased at a controlled rate. The temperature at which the drug began to melt and the temperature at which it completely melted were noted. The experiment was performed in triplicate, and the average melting point was calculated.

3. Solubility Study

The solubility of Metoclopramide Hydrochloride was determined in various solvents, including distilled water, methanol, ethanol, phosphate buffer (pH 6.8), phosphate buffer (pH 7.4), and 0.1 N hydrochloric acid. An excess quantity of the drug was added separately to 10 mL of each solvent in tightly closed glass vials. The vials were shaken using a mechanical shaker for 24 hours at room temperature (25 ± 2°C) to attain equilibrium. After equilibration, the samples were filtered through Whatman No. 1 filter paper (or a 0.45 µm membrane filter). The filtrates were suitably diluted, if required, and analyzed using a UV–Visible spectrophotometer at the drug's λmax. The solubility of the drug in each solvent was calculated and expressed as mg/mL. All measurements were carried out in triplicate, and the mean value was reported.Preparation of standard curve of Metoclopramide
Drug was analyzed using UV/visible spectrophotometer, using solution prepared in 6.8 pH buffer at nm.
Preparation of 6.8-pH
28.80 gm of Disodium hydrogen phosphate and 11.45 gm of potassium dihydrogen phosphate in 1000 ml of water.

Preparation of standard curve of Metoclopramide in 6.8 pH
For the standard graph, Metoclopramide 10 mg was accurately weighed and dissolved in 10ml of 6.8 phosphate buffer. From the stock solution (1mg/ml), different concentration of Metoclopramide viz, 10, 20, 30, 40, 50 mcg/ml were prepared and made up to volume with 6.8 phosphate buffer.

Drug excipient compatibility
Drug–excipient compatibility studies were carried out to determine any possible interaction between Metoclopramide Hydrochloride and the selected excipients used in the formulation. The study was performed using Fourier Transform Infrared (FTIR) spectroscopy. For FTIR analysis, pure drug, individual excipients, and their physical mixtures were mixed separately with dried potassium bromide (KBr) in the ratio of 1:100 and compressed into transparent pellets using a hydraulic press. The prepared pellets were scanned in an FTIR spectrophotometer over the wavelength range of 4000–400 cm^{-1}. The obtained spectra of the pure drug were compared with those of the drug–excipient physical mixtures to identify any changes in the characteristic absorption peaks. The absence of significant shifts, disappearance, or appearance of new peaks indicated compatibility between the drug and excipients, whereas any major changes suggested possible interactions.
Evaluation parameters

Angle of Repose

The angle of repose was determined by the fixed funnel method. A funnel was fixed at a suitable height above a flat surface, and the powder blend was allowed to flow freely through the funnel to form a conical heap. The height (**h**) and radius (**r**) of the powder cone were measured. The angle of repose (θ) was calculated using the following equation:

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

The angle of repose was used to assess the flow properties of the powder blend.

2. Bulk Density

Approximately **10 g** of the powder blend was accurately weighed and transferred into a clean, dry **50 mL graduated measuring cylinder** without compacting the powder. The initial volume occupied by the powder was noted as the bulk volume. Bulk density was calculated using the following equation:

Bulk Density (g/cm^3) = Weight of Powder / Bulk Volume

3. Tapped Density

The measuring cylinder containing the powder blend was tapped mechanically using a tapped density tester for **500 taps**. If the volume continued to decrease, tapping was continued up to **750–1250 taps** until a constant volume was obtained. The final tapped volume was recorded, and tapped density was calculated using the following equation:

Tapped Density (g/cm³) = Weight of Powder / Tapped Volume

4. Carr's Compressibility Index

Carr's Compressibility Index was calculated using the values of bulk density and tapped density obtained from the above experiments. It provides information about the compressibility and flow characteristics of the powder blend.

Carr's Index (%) = [(Tapped Density − Bulk Density) / Tapped Density] × 100

Lower values indicate better flowability, whereas higher values indicate poor flow properties.

5. Hausner's Ratio

Hausner's Ratio was calculated using the values of bulk density and tapped density. It is another useful parameter for evaluating the flowability of powder blends.

Hausner's Ratio = Tapped Density / Bulk Density

A Hausner's ratio close to **1.0** indicates excellent flow, while higher values indicate poor flowability.

6. Compressibility of Powder Blend

The compressibility of the powder blend was assessed indirectly from the Carr's Compressibility Index and Hausner's Ratio values. Powder blends exhibiting low compressibility index and low Hausner's ratio were considered suitable for direct compression due to their good flow and packing characteristics.

Formulation table:

Table-: Composition of Metoclopramide Mouth dissolving tablets

Table-1: Formulation table

S. No	Ingredient	F1	F2	F3	F4	F5	F6	F7	F8
1	Metoclopramide HCl	10	10	10	10	10	10	10	10
2	Cross caramellose sodium	10	20	30	40	-	-	-	-
3	Sodium starch glycol ate	-	-	-	-	10	20	30	40
4	Mannitol	65	55	45	35	65	55	45	35
5	Micro crystalline cellulose	10	10	10	10	10	10	10	10
6	Magnesium stearate	2	2	2	2	2	2	2	2
7	Talc	3	3	3	3	3	3	3	3
8	Total wt.	100	100	100	100	100	100	100	100

Procedure

Direct compression technique

Accurately weighed quantities of Metoclopramide Hydrochloride, mannitol, microcrystalline cellulose (MCC), and the selected super disintegrant (croscarmellose sodium for formulations F1–F4 or sodium starch glycolate for formulations F5–F8) were passed separately through #60 mesh sieve to obtain uniform particle size and remove agglomerates. The sieved ingredients were transferred into a clean, dry mortar or polyethylene bag and blended thoroughly for 10–15 minutes to obtain a homogeneous powder mixture. Mannitol was incorporated as a diluent to improve mouthfeel, while microcrystalline cellulose served as a directly compressible filler and dry binder. After obtaining a uniform blend, talc and magnesium stearate, previously passed through #80 mesh sieve, were added to the powder blend. The mixture was gently blended for an additional 2–3

minutes to ensure uniform distribution of the lubricant and glidant while avoiding over-lubrication. Finally, the lubricated blend was compressed into tablets of 100 mg total weight using a single-station tablet compression machine fitted with 6 mm flat-faced round punches. The compression force was adjusted to obtain tablets with adequate hardness while ensuring rapid disintegration.

Evaluation of tablet

1.Weight Variation

The weight variation test was performed according to the Indian Pharmacopoeia (IP). Twenty tablets were selected randomly from each formulation batch and individually weighed using a calibrated digital analytical balance. The average weight of the twenty tablets was calculated, and the weight of each individual tablet was compared with the average weight. The percentage deviation of each tablet from the average weight was determined to assess the uniformity of tablet weight. The tablets were considered to comply with pharmacopeial specifications if the percentage weight variation was within the prescribed limits.

2. Thickness

The thickness of the tablets was measured using a digital Vernier caliper. Ten tablets were selected randomly from each formulation batch, and the thickness of each tablet was measured individually. The measurements were recorded in millimeters (mm), and the average thickness along with the standard deviation was calculated. Uniform tablet thickness indicates consistent die filling and compression during tablet manufacture.

3. Hardness

The hardness of the tablets was determined using a Monsanto hardness tester (or Pfizer hardness tester). Ten tablets from each formulation were selected randomly and placed individually between the anvils of the hardness tester. Pressure was applied until the tablet fractured, and the force required to break the tablet was recorded in kg/cm². The average hardness of the tablets was calculated. Adequate hardness is essential to withstand handling, packaging, and transportation while ensuring rapid disintegration of mouth dissolving tablets.

4. Friability

Friability was determined using a Roche friabilator. Twenty tablets were accurately weighed, and the initial weight (W_1) was recorded. The tablets were placed in the friabilator and rotated at 25 rpm for 4 minutes (100 revolutions). After completion of the test, the tablets were removed, dedusted, and reweighed to obtain the final weight (W_2). The percentage friability was calculated using the following equation: The percentage friability was measured using the formula,

$$\% F = \{1-(Wo/W)\} \times 100$$

Where,

% F = friability in percentage

Wo = Initial weight of tablet

W = weight of tablets after revolution

Content uniformity was determined according to the Indian Pharmacopoeia (IP). Twenty tablets were selected randomly and weighed individually. The tablets were finely powdered, and an amount of powder equivalent to 10 mg of Metoclopramide Hydrochloride was accurately weighed and transferred into a 100 mL volumetric flask. About 70 mL of phosphate buffer (pH 6.8) was added, and the solution was sonicated for 15 minutes to ensure complete dissolution of the drug. The volume was then made up to 100 mL with the same buffer and filtered through Whatman No. 1 filter paper. Suitable dilutions were prepared, and the absorbance was measured using a UV–Visible spectrophotometer at the predetermined λmax. The drug content was calculated from the calibration curve and expressed as percentage drug content.

Wetting Time

The wetting time was determined by placing a piece of folded tissue paper in a Petri dish containing 6 mL of distilled water. A tablet was carefully placed on the surface of the tissue paper, and the time required for water to completely wet the upper surface of the tablet was recorded using a stopwatch. The test was carried out in triplicate, and the average wetting time was calculated. Lower wetting time indicates faster penetration of saliva into the tablet and rapid disintegration.

In-vitro Disintegration Time

The in-vitro disintegration time was determined using the USP disintegration test apparatus. Six tablets were placed individually in the tubes of the basket rack assembly containing distilled water maintained at 37 ± 0.5°C as the disintegration medium. The apparatus was operated according to pharmacopeial specifications, and the time required for complete disintegration of each tablet without leaving any palpable residue was recorded. The average disintegration time was calculated and expressed in seconds.

In-vitro Release Study

The in-vitro drug release study was performed using the USP Dissolution Apparatus II (Paddle method). The dissolution medium consisted of 900 mL phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C, and the paddle speed was maintained at 50 rpm. One tablet was placed in the dissolution vessel, and 5 mL samples were withdrawn at predetermined time intervals (e.g., 2, 5, 10, 15, 20,

and 30 minutes). Each withdrawn sample was immediately replaced with an equal volume of fresh dissolution medium maintained at the same temperature. The samples were filtered, suitably diluted if necessary, and analyzed using a UV–Visible spectrophotometer at the predetermined λmax. The cumulative percentage drug release was calculated and plotted against time.

Kinetics of Drug Release Studies

The dissolution data obtained from the optimized formulation were analyzed using different mathematical kinetic models to determine the mechanism of drug release. The cumulative percentage drug release data were fitted into Zero-order, First-order, Higuchi, Korsmeyer–Peppas, and Hixson–Crowell kinetic models. The regression coefficient (R^2) for each model was calculated, and the model showing the highest R^2 value was considered to best describe the drug release mechanism from the mouth dissolving tablets.

Stability Studies

The optimized formulation was subjected to accelerated stability studies according to ICH Q1A (R2) guidelines. The tablets were packed in suitable moisture-resistant containers or aluminum blister packs and stored at 40 ± 2°C and 75 ± 5% Relative Humidity (RH) for a period of three months. Samples were withdrawn initially and after 1, 2, and 3 months of storage. The tablets were evaluated for physical appearance, hardness, friability, drug content, disintegration time, and in-vitro drug release. The results obtained after storage were compared with the initial values to assess the stability of the optimized mouth dissolving tablet formulation.

RESULTS AND DISCUSSION:

In the present study 8 formulations with variable concentration of polymer were prepared and evaluated for physic-chemical parameters, in vitro release studies and stability studies.

Preformulation studies

a) Organoleptic evaluation

Table-2: Organoleptic properties of Metoclopramide

Properties	Results
Description	Crystalline powder
Taste	Tasteless
Odour	Odorless
Color	White or almost white crystalline powder

b) Determination of melting point

Melting point of Metoclopramide was found in the range of 147-150 ^{0}c, which complied with the standard, indicating purity of the drug sample.

c) Solubility

Metoclopramide is soluble in Freely soluble in water, ethanol, and methanol

Preparation of standard curve of Metoclopramide

Standard curve of Metoclopramide was determined by plotting absorbance V/s concentration at 245 nm. Using solution prepared in pH 6.8 at 245 nm. And it follows the Beer's law. The R^2 value is 0.998.

Table-3: Calibration curve of Metoclopramide

S. no	Concentration (µg/mol)	Absorbance
1	0	0
2	10	0.116
3	20	0.237
4	30	0.341
5	40	0.439
6	50	0.548

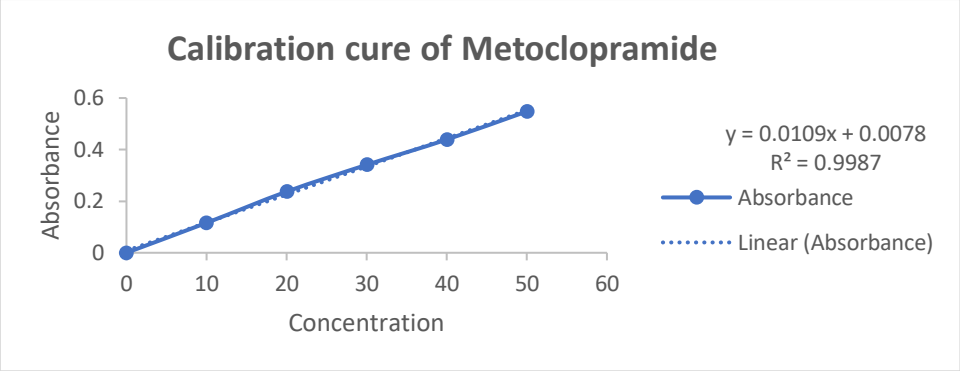


Fig-1: Calibration curve of Metoclopramide

FT-IR Spectrum of Metoclopramide

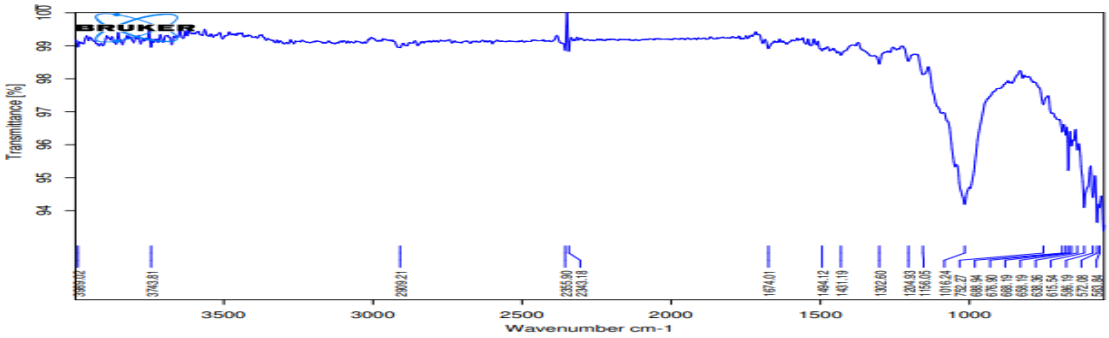


Fig-2: FT-IR Sample for Metoclopramide

Table-4: Characteristic Peaks and frequency of Metoclopramide

S. No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3000-3500	3370.98cm-1
2	OH Bending	2500-3000	2921.31cm-1
3	C-H stretching	1500-2000	1703.01 cm-1
4	C-N stretching	1000-1500	1267.33 cm-1

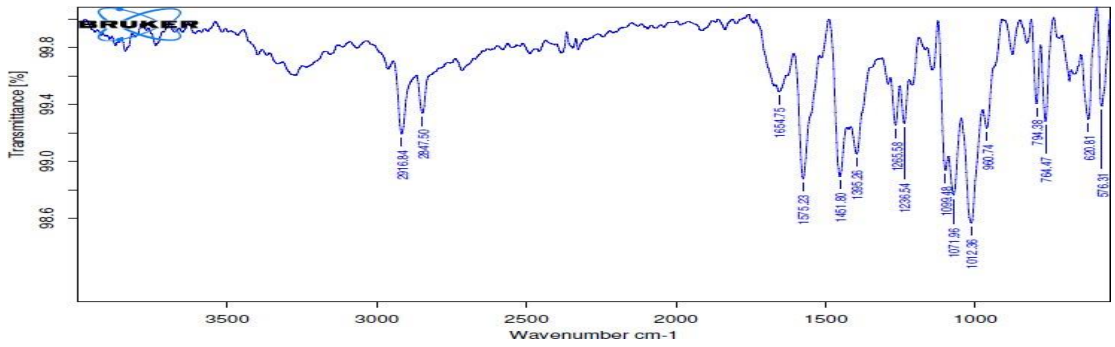


Fig-3: FT-IR Sample for physical mixture of drug and excipients

Table-5: Characteristic Peaks and frequency of physical mixture of drug and excipients

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	2500-3000	2847.50cm-1
2	OH Bending	1500-2000	1654.75 cm-1
3	C-N stretching	1000-1500	1236.54 cm-1
4	C-H stretching	1000	620.81 cm-1

Evaluation studies

Pre compression parameters

Characterization of Formulation

Table-6: Pre compression parameters of Metoclopramide Mouth dissolving tablets

F. no	Bulk density	Tapped density	Compressibility index	Hausner ratio	Angle of repose(0)
F1	0.465	0.579	19.69	1.245	30^0c
F2	0.442	0.563	21.49	1.274	28^0c
F3	0.469	0.567	17.26	1.209	27^0c
F4	0.458	0.55	16.73	1.201	28^0c
F5	0.461	0.57	19.12	1.236	26^0c
F6	0.45	0.566	20.49	1.258	26^0c
F7	0.469	0.571	17.85	1.217	25^0c
F8	0.476	0.573	16.9	1.204	29^0c

The bulk density of all formulations ranged from 0.442 to 0.476 g/cm³, while the tapped density ranged from 0.550 to 0.579 g/cm³. These values indicate satisfactory packing characteristics of the powder blends. Formulation F8 exhibited the highest bulk density (0.476 g/cm³), whereas F2 showed the lowest (0.442 g/cm³).

The Carr's Compressibility Index values varied between 16.73% and 21.49%. The lowest compressibility index was observed for F4 (16.73%), followed by F8 (16.90%) and F3 (17.26%), indicating better compressibility and flow properties. In contrast, F2 (21.49%) and F6 (20.49%) exhibited comparatively higher values, suggesting slightly reduced flowability. However, all formulations remained within the acceptable range for direct compression.

The Hausner's ratio ranged from 1.201 to 1.274. Formulations F4 (1.201) and F8 (1.204) showed the lowest Hausner's ratio, indicating superior flow characteristics, while F2 (1.274) exhibited the highest value, suggesting relatively poorer flow. Nevertheless, all formulations demonstrated acceptable flow properties suitable for tablet manufacturing.

The angle of repose values ranged from 25° to 30°. The lowest angle of repose was recorded for F7 (25°), followed by F5 (26°) and F6 (26°), indicating excellent flowability of these powder blends. Formulation F1 exhibited the highest angle of repose (30°), although it was still within the acceptable limit, indicating good powder flow.

Post compression parameter

Table-7: Evaluation parameters of Metoclopramide mouth dissolving tablets

F. No.	Weight variation (mg)*	Thickness (mm)*	Hardness (kg/cm^2) *	Friability (%)	Drug content (%)	Disintegration Time (sec)	Wetting time (sec)
F1	101	2.6	3.5	0.37	71.25	25	35
F2	99	2.4	3.4	0.38	75.21	32	46
F3	100	2.9	2.9	0.42	72.1	26	38
F4	100	3.1	2.8	0.49	65.39	22	30
F5	99	2.3	3.1	0.52	62.25	30	37
F6	100	2.9	2.5	0.5	74.81	26	35
F7	101	2.8	3.6	0.48	82.35	22	32
F8	100	2.2	3.7	0.56	83.33	25	23

DISCUSSION:

The weight variation of all formulations ranged from 99 to 101 mg, which was within the acceptable pharmacopoeial limits for tablets of this weight. This indicates uniform die filling during compression and consistency in tablet weight among all formulations.

The thickness of the tablets varied between 2.2 and 3.1 mm. Formulation F8 exhibited the minimum thickness (2.2 mm), whereas F4 showed the maximum thickness (3.1 mm). The small variation in tablet thickness suggests that the compression process was well controlled and produced tablets of uniform dimensions.

The hardness of the formulations ranged from 2.5 to 3.7 kg/cm², indicating adequate mechanical strength while maintaining the ability to disintegrate rapidly in the oral cavity. Formulation F8 showed the highest hardness (3.7 kg/cm²), followed by F7 (3.6 kg/cm²), whereas F6 exhibited the lowest hardness (2.5 kg/cm²). All formulations possessed sufficient hardness to withstand handling and transportation.

The friability values ranged from 0.37% to 0.56%, which were well below the acceptable limit of 1%, confirming good mechanical integrity of the prepared tablets. Formulation F1 exhibited the lowest friability (0.37%), indicating excellent resistance to abrasion, while F8 showed the highest friability (0.56%), although it remained within acceptable limits.

The drug content of the formulations varied from 62.25% to 83.33%. The highest drug content was observed in F8 (83.33%), followed by F7 (82.35%), indicating comparatively better drug distribution within these formulations. Formulation F5 showed the lowest drug content (62.25%). Although all formulations were successfully prepared, the relatively low drug content values suggest that further optimization of the blending and compression process may be required to achieve pharmacopeial content uniformity.

The disintegration time ranged from 22 to 32 seconds, demonstrating the rapid disintegration characteristics required for mouth dissolving tablets. Formulations F4 and F7 exhibited the shortest disintegration time (22 seconds), indicating the most efficient tablet breakup in the oral cavity. Formulation F2 showed the longest disintegration time (32 seconds), but it still complied with the requirements for mouth dissolving tablets.

The wetting time of the tablets ranged between 23 and 46 seconds. Formulation F8 exhibited the shortest wetting time (23 seconds), indicating rapid penetration of water into the tablet matrix, while F2 showed the longest wetting time (46 seconds). A shorter wetting time generally corresponds to faster tablet disintegration and improved patient acceptability.

Dissolution studies

Table-8: In vitro drug release studies

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
5	25.25	28.60	36.58	32.16	29.82	25.69	22.36	32.36
10	39.80	45.36	56.93	45.87	43.18	40.25	38.49	43.59
15	55.10	62.22	60.15	59.86	50.25	52.39	49.68	63.62
20	63.37	73.69	79.86	72.39	61.25	71.29	65.37	70.18
25	73.69	80.25	85.69	80.25	76.39	82.36	78.10	82.53
30	86.98	95.37	97.42	93.19	87.86	90.12	95.21	98.75

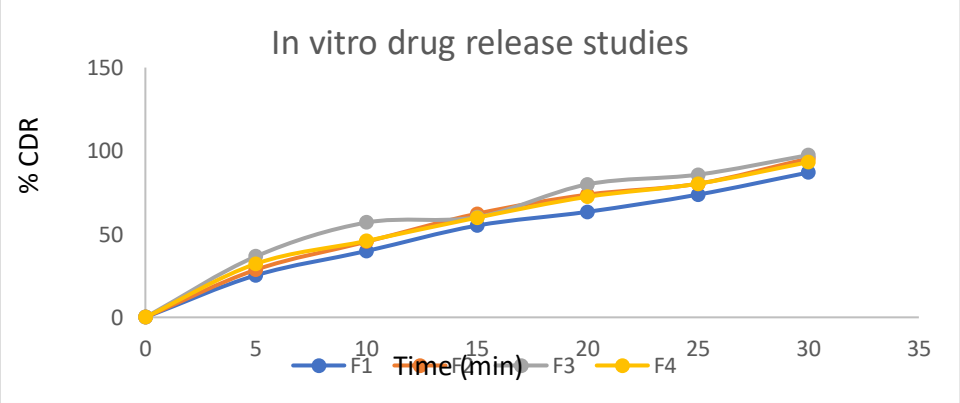


Fig-4: Drug release studies of F1-F4 formulation

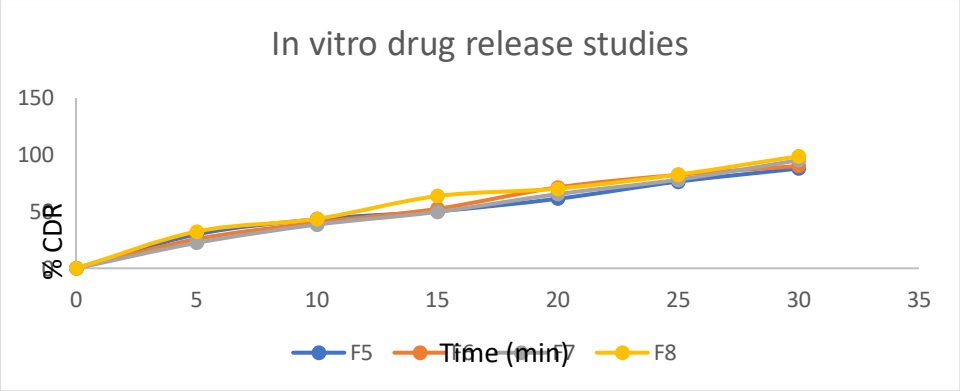


Fig-5: Dissolution Profile of F5 to F8 formulations

Kinetic modelling of drug release

Table-9: Drug Release Kinetics of Formulation F8

TIME	%CDR	SQARE T	LOG T	LOG%CDR	ARA	LOG%ARA
0	0	0	0	0	0	0
5	32.36	2.23606798	0.69897	1.5100085	67.64	1.84674
10	43.59	3.16227766	2	1.6393869	56.41	1.81681
15	63.62	3.87298335	2.35218252	1.8035937	36.38	1.84436
20	70.18	4.47213595	2.60205999	1.8462134	29.82	1.77745
25	82.53	5	2.79588002	1.9166118	17.47	1.67169
30	98.75	5.47722558	2.95424251	1.9945371	1.25	1.67169

Zero order kinetics

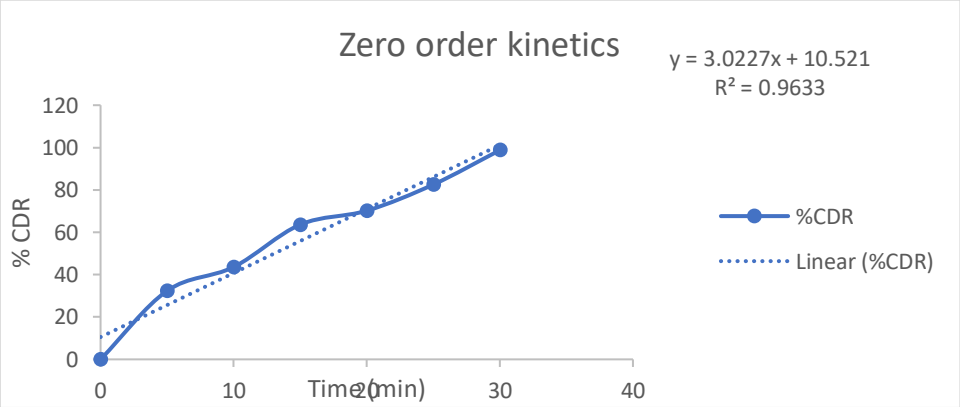


Fig-6: Zero order kinetics of optimized formulation

First order kinetics

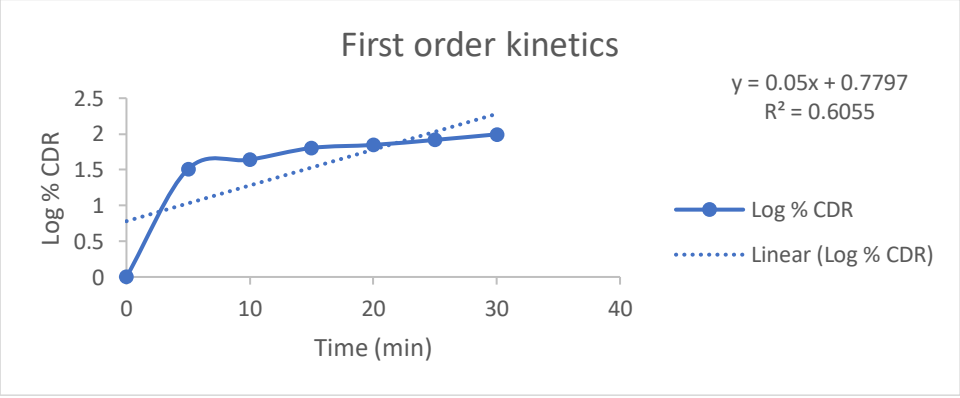


Fig-7: First order kinetics of optimized formulation

Higuchi model

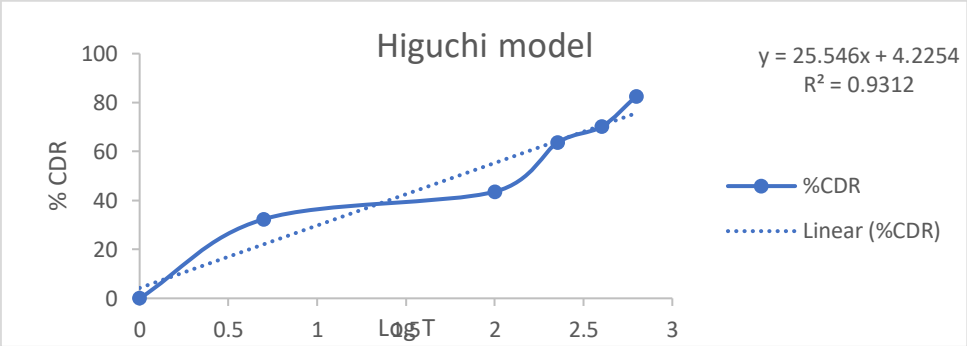


Fig-8: Higuchi model of optimized formulation

korsmeyer peppas

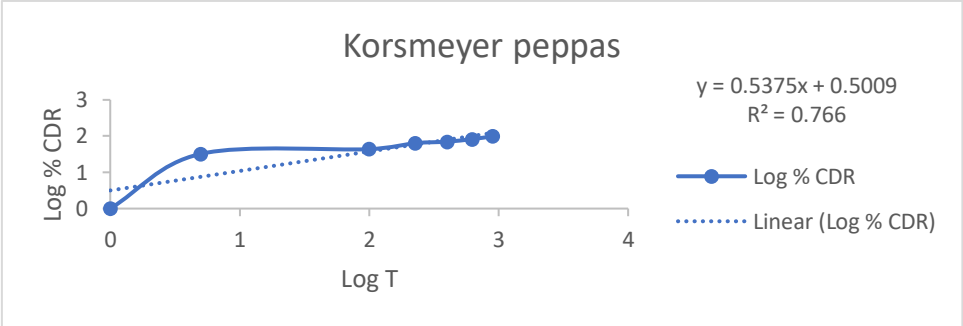


Fig-9: Korsmeyer peppas of optimized formulation

Discussion

Overall, the kinetic analysis demonstrated that formulation F8 provided rapid and consistent drug release with a release profile best described by the Zero-order kinetic model, making it suitable for immediate therapeutic action and improved patient compliance.

Table-10: Regression equations of mouth dissolving tablets F8

Film code	In vitro release in phosphate buffer P^H 6.8 Regression values			
	Zero order	First order	Higuchi Plot	Korsmeyer peppas
F8	0.963	0.605	0.931	0.766

Stability Study

Table-11: Stability studies of all formulations

Formulation Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-8	25^0C/60%RH % Release	98.75	97.53	96.38	95.47	Not less than 85 %
F-8	30^0C/75% RH % Release	98.75	97.45	96.20	95.43	Not less than 85 %
F-8	40^0C/75% RH % Release	98.75	97.15	96.15	95.20	Not less than 85 %

Discussion

The stability results confirmed that the optimized formulation F8 retained its physicochemical integrity and dissolution characteristics throughout the study period. Therefore, the formulation can be considered stable under both long-term and accelerated storage conditions, demonstrating its suitability for commercial development and storage without significant loss of quality or therapeutic performance.

CONCLUSION:

The present investigation successfully developed Metoclopramide Hydrochloride Mouth Dissolving Tablets by the direct compression technique using different concentrations of super disintegrants. The study demonstrated that the type and concentration of super disintegrant significantly influenced tablet disintegration and drug release characteristics. Among the prepared formulations, F8, containing 40 mg of sodium starch glycolate, was identified as the optimized formulation because of its satisfactory pre-compression and post-compression properties, rapid wetting and disintegration, excellent mechanical strength, and maximum cumulative drug release of 98.75% within 30 minutes. The optimized formulation also exhibited Zero-order drug release kinetics, indicating a consistent release pattern.Furthermore, stability studies confirmed that the optimized formulation remained stable under accelerated storage conditions for three months without any significant changes in drug release or physical characteristics. Therefore, the developed mouth dissolving tablet formulation offers a promising dosage form for Metoclopramide Hydrochloride, providing rapid onset of action, improved patient compliance, ease of administration, and enhanced therapeutic effectiveness, particularly for paediatric, geriatric, and dysphagic patients.

REFERENCES:

1. Litchenckert, S.; Lurdgren, C. and Ferno, O.; "Chewable smoking substitute composition", US Patent, 1975, 3901248.
2. Siegel, S.; "Journal of Pharmaceutical Science", 51, 1962, pp 1069. Allen, L.V., Wang, B. and Davis, J.D.," Rapidly Dissolving Tablet", **US patent No.,** US5807576, 1998. , Bhaskaran, S. and Narmada, G.V., Fast Dissolving drug delivery systems: A brief overview, **Indian Pharmacist**, 2002, 1 (2), 9-12.
3. Devrajan, P.V, Gore, S.P., Fast Dissolving Tablets: The Future Compaction, Express Pharma Pulse, 2000: 23, 7(1), 16.
4. Reddy, L. H., Ghose, B. and Rajneesh, Fast Dissolving drug delivery systems: A brief overview, Indian J. Pharm. Sci.**, 2002**, 64(4): 331- 336, Parakh, S.R. and Gothoskar, A.V., Fast Dissolving drug delivery systems: A brief overview, **Pharma. Tech.**, 2003, 92- 100.
5. Lachmman L, LibermanHA, KonigJl. The theory & practice of industrial pharmacy,3rdEdn,Vargheese publishing house, Bombay,1991:297-300.
6. G.r Chatwal textbook of pharmaceutical inorganic chemistry.
7. Subrahmanyam cvs and thimmasettyj. Laboratory manual of physical pharmaceutics,1 stEdn, Vallabh prakasham ,Delhi;2002:24-25
8. Siji Rose raj formulation and evaluation of mouth dissolving famotidine tablet, International Journal of Pharm Tech Research;Oct-Dec2009, Vol. 1 Issue 4, p1251.
9. Seema Farheen "formulation and evaluation of fast dissolving tablets of lansoprazole" world journal of pharmacy and pharmaceutical sciences, Volume 6, Issue 7, 979-1002.
10. Shaik shabbeer, Aruri madhavi, Santhosh Illendula. Formulation and in vitro evaluation of timolol Maleate of sustained release matrix tablets by using different polymers, World journal of pharmacy and pharmaceutical sciences, 2024; 13(06): 511-524.
11. Shaik shabbeer, K Anjaneyulu, Santhosh Illendula, Nanoparticle based drug delivery system for sulfadiazine drug along with herbal extract, International research journal of education and technology, 2024; 06(05): 307-326.
12. Shaik shabbeer, G. Uma Maheshwari, Santhosh Illendula, Formulation and evaluation of Idarubicin, International Journal of Pharmacy and Biological Sciences-IJPBS (2022) 12 (3): 127-141
13. Mangesh Machhindranath Satpute, Formulation and in vitro evaluation of fast dissolving tablets of metoprolol tartrate, Brazilian Journal of Pharmaceutical Sciences vol. 49, n. 4, oct./dec., 2013.
14. Divya Vishwakarma., Formulation and Evaluation of Metoprolol Tartrate Fast Dissolving Tablet, Am. J. Pharm Tech Res. 2012; 2(4) ISSN: 2249-3387.
15. Santhosh Illendula, Peddaboina Shiva prasad., Analytical Method Development and Validation of RP-HPLC for The Quantitative Determination of Baricitinib in Pure Substances and Marketed Formulation. International Journal of Pharmacy and Biological Sciences-IJPBS™ (2022) 12 (3): 108-114. DOI: https://doi.org/10.21276/ijpbs.2022.12.3.15
16. B P Patel Formulation and Evaluation of Mouth Dissolving Tablets of Cinnarizine, Indian J Pharm Sci. 2010 Jul-Aug; 72(4): 522–525.
17. Santhosh Illendula et al., Method Development and Validation of Afatinib in Bulk and Pharmaceutical Dosage Form by UV-Spectroscopic Method, Indo Am. J. P. Sci, 2018; 05(03).
18. Abhijit Jadhav Formulation and Evaluation of Mouth Dissolving Tablets of Metformin HCl by Direct Compression Technique. Journal of Current Pharma Research 4 (4), 2014, 1271-1273.

19. K. Vinod Kumar, formulation and evaluation of losartan potassium mouth dissolving tablets, ijrpc 2013, 3(2).
20. Praveen Rawat Formulation and Characterization of Mouth Dissolving Tablet for Controlled Delivery of Ketoconazole, Int J Pharma Res Health Sci. 2016; 4 (6): 1495-1500.
21. Deepthi Mathew et al., Formulation and Evaluation of Mouth Dissolving Tablet of Azithromycin Using Natural Super disintegrant, Br J Med Health Res. 2016;3(7).
22. Ashish Garg, Mouth dissolving tablets: a review Journal of Drug Delivery & Therapeutics; 2013, 3(2), 207-214.
23. Garima Yadav, fast dissolving tablets recent advantages: a review, http://dx.doi.org/10.13040/IJPSR.0975-8232.3(3).727-36.
24. Mayur Karvekar, A Brief Review on Sustained Release Matrix Type Drug Delivery System, Journal of Pharmaceutical Research Volume 16, Issue 3, Jul-Sep, 2017: 282.
25. Sheshala, Formulation and in vivo evaluation of ondansetron orally disintegrating tablets using different super disintegrants, 2011 Nov;34(11):1945-56.
26. Rajnikant M. Suthar, Formulation and Evaluation of Fast Dissolving Tablets of Ondansetron by Solid Dispersion in Super disintegrants, Indian Journal of Pharmaceutical Education and Research | Vol 47 | Issue 3 | Jul–Sep, 2013
27. Basawaraj S Patil Formulation and evaluation of mouth dissolving tablets of nimesulide by new co processed technique Research Journal of Pharmaceutical, Biological and Chemical Sciences 2010 RJPBCS 1(4).
28. Lou J, Duan H, Qin Q, Teng Z, Gan F, Zhou X, Zhou X. Advances in Oral Drug Delivery Systems: Challenges and Opportunities. Pharmaceutics. 2023 Feb 1;15(2):484.
29. Pawar, P., Varkhade, C., Jadhav, V., Mehra, D. (2011). Mouth dissolving tablets: An overview of formulation technology. International Journal of Pharmacy and Pharmaceutical Sciences, 3(1), 1–7.
30. Joshi, P., Patel, H., & Shah, M. (2019). Oro dispersible tablets: A comprehensive review. International Journal of Current Pharmaceutical Research, 11(5), 1–7.
31. Priyanka Raj (2024) A Review of Formulation Techniques and Evaluation Parameters of Fast Dissolving Tablets: Review Article. (2024). Journal of Pharma Insights and Research, 2(4), 212-217.
32. Kushagra Khanna, Fast Dissolving Tablets- A Novel Approach International Journal of Pharmaceutical Research & Allied Sciences, 2016, 5(2):311-322
33. Sreenivas SA, Dandagi PM, Gadad AP, Godbloe AM, Hiremath SP, Mastiholimath VS, Oro dispersible tablets: New-fangled drug delivery systems-A review. Indian J Pharm Educ Res. Oct 2005; 39(4):177-81.