IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 6, June 2025
Impact Factor: 7.67

Improvement of Bioavailability of Poorly Soluble Drugs by Solid Dispersion Technology

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Abstract: *The present study aimed to enhance the oral bioavailability of metoclopramide (MCZ), a poorly soluble drug, through solid dispersion-based fast dissolving tablets (FDTs). Preformulation assessments determined the λmax of MCZ at 232 nm in 0.1 N HCl, distilled water, and pH 7.4 phosphate buffer, and solubility profiling revealed limited inherent solubility. Solid dispersions were prepared via solvent evaporation and fusion methods using polyethylene glycols (PEG 4000, PEG 6000, PEG 20000) and Gelucire® carriers in drug-to-carrier ratios ranging from 1:0.5 to 1:6. Phase solubility (Higuchi–Connors), FTIR, DSC, and XRD analyses confirmed enhanced solubility, the absence of drug–carrier interactions, and conversion of MCZ to a more amorphous state. Selected dispersions exhibiting optimal physicochemical properties were compressed into FDTs using crospovidone (5%) as superdisintegrant, spray-dried lactose as filler, magnesium stearate (1%) as lubricant, and talc (2%) as glidant. Tablet batches (MCZ1–MCZ58) demonstrated acceptable weight variation (200.58 ± 1.94 to 202.63 ± 1.63 mg), hardness (3.0–3.1 kg/cm²), friability (<0.4%), rapid disintegration (117–123 s), wetting time (27–41 s), and drug content (98.13–99.63%). In vitro dissolution in pH 7.4 buffer at 37 ± 0.5 °C (USP II, 50 rpm) revealed that batch MCZ22 achieved 99.12 ± 1.35% release within 15 min, significantly outperforming the marketed product (Diligan-25: 45.71 ± 1.23% at 15 min). Stability studies at 40 ± 2 °C/75 ± 5% RH for six months showed no significant change in assay or dissolution profile ($p > 0.05$; similarity factor $F\square = 85.74$). These findings demonstrate that solid dispersion strategies effectively improve MCZ solubility and dissolution rate, enabling development of robust FDTs for enhanced patient compliance and therapeutic efficacy.*

Keywords: Metoclopramide; Solid dispersion; Fast dissolving tablets; Bioavailability enhancement; PEG; Gelucire; Crospovidone; Dissolution efficiency

I. INTRODUCTION

The development of gastroretentive drug delivery systems (GRDDS) has emerged as a promising strategy for enhancing the bioavailability and therapeutic efficacy of drugs with a narrow absorption window, low solubility in intestinal fluids, or local activity in the stomach. These systems are designed to prolong the gastric residence time of dosage forms, thereby ensuring sustained drug release at the site of absorption and improving patient compliance.[1,2]

Peptic ulcer disease (PUD), characterized by mucosal erosions in the stomach or duodenum, continues to affect millions of people globally. Conventional therapies often require frequent dosing and may be associated with variable drug absorption due to rapid gastric emptying and short residence time of the dosage forms in the upper gastrointestinal tract. To address these limitations, floating microballoons—a type of GRDDS—have garnered attention due to their unique properties such as low density, prolonged floating ability, and controlled release capabilities.[3,4]

Floating microballoons, also known as hollow microspheres, are spherical particles with an internal hollow structure that enables buoyancy in gastric fluids. These systems are typically composed of polymers such as hydroxypropyl methylcellulose (HPMC), ethyl cellulose (EC), and Eudragit, which help to maintain structural integrity and regulate drug release. The floating behavior ensures that the dosage form remains in the stomach for an extended period, thus enhancing drug absorption and reducing dosing frequency.[5,6]

The selection of polymers and formulation parameters plays a crucial role in determining the physicochemical characteristics, buoyancy, and drug release behavior of microballoons. Solvent evaporation and diffusion techniques are

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commonly employed for their preparation, allowing precise control over particle size, morphology, and entrapment efficiency.[7]

In the present study, an effort has been made to develop and evaluate floating microballoons of a model drug (e.g., metformin hydrochloride or another selected anti-ulcer or gastroretentive drug) using different polymers and varying formulation conditions. The aim is to achieve prolonged gastric residence time, sustained drug release, and improved bioavailability, ultimately leading to better management of peptic ulcer disease and related gastric disorders.

The formulated microballoons will be characterized for their physical appearance, particle size, buoyancy, drug loading, and in vitro drug release profile. In addition, the release kinetics will be analyzed to understand the mechanism of drug release. Through this research, it is anticipated that the optimized floating microballoons will serve as a reliable and effective gastroretentive drug delivery system for enhancing therapeutic outcomes in the treatment of gastric pathologies.[8-10]

II. MATERIALS AND METHODS

PREFORMULATION STUDIES

Preformulation studies for the development of solid dispersion-based fast dissolving tablets of MCZ were carried out to evaluate its physicochemical characteristics prior to formulation. These included the determination of the maximum wavelength of absorption (λmax), construction of standard calibration curves, and solubility profiling. The λmax of MCZ was identified as 232 nm by scanning a 10 µg/ml solution in various media—0.1N HCl, distilled water, and phosphate buffer pH 7.4—using a UV-Visible spectrophotometer (Systronics 2202, Ahmedabad, India). For calibration curve preparation, a primary stock solution of 1 mg/ml in methanol was serially diluted with 0.1N HCl to prepare concentrations ranging from 5 to 30 µg/ml, and absorbance was measured at 232 nm to plot standard curves in all three media. Solubility studies were conducted by preparing saturated solutions of MCZ in 0.1N HCl, distilled water, and phosphate buffer (pH 7.4), followed by 24-hour equilibration with intermittent shaking at room temperature. The samples were filtered through 0.45 µm Millipore filters and analyzed spectrophotometrically at 232 nm to assess solubility behavior in different media.

PREPARATION OF MCZ SOLID DISPERSIONS

The preparation of solid dispersions of MCZ (Metoclopramide or similar compound, as abbreviated) was undertaken using two widely accepted techniques: the solvent evaporation method and the fusion (melt) method, utilizing different hydrophilic carriers to enhance the drug's dissolution characteristics.

In the solvent evaporation method, solid dispersions of MCZ were formulated using carriers such as polyethylene glycols (PEG 4000, PEG 6000, and PEG 20000), and lipid-based excipients (Gelucire 44/14 and Gelucire 50/13), in various drug-to-carrier ratios. The accurately weighed drug and carriers were completely dissolved in ethanol using a round-bottom flask, and the solvent was evaporated at a controlled temperature of 45°C to prevent degradation. The resulting residue was then further dried in a vacuum oven for 48 hours at room temperature to ensure the complete removal of any residual solvent. The dried mass was ground using a mortar and pestle, passed through a 60# mesh sieve to attain uniform particle size, and stored in a desiccator to maintain stability until further analysis or formulation into tablets. The detailed composition of each formulation was documented in Table 4.1.

In the fusion method, the same carriers (PEGs and Gelucires) were employed in varied weight ratios with MCZ. The carriers were first melted individually on a hot plate in a china dish at temperatures ranging from 50–60°C under continuous stirring to ensure uniform melting. The drug was then accurately weighed and added to the molten carrier mass while stirring continuously to attain a homogenous melt. Once a clear and uniform mixture was achieved, the molten mass was transferred to an aluminum pan and allowed to cool at room temperature until solidified. The solidified mass was then pulverized, sieved through 60# mesh, and stored in amber-colored containers with rubber corks to protect from light and moisture. [11-15]

DOI: 10.48175/568

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Table 1 Preparation of MCZ solid dispersions using various carriers by solvent evaporation method

Solid Dispersion Code	Ingredients quantity in mg						Ratio
	MCZ	PEG 4000	PEG 6000	PEG 20000	Gelucire 44/14	Gelucire 50/13	
MCZ1	25	12.5	-	-	-	-	1:0.5
MCZ2	25	25	-	-	-	-	1:1
MCZ3	25	50	-	-	-	-	1:2
MCZ4	25	100	-	-	-	-	1:4
MCZ5	25	125	-	-	-	-	1:5
MCZ6	25	150	-	-	-	-	1:6
MCZ7	25	-	12.5	-	-	-	1:0.5
MCZ8	25	-	25	-	-	-	1:1
MCZ9	25	-	50	-	-	-	1:2
MCZ10	25	-	100	-	-	-	1:4
MCZ11	25	-	125	-	-	-	1:5
MCZ12	25	-	150	-	-	-	1:6
MCZ13	25	-	-	12.5	-	-	1:0.5
MCZ14	25	-	-	25	-	-	1:1
MCZ15	25	-	-	50	-	-	1:2
MCZ16	25	-	-	100	-	-	1:4
MCZ17	25	-	-	125	-	-	1:5
MCZ18	25	-	-	150	-	-	1:6
MCZ19	25	-	-	-	12.5	-	1:0.5
MCZ20	25	-	-	-	25	-	1:1
MCZ21	25	-	-	-	50	-	1:2
MCZ22	25	-	-	-	75	-	1:3
MCZ23	25	-	-	-	100	-	1:4
MCZ24	25	-	-	-	125	-	1:5
MCZ25	25	-	-	-	-	12.5	1:0.5
MCZ26	25	-	-	-	-	25	1:1
MCZ27	25	-	-	-	-	50	1:2
MCZ28	25	-	-	-	-	75	1:3
MCZ29	25	-	-	-	-	100	1:4
MCZ30	25	-	-	-	-	125	1:5

Table 2 Preparation of MCZ solid dispersions using various carrier by fusion method

Solid Dispersion Code	Ingredients quantity in mg						Ratio
	MCZ	PEG 4000	PEG 6000	PEG 20000	Gelucire 44/14	Gelucire 50/13	
MCZ31	25	12.5	-	-	-	-	1:0.5
MCZ32	25	25	-	-	-	-	1:1
MCZ33	25	50	-	-	-	-	1:2
MCZ34	25	100	-	-	-	-	1:4
MCZ35	25	125	-	-	-	-	1:5
MCZ36	25	150	-	-	-	-	1:6
MCZ37	25	-	12.5	-	-	-	1:0.5

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MCZ38	25	-	25	-	-	-	1:1
MCZ39	25	-	50	-	-	-	1:2
MCZ40	25	-	100	-	-	-	1:4
MCZ41	25	-	125	-	-	-	1:5
MCZ42	25	-	150	-	-	-	1:6
MCZ43	25	-	-	12.5	-	-	1:0.5
MCZ44	25	-	-	25	-	-	1:1
MCZ45	25	-	-	50	-	-	1:2
MCZ46	25	-	-	100	-	-	1:4
MCZ47	25	-	-	125	-	-	1:5
MCZ48	25	-	-	150	-	-	1:6
MCZ49	25	-	-	-	12.5	-	1:0.5
MCZ50	25	-	-	-	25	-	1:1
MCZ51	25	-	-	-	50	-	1:2
MCZ52	25	-	-	-	75	-	1:3
MCZ53	25	-	-	-	100	-	1:4
MCZ54	25	-	-	-	125	-	1:5
MCZ55	25	-	-	-	-	12.5	1:0.5
MCZ56	25	-	-	-	-	25	1:1
MCZ57	25	-	-	-	-	50	1:2
MCZ58	25	-	-	-	-	75	1:3
MCZ59	25	-	-	-	-	100	1:4
MCZ60	25	-	-	-	-	125	1:5

STUDIES OF MCZ SOLID DISPERSIONS

The phase solubility studies of MCZ were conducted following the Higuchi and Connors method (1965), wherein excess MCZ was added to 10 mL of various media (0.1 N HCl, distilled water, and pH 7.4 phosphate buffer) in conical flasks. These mixtures were sonicated for 2 hours at room temperature, then agitated on a shaker for 48 hours. After equilibration, the solutions were filtered using Whatman No. 1 filter paper, suitably diluted, and analyzed spectrophotometrically at 232 nm to determine the solubility enhancement. Drug–carrier interaction studies were subsequently performed to assess the compatibility and possible physical or chemical interactions between MCZ and the excipients used in solid dispersions. FTIR spectroscopy (Shimadzu, Japan) was utilized to detect any shifts or disappearance of characteristic peaks, indicating potential interactions. Samples were prepared using the KBr pellet method and scanned from 4000 to 400 cm^{-1}. DSC studies were carried out using accurately weighed samples (5–10 mg) in sealed aluminum pans, heated from 50°C to 350°C at a rate of 15°C/min under nitrogen flow (50 mL/min) to detect changes in melting behavior, which reflect drug crystallinity and interaction. Additionally, X-ray diffraction (XRD) analysis was employed using a Siemens D5000 diffractometer with Cu Kα radiation (λ = 1.540 Å), scanned over a 2θ range of 10°–80° at 30 mA and 40 kV, to determine the crystalline or amorphous nature of MCZ in the solid dispersions and to observe any structural transformation upon formulation.

REPARATION OF MCZ FAST DISSOLVING TABLETS

The fast dissolving tablets (FDTs) were prepared for selected solid dispersion preparations and the composition was given in Table 4.3. The FDTs were prepared by direct compression method. The solid dispersion powder equivalent to 25 mg of MCZ and other excipients were passed through a mesh no. 60#. The powdered solid dispersion was mixed with proper portion of crospovidone. Then excipients other than glidant and lubricant were added and mixed in a poly bag for 5-10 min. The obtained blend was lubricated with talc and magnesium stearate for another 5 min and the resultant mixture was directly compressed into tablets by 8 mm round, flat punches using rotary tablet machine.

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The tablet formulations (MCZ1 to MCZ58) were designed using MCZ solid dispersions equivalent to 25 mg MCZ, with Crospovidone (5%) as a superdisintegrant, spray-dried lactose as the filler, magnesium stearate (1%) as the lubricant, and talc (2%) as the glidant. Each tablet had a uniform total weight of 200 mg, except for the Control, which used pure MCZ (25 mg) instead of solid dispersion, with reduced excipients and a total weight of 100 mg. Solid dispersion levels varied (37.5, 50, 75, 100, and 125 mg) based on drug-carrier ratios in different batches to optimize disintegration and dissolution profiles.

EVALUATION OF PHYSICAL PARAMETERS OF MCZ FAST DISSOLVING TABLETS

The prepared MCZ fast dissolving tablets (FDTs) were evaluated for various physical and quality parameters including weight variation, hardness, friability, disintegration time, wetting time, drug content, and in vitro dissolution. Weight variation was assessed by weighing 20 tablets individually and calculating the % deviation from the average. Hardness was tested using a Monsanto tester for six tablets per batch, while friability was determined by rotating tablets in a friabilator and calculating the percentage weight loss. Disintegration time was measured in a petri dish containing 10 ml water, and wetting time was assessed using tissue paper moistened with amaranth solution. Drug content was estimated by crushing tablets, diluting in phosphate buffer (pH 7.4), filtering, and analyzing spectrophotometrically. In vitro dissolution studies were carried out in 900 ml of 7.4 pH phosphate buffer using USP Type II apparatus at 50 rpm and 37±0.5°C, with samples analyzed at 232 nm. The dissolution profile of the optimized formulation was compared with that of a marketed tablet (Diligan-25) under identical conditions. Key dissolution parameters such as Initial Dissolution Rate (IDR), Dissolution Efficiency (DE), and Relative Dissolution Rate (RDR) were calculated. Stability studies on the optimized formulation were performed according to ICH Q1A guidelines at 40±2°C/75±5% RH for six months, and the tablets were evaluated post-storage for assay and dissolution behavior; results were statistically analyzed using paired t-test with significance considered at $p<0.05$.

III. RESULTS AND DISCUSSION

PREFORMULATION STUDIES

Determination of λmax of MCZ

The absorption maximum (λmax) of MCZ was obtained by scanning 10 µg/ml stock solution in different media (0.1N HCl, distilled water and 7.4 pH phosphate buffer). The solutions were scanned in the range of 200-400 nm using UV spectrophotometer (Systronics 2202, Ahmedabad, India) and the scans are shown in Figure 4.1.

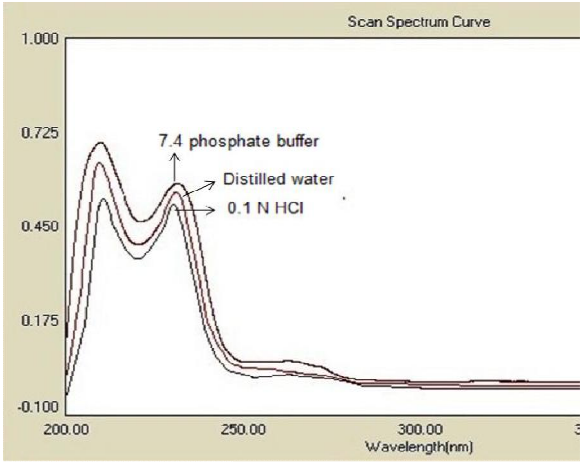

Figure 1: UV scan of MCZ in 0.1N HCl, distilled water and 7.4 pH phosphate buffer

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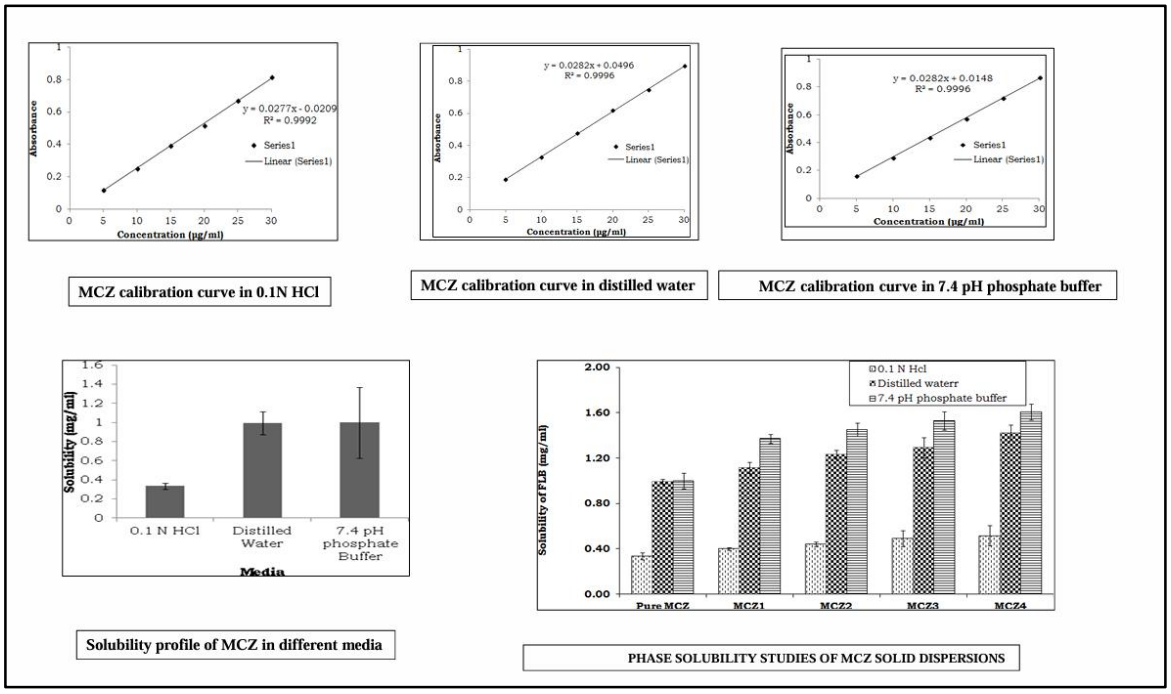
Standard curve of MCZ

From the UV spectrophotometric analysis the λmax of MCZ was found as 232 nm. . Linearity was observed in the concentration range of 5-30µg/ml. The standard graphs showed r2 value 0.9992 in 0.1 N HCl, 0.9996 in distilled water 0.9996 in 7.4 pH phosphate buffers which suggest that it, obeys the Beer- Lambert law (Table 4.4 and Figure 4.2, 4.3 & 4.4).

Table 3 MCZ Standard curve in different media

Concentration (µg/ml)	Absorbance		
	0.1 N HCl	Distilled water	7.4 pH Phosphate buffer
5	0.123	0.162	0.189
10	0.253	0.293	0.328
15	0.397	0.438	0.476
20	0.519	0.572	0.621
25	0.671	0.719	0.746
30	0.816	0.867	0.895



DRUG-CARRIER INTERACTION STUDIES

Fourier transform infrared spectroscopy (FTIR) studies

The FTIR spectra of MCZ is characterized by 3395.32 cm-1 (–N– stretch), 1629.97 cm-1 (C=C stretch of aromatic), 2974.35cm-1 (C–H stretch aliphatic), 1192.74cm-1 (C–Cl stretch). The presence of peak corresponding to –N- stretching at 3357.62 cm-1, C=C stretch of aromatic at 1600.22 cm-1, C–H stretch aliphatic at 2931.64cm-1, C–Cl stretch at 1105.76cm-1 in the optimized solid dispersion MCZ-Gelucire 44/14 (Figure 4.15) and absence of additional peaks indicates there were no interaction between drug and excipients. Similar observations were made in case of MCZ-PEG 4000, MCZ-PEG 6000, MCZ-PEG 20000 and MCZ-Gelucire 50/13 dispersions.

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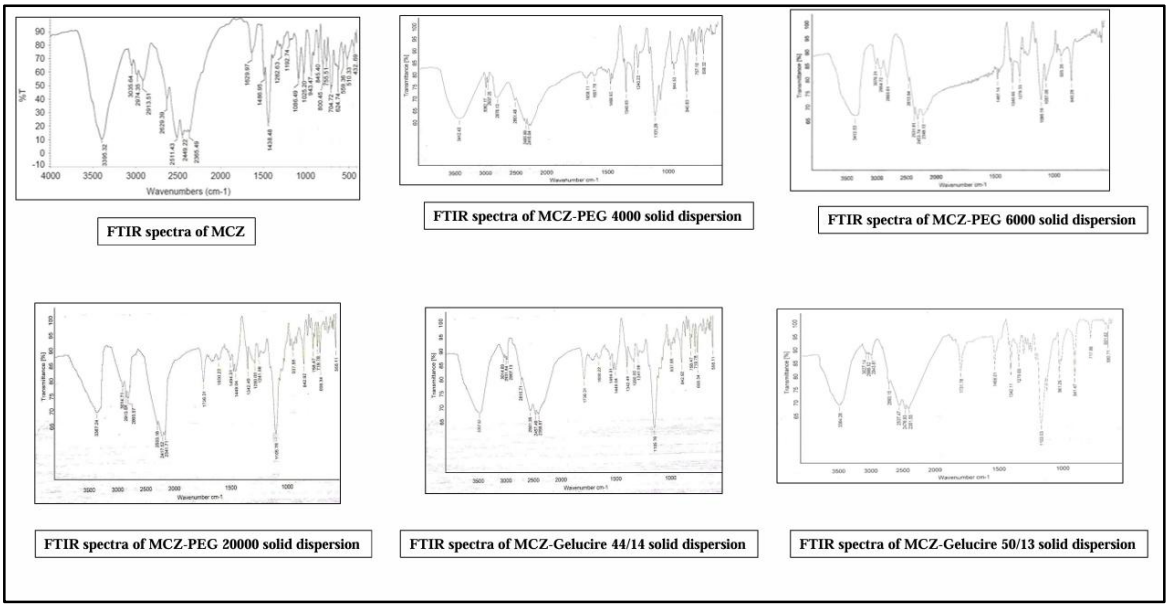

POWDER CHARACTERIZATION OF MCZ SOLID DISPERSIONS

The characterizations of MCZ solid dispersions powder blend are shown in Table 4.10. Angle of repose was found to be 27.87±1.56 to 30.85±0.73. Bulk and tapped density values were found to be 0.324 to 0.341 and 0.379 to 0.415. % Carr's index was found to be 12.95 to 18.31.

Table 4 Characterization of MCZ solid dispersion powder blend

Formulation	Angle of Repose (^{0})	Bulk Density (gm/cc^3)	Tapped Density (gm/cc^3)	Carr's Index (%)
MCZ 1	29.64±0.86	0.332	0.384	13.54
MCZ 2	29.34±0.37	0.329	0.387	14.99
MCZ 3	30.85±0.73	0.325	0.385	15.58
MCZ 4	29.47±0.62	0.331	0.388	14.69
MCZ 7	29.65±0.68	0.336	0.386	12.95
MCZ 8	30.29±1.02	0.327	0.379	13.72
MCZ 9	29.63±0.94	0.331	0.385	14.02
MCZ 10	30.12±0.41	0.338	0.399	15.28
MCZ 13	29.68±0.64	0.324	0.379	14.51
MCZ 14	28.73±0.82	0.329	0.381	13.64
MCZ 15	28.37±0.12	0.330	0.385	14.28
MCZ 16	29.37±1.28	0.341	0.402	15.17
MCZ 19	30.06±0.79	0.326	0.385	15.32
MCZ 20	29.49±0.72	0.327	0.383	14.62
MCZ 21	27.87±1.56	0.324	0.382	15.18
MCZ 22	29.83±0.51	0.336	0.402	16.42
MCZ 25	30.06±0.79	0.326	0.385	15.32
MCZ 26	30.24±0.62	0.326	0.383	14.88
MCZ 27	28.64±0.93	0.328	0.389	15.68
MCZ 28	30.28±0.32	0.339	0.415	18.31

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MCZ31	28.94±0.35	0.332	0.382	13.09
MCZ32	29.63±0.94	0.331	0.385	14.03
MCZ33	30.24±0.62	0.326	0.383	14.88
MCZ34	30.64±1.31	0.324	0.388	16.49
MCZ37	30.46±0.83	0.334	0.385	13.25
MCZ38	29.49±0.72	0.327	0.383	14.62
MCZ39	29.64±0.86	0.332	0.384	13.54
MCZ40	30.06±0.79	0.326	0.385	15.32
MCZ43	30.28±1.02	0.327	0.379	13.72
MCZ44	29.65±0.68	0.336	0.386	12.95
MCZ45	29.34±0.37	0.329	0.387	14.99
MCZ46	27.93±1.52	0.325	0.382	14.92
MCZ49	28.64±0.93	0.328	0.389	15.68
MCZ50	30.75±1.76	0.325	0.385	15.58
MCZ51	28.59±0.95	0.328	0.384	14.58
MCZ52	27.88±1.56	0.324	0.382	15.18
MCZ55	28.24±0.57	0.326	0.378	13.76
MCZ56	30.06±0.79	0.326	0.385	15.32
MCZ57	27.89±1.53	0.327	0.385	15.06
MCZ58	29.83±0.51	0.336	0.398	15.58
Control	28.14±2.19	0.334	0.395	15.44

* All Values Represent Mean ± Standard Deviation, n=3

EVALUATION OF MCZ FAST DISSOLVING TABLETS

Based on the solubility studies, the better solid dispersions were prepared into fast dissolving tablets. showed all the evaluation parameters determined for MCZ tablets. In weight variation test, the pharmacopoeial limits for the tablets of not more than 5% of the average weight and found to be 200.58±1.94 to 202.63±1.63 mg. The tablet hardness and friability were found to be 3.0±0.23 to 3.1±0.74 kg/cm2 and 0.32 to 0.39%, demonstrating the integrity and strength of tablets. From the disintegration test, the prepared tablets were disintegrated rapidly and it was found in the range of 117±5 to 123±5 sec. The wetting time was found to be 27±5 to 41±7 sec. The tablets assay was found to contain 98.13±1.63% to 99.63±1.47%.

Table 5 Evaluation of MCZ fast dissolving tablets

Formulation	Weight variation* (mg)	Hardness† (Kg/cm^2)	Friability (%)	Disintegration time‡ (sec)	Wetting time‡ (sec)	Drug content‡ (%)
MCZ 1	200.67±1.46	3.1±0.53	0.34	120±4	29±4	98.67±1.53
MCZ 2	202.63±1.63	3.1±0.24	0.34	121±2	31±6	99.38±1.27
MCZ 3	201.63±1.47	3.0±0.28	0.39	120±4	27±5	98.94±1.28
MCZ 4	201.68±1.31	3.0±0.42	0.33	122±4	35±3	99.08±1.62
MCZ 7	201.851.65	3.1±0.19	0.35	121±4	40±2	98.67±1.59
MCZ 8	202.23±1.94	3.0±0.47	0.34	120±3	37±8	98.95±1.43
MCZ 9	201.36±1.71	3.0±0.23	0.38	121±3	29±3	99.63±1.47
MCZ 10	201.92±1.46	3.0±0.64	0.33	121±4	41±6	99.12±1.34
MCZ 13	200.86±1.25	3.0±0.26	0.32	120±3	38±4	99.48±1.63
MCZ 14	201.54±1.96	3.1±0.15	0.33	122±5	28±3	98.36±1.57
MCZ 15	201.25±1.38	3.0±0.49	0.34	121±3	34±7	98.73±1.52

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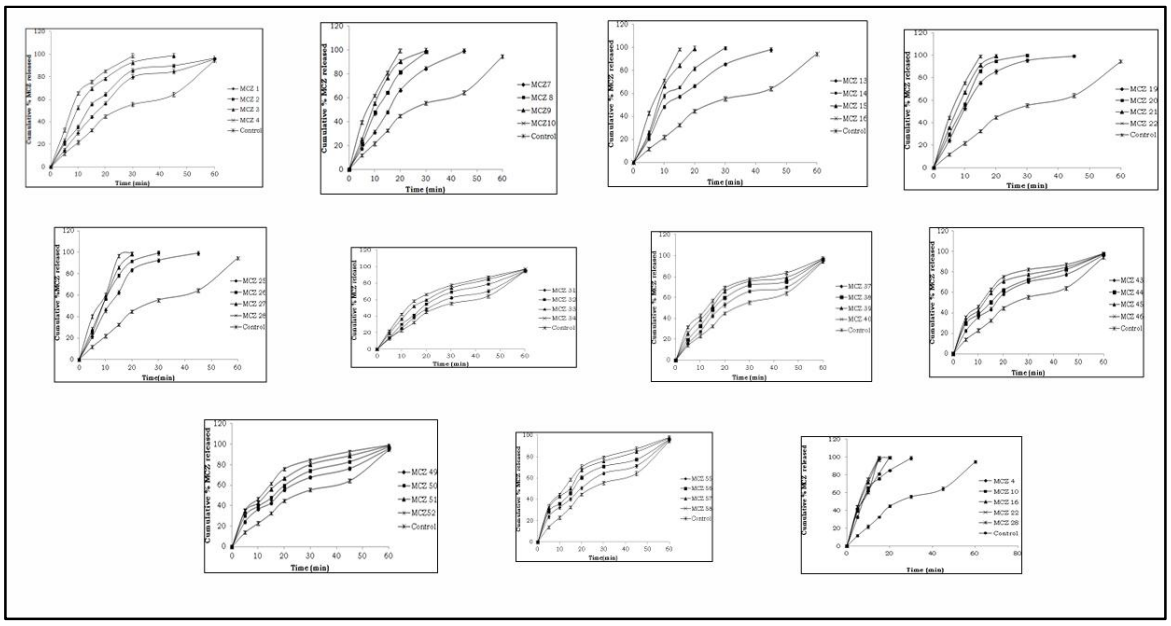
MCZ 16	201.47±1.34	3.0±0.48	0.33	122±4	41±7	98.92±1.58
MCZ 19	202.61±1.42	3.0±0.25	0.33	121±3	37±8	98.13±1.63
MCZ 20	201.36±1.73	3.1±0.74	0.35	120±2	35±6	99.17±1.73
MCZ 21	202.27±1.47	3.1±0.24	0.33	120±3	32±2	99.52±1.83
MCZ 22	202.34±1.62	3.0±0.23	0.33	117±5	36±3	99.14±1.17
MCZ 25	200.58±1.94	3.1±0.34	0.33	119±3	40±3	98.95±1.43
MCZ 26	200.64±1.32	3.1±0.25	0.37	120±3	38±4	99.13±1.52
MCZ 27	202.37±1.72	3.0±0.29	0.35	121±4	40±2	98.46±1.28
MCZ 28	201.56±3.75	3.1±0.19	0.33	123±5	35±4	98.86±1.72
MCZ31	200.62±1.29	3.0±0.39	0.32	119±3	40±5	98.24±1.32
MCZ32	201.28±1.68	3.0±0.29	0.35	121±4	30±3	98.46±1.28
MCZ33	200.68±1.93	3.0±0.23	0.38	121±3	31±4	99.55±1.64
MCZ34	200.72±1.72	3.1±0.43	0.33	121±3	34±3	99.34±1.26
MCZ37	201.95±1.35	3.1±0.53	0.34	120±4	31±4	98.67±1.53
MCZ38	200.59±1.34	3.1±0.34	0.33	119±3	34±2	98.95±1.43
MCZ39	201.83±1.57	3.0±0.42	0.34	120±3	40±7	99.38±1.72
MCZ40	200.63±3.68	3.1±0.29	0.33	122±5	37±9	99.03±1.82
MCZ43	200.75±1.94	3.0±0.26	0.32	120±3	30±9	99.48±1.63
MCZ44	201.69±1.67	3.1±0.19	0.35	121±4	41±5	98.67±1.59
MCZ45	200.68±1.84	3.1±0.24	0.33	120±3	32±3	99.52±1.83
MCZ46	201.42±1.46	3.0±0.45	0.38	119±5	29±6	99.12±1.16
MCZ49	200.61±1.05	3.0±0.34	0.36	122±4	28±6	98.98±1.35
MCZ50	201.12±1.25	3.0±0.57	0.37	119±3	26±3	99.04±1.24
MCZ51	201.22±1.36	3.0±0.28	0.39	120±4	40±2	98.94±1.28
MCZ52	201.51±1.18	3.0±0.29	0.38	120±4	34±4	98.92±1.53
MCZ55	200.72±1.68	3.1±0.25	0.37	120±3	30±4	99.13±1.52
MCZ56	201.23±1.68	3.1±0.24	0.34	121±2	30±6	99.38±1.27
MCZ57	201.23±1.45	3.0±0.34	0.38	120±4	31±7	98.49±1.58
MCZ58	201.72±1.26	3.0±0.41	0.38	121±4	28±2	99.14±1.32
Control	101.82±1.27	3.0±0.26	0.27	119±4	33±5	99.58±1.13

* All values represent mean ± standard deviation, n=20; † n=6; ‡ n=3

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 6, June 2025
Impact Factor: 7.67

IN VITRO DISSOLUTION STUDIES OF MCZ FAST DISSOLVING TABLETS



COMPARISION OF IN VITRO DISSOLUTION STUDIES OF OPTIMIZED MCZ FAST DISSOLVING TABLETS WITH MARKETED TABLETS

The cumulative mean percent of MCZ released from formulation MCZ22 showed more release and found to be 99.12±1.35% in 15 min compared with marketed tablets (Diligan-25).

Table 6 Dissolution data of optimized MCZ22 fast dissolving tablets and marketed tablets

Time (min)	Cumulative percent of MCZ released (Mean ± S.D.)	
	MCZ22 fast dissolving tablets	Diligan - 25
0	0.00±0.00	0.00±0.00
5	44.34±1.58	15.38±1.85
10	75.26±1.21	37.24±1.61
15	99.12±1.35	45.71±1.23
20	-	56.86±1.49
30	-	67.53±1.57
45	-	81.62±1.36
60	-	98.49±1.42

STABILITY STUDIES OF OPTIMIZED MCZ FAST DISSOLVING TABLETS

In the stability studies, assay values and drug release were calculated after six months storage The data was subjected to statistical analysis and proved that they were not significantly different from each other (P>0.05).

DOI: 10.48175/568

IJARSCT
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ISSN: 2581-9429
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Table 7 Stability studies of MCZ22 fast dissolving tablets

Time (min)	Cumulative percent of FLB released (Mean ± S.D.)		*t*-test at 0.05 LS	Similarity Factor (F2)
	Before storage	After 6 months storage		
0	0.00±0.00	0.00±0.00	Not Significant	85.74
5	44.34±1.58	41.67±1.32		
10	75.26±1.21	73.52±1.48		
15	99.12±1.35	98.27±1.24		
% Assay	99.14±1.17	98.81±1.02	Not Significant	--

IV. CONCLUSION

Solid dispersion techniques employing PEGs and Gelucire carriers successfully converted MCZ into an amorphous form, markedly improving its solubility and dissolution behavior. Fast dissolving tablets formulated from these dispersions exhibited rapid disintegration, robust mechanical properties, and significantly enhanced in vitro release compared to a marketed standard. The optimized formulation, MCZ22, achieved nearly complete drug release within 15 minutes and maintained its performance after accelerated stability testing. Consequently, solid dispersion-based FDTs represent a viable strategy to overcome solubility-limited bioavailability of MCZ, offering a promising dosage form for improved patient adherence and therapeutic outcomes

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ISSN: 2581-9429
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