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FORMULATION, DEVELOPMENT AND EVALUATION OF MEMANTINE FAST DISSOLVING TABLETS USING NATURAL POLYMERS

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ABSTRACT

The present study aimed to formulate and evaluate fast dissolving tablets of Memantine using natural polymers. Memantine is used in the treatment of Alzheimer's disease, and fast dissolving tablets improve patient compliance by disintegrating quickly in the oral cavity without water. Preformulation studies confirmed the purity and suitability of the drug for formulation. Tablets were prepared by the direct compression method using natural polymers such as guar gum and xanthan gum along with superdisintegrants. The prepared formulations were evaluated for pre-compression and post-compression parameters including flow properties, hardness, friability, weight variation, drug content, disintegration time, and in-vitro drug release. Among all formulations, F3 showed the best performance with rapid disintegration (45 seconds) and 98.85% drug release within 15 minutes. The study concluded that Memantine fast dissolving tablets using natural polymers provide rapid drug release and improved patient compliance.

KEYWORDS: Memantine, Fast Dissolving Tablets, Natural Polymers, Direct Compression, Superdisintegrants, In-vitro Drug Release, Alzheimer's Disease.

INTRODUCTION

Oral drug delivery remains the most widely accepted and convenient route for the administration of pharmaceutical agents due to its ease of use, patient compliance, and cost-effectiveness. However, conventional oral dosage forms such as tablets and capsules may present challenges for certain patient populations, particularly pediatric, geriatric, and psychiatric patients who often experience difficulty in swallowing (dysphagia). To overcome these limitations, fast dissolving tablets (FDTs), also known as orally disintegrating tablets (ODTs), have been developed as an innovative drug delivery system. These tablets are designed to disintegrate rapidly in the mouth within a few seconds without the need for water, thereby improving patient compliance and providing a faster onset of action. Fast dissolving tablets are especially beneficial for patients suffering from neurological disorders such as Alzheimer's disease, where swallowing difficulties and compliance issues are common.

Fast dissolving tablets are prepared using various techniques such as direct compression, freeze-drying, spray drying, sublimation, and mass extrusion. Among these, the direct compression method is widely preferred due to its simplicity, cost-effectiveness, and suitability for heat-sensitive drugs. The formulation of FDTs primarily involves the use of superdisintegrants and suitable polymers that facilitate rapid tablet disintegration and drug release. Recently, there has been a growing interest in the use of natural polymers in pharmaceutical formulations due to their biocompatibility, biodegradability, low toxicity, wide availability, and cost-effectiveness. Natural polymers such as guar gum, xanthan gum, locust bean gum, chitosan, and various plant mucilages have shown promising potential as disintegrants and release-modifying agents in tablet formulations.

Memantine hydrochloride is an N-methyl-D-aspartate (NMDA) receptor antagonist widely used in the treatment of moderate to severe Alzheimer's disease.

Alzheimer's disease is a progressive neurodegenerative disorder characterized by cognitive decline, memory impairment, and behavioral disturbances. Excessive stimulation of NMDA receptors by the neurotransmitter glutamate leads to neuronal damage and contributes to the progression of Alzheimer's disease. Memantine works by blocking these NMDA receptors and regulating the abnormal activity of glutamate, thereby protecting neurons from excitotoxic damage and improving cognitive function.

Memantine hydrochloride is well absorbed after oral administration and exhibits good bioavailability. However, conventional tablet formulations may not be suitable for elderly patients who commonly suffer from dysphagia and reduced swallowing ability. In such cases, fast dissolving tablets of Memantine offer a significant advantage as they disintegrate quickly in the oral cavity and facilitate rapid drug release and absorption. This not only enhances patient compliance but may also improve therapeutic outcomes by ensuring prompt drug availability.

The use of natural polymers in the formulation of fast dissolving tablets provides additional benefits, including enhanced disintegration properties, improved mouthfeel, and reduced reliance on synthetic excipients. Natural polymers derived from plant sources contain mucilage and polysaccharides that possess excellent swelling and water absorption properties, which promote rapid tablet disintegration. Moreover, natural polymers are environmentally friendly and sustainable, making them an attractive alternative to synthetic polymers in modern pharmaceutical research.

The present study focuses on the formulation, development, and evaluation of Memantine fast dissolving tablets using natural polymers. The objective of the research is to develop a stable and effective tablet formulation that rapidly disintegrates in the oral cavity while maintaining adequate mechanical strength and uniform drug release. Various formulation parameters such as drug–excipient compatibility, preformulation characteristics, tablet hardness, friability, disintegration time, wetting time, drug content uniformity, and in vitro drug release will be evaluated to ensure the quality and performance of the developed formulation.

Thus, the development of Memantine fast dissolving tablets using natural polymers represents a promising approach to improve patient compliance and therapeutic efficacy in the management of Alzheimer's disease. This research contributes to the advancement of patient-friendly dosage forms and highlights the potential role of natural polymers in the development of innovative pharmaceutical formulations.

Preformulation Studies of Memantine Hydrochloride

Preformulation studies were carried out to evaluate the physicochemical properties of Memantine Hydrochloride before formulation development. These studies are essential for understanding the fundamental characteristics of the drug, which helps in selecting suitable excipients and designing a stable, safe, and effective dosage form. Preformulation parameters such as organoleptic properties, solubility, melting point, moisture content, and spectroscopic analysis were evaluated.

1. Organoleptic Properties

The drug sample was visually examined to determine its organoleptic characteristics such as color, odor, and physical appearance. A small quantity of Memantine Hydrochloride powder was observed under normal lighting conditions. The drug was found to be a white to off-white crystalline powder with a characteristic odor and uniform appearance. These observations help in preliminary identification and quality assessment of the drug.

2. Solubility Analysis

Solubility studies were performed to determine the solubility behavior of Memantine Hydrochloride in different solvents. Approximately 5 mg of the drug was added separately to 10 ml of different solvents such as methanol, ethanol, chloroform, and distilled water in clean test tubes. The solutions were shaken gently for a few minutes at room temperature to facilitate dissolution. The solubility of the drug in each solvent was visually observed. The study helps in selecting suitable solvents for further analytical and formulation studies.

3. Loss on Drying (LOD)

Loss on drying was determined to evaluate the moisture content present in the drug sample. Approximately 5 g of Memantine Hydrochloride was accurately weighed and placed in an infrared (IR) moisture balance. The sample was heated at a temperature of 100–105°C for about 15 minutes. The loss in weight after drying was recorded and the percentage moisture content was calculated. Determination of moisture content is important because excessive moisture may affect the stability and shelf life of the formulation.

4. Melting Point Determination

The melting point of Memantine Hydrochloride was determined using the open capillary method. A small amount of the drug powder was filled into a thin capillary tube, which was then placed in a melting point apparatus. The sample was heated gradually and the temperature at which the drug started melting and completely liquefied was recorded. The melting point determination helps in confirming the purity and identity of the drug substance.

5. UV–Visible Spectrophotometric Analysis

UV–Visible spectrophotometric analysis was carried out to determine the maximum absorption wavelength (λmax) of Memantine Hydrochloride. A stock solution of the drug (1000 µg/ml) was prepared using methanol and

0.1 N hydrochloric acid as solvent systems. From the stock solution, further dilutions were prepared to obtain solutions of suitable concentrations. These samples were analyzed using a UV–Visible spectrophotometer over a wavelength range of 200–400 nm to determine the λmax of the drug. A calibration curve of concentration versus absorbance was then plotted, which was used for quantitative estimation of the drug in further studies.

FTIR Spectroscopy of Memantine Hydrochloride

Fourier Transform Infrared (FTIR) spectroscopy was performed to confirm the identity and purity of Memantine Hydrochloride and to identify the characteristic functional groups present in the drug molecule. Approximately 10 mg of the drug was mixed thoroughly with about 100 mg of dry potassium bromide (KBr) in a mortar. The mixture was compressed to form a transparent pellet using a KBr pellet press. The prepared pellet was scanned in an FTIR spectrophotometer in the wavelength range of 400–2000 cm^{-1}. The obtained spectrum was analyzed for characteristic peaks corresponding to functional groups present in Memantine Hydrochloride. This study also helps in identifying possible drug–excipient interactions during formulation development.

Formulation of Fast Dissolving Tablets of Memantine Using Natural Polymers

Selection of Compression Method

Tablet formulation depends largely on the flow and compressibility characteristics of the powder blend. In the pharmaceutical industry, tablets are commonly prepared by **dry granulation, wet granulation, and direct compression** methods. Among these techniques, **direct compression** was selected for the present study due to its simplicity, cost-effectiveness, and suitability for fast dissolving tablet formulations.

Preparation of Memantine Fast Dissolving Tablets

Fast dissolving tablets of Memantine were prepared by the **direct compression method** using natural polymers such as **guar gum and xanthan gum**, either individually or in combination with superdisintegrants including **sodium starch glycolate, crospovidone, and croscarmellose sodium**. A total of **nine formulations (F1–F9)** were designed to evaluate the effect of polymer type and superdisintegrant concentration on tablet characteristics.

Accurately weighed quantities of **Memantine (5 mg)**, natural polymers, superdisintegrants, and **microcrystalline cellulose** (as diluent) were blended uniformly using geometric dilution to maintain a **total tablet weight of 150 mg**. The mixture was passed through **sieve No. 60** to obtain uniform particle size and improve flow properties. **Talc (5 mg)** and **magnesium stearate (6 mg)** were then added as glidant and lubricant, respectively, and mixed gently.

The prepared powder blends were evaluated for **pre-compression parameters** such as **angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio** to assess flowability and compressibility. The final blends were compressed into tablets using an **8 mm flat-faced punch on a Rimek mini press (16-station rotary tablet compression machine)**.

The compressed tablets were further evaluated for **post-compression parameters** including **hardness, thickness, friability, weight variation, drug content uniformity, wetting time, disintegration time, and in-vitro drug release** to determine their suitability as fast dissolving tablets.

Evaluation of Pre-Compression Parameters

Bulk Density and Tapped Density

Bulk density and tapped density of the powder blend were determined by transferring a known weight of powder into a measuring cylinder and tapping it 100 times. These values were used to evaluate powder flow characteristics.

Compressibility Index (Carr's Index)

Compressibility index was calculated from bulk and tapped density values to determine the flowability of the powder blend.

Hausner's Ratio

Hausner's ratio was calculated as the ratio of tapped density to bulk density. A value **less than 1.25** indicates good flow properties.

Evaluation of Post-Compression Parameters

Appearance (Shape and Colour)

Tablets were visually examined for their shape and colour under proper lighting conditions.

Thickness

The thickness of tablets was measured using a **dial caliper**, and the average value was recorded.

Weight Variation Test

Twenty tablets from each formulation were weighed individually and compared with the average weight. According to pharmacopeial limits, tablets weighing **130–324 mg should not deviate more than ±7.5%** from the average weight.

Hardness Test

Tablet hardness was determined using a **Pfizer hardness tester**, and the results were expressed in **kg/cm^2**.

Friability Test

Friability was evaluated using a **Roche friabilator** at **25 rpm for 4 minutes**. Tablets showing **less than 1% weight loss** were considered acceptable.

Drug Content Uniformity

Ten tablets were powdered and an amount equivalent to the required drug dose was dissolved in **phosphate buffer (pH 6.8)**, filtered, diluted with **0.1 N HCl**, and analyzed using a **UV–Visible spectrophotometer at 212 nm**.

In-Vitro Dissolution Studies

Drug release studies were carried out using the **USP paddle type dissolution apparatus**. The tablets were placed in **900 ml of dissolution medium maintained at 37 ± 0.2°C and stirred at 75 rpm**. Samples were withdrawn at predetermined time intervals and replaced with fresh medium. The samples were analyzed spectrophotometrically at **212 nm**.

The dissolution data were analyzed using different **kinetic models**, including **zero-order kinetics**, which describes drug release at a constant rate over time.

Composition of fast dissolving tablets of Memantine using natural polymers

Ingredients (mg)	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Memantine	5	5	5	5	5	5	5	5	5
Guar gum	5	10	15	-	-	-	2.5	5	7.5
Xanthan gum	-	-	-	5	10	12	2.5	5	7.5
Sodium Starch glycolate	10	15	20	-	-	-	10	15	20
Crospovidone	10	15	20	10	15	20	-	-	-
Croscarmellose sodium	-	-	-	10	15	20	10	15	20
Microcrystalline cellulose	109	94	79	109	94	82	109	94	79
Talc	5	5	5	5	5	5	5	5	5
Magnesium stearate	6	6	6	6	6	6	6	6	6
Total weight	150	150	150	150	150	150	150	150	150

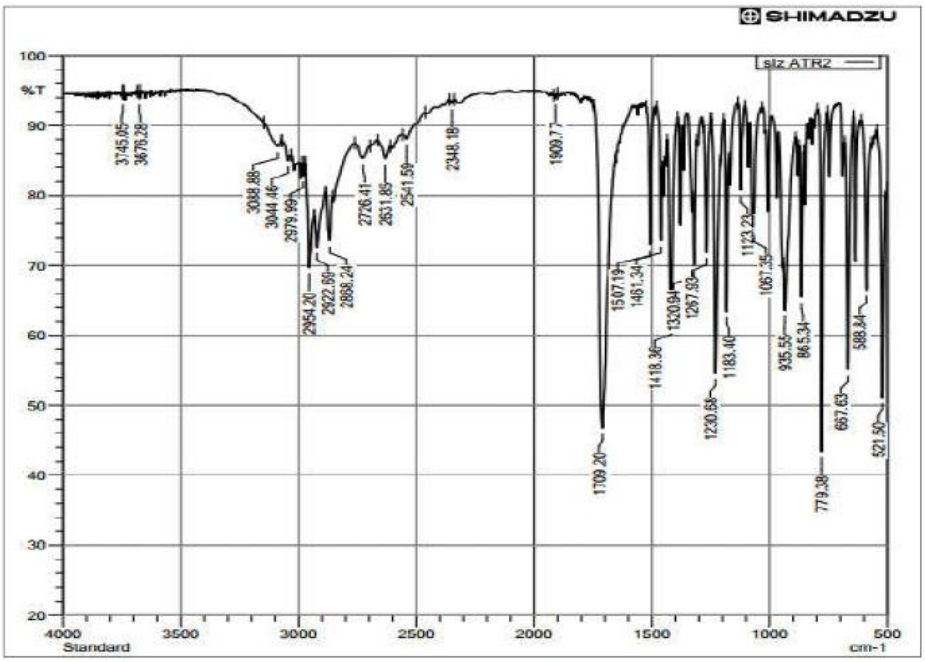

Figure 1: FT-IR Spectrum of pure drug (Memantine).

Table 1: FT-IR Interpretation of Memantine.

Wavenumber (cm^{-1})	Assignment	Remark
3088.88	N–H stretching (primary amine / NH_3^+)	Broad in salt form due to protonation and hydrogen bonding
2868.24	Aliphatic C–H stretching (CH, CH_2, CH_3)	From adamantane cage and methyl groups
1507.19	N–H bending (NH_2/NH_3^+ deformation) and C–C skeletal modes	More pronounced in salt form
1461.34	C–H bending (CH_2 scissoring, CH_3 deformation)	Supports aliphatic nature
1067.35	C–N stretching and cage skeletal vibrations	Characteristic of adamantane framework
935.55	Skeletal deformation and CH rocking	Diagnostic pattern for adamantane
588.84	Cage skeletal modes	Contributes to fingerprint region

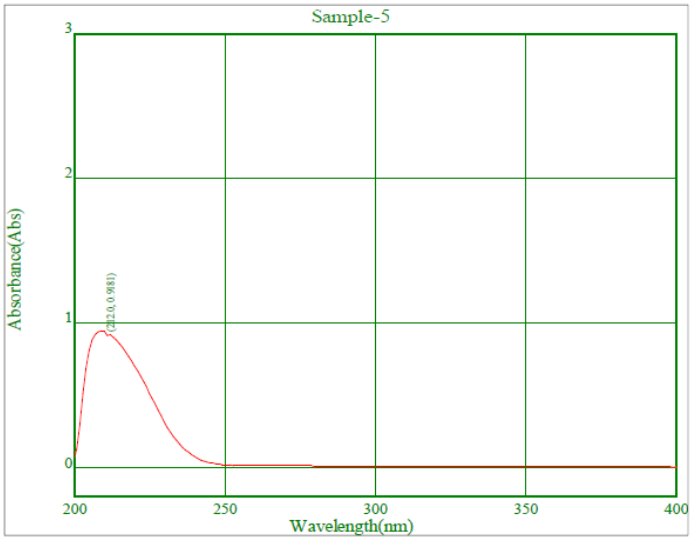

Figure 2: U.V. Spectra of pure drug (Memantine).

Table 2: Results of pre-compression parameters of Memantine

Formulation code	Parameters			
	Loose Bulk density(gm/ml)	Tapped bulk density(gm/ml)	Carr's Index (%)	Hausner's Ratio
F1	0.39	0.47	17.02	1.205
F2	0.36	0.45	20.00	1.250
F3	0.38	0.46	17.39	1.211
F4	0.37	0.46	19.57	1.243
F5	0.38	0.45	15.56	1.184
F6	0.39	0.46	15.22	1.179

Table 3: Results of post-compression parameters of all formulations.

F. Code	Hardness (kg/cm²)	Friability (%)	Weight Variation	Thickness (mm)	Drug Content (%)
F1	3.4±2	0.62±0.05	152±6	1.25±0.03	98.10±0.95
F2	3.5±1	0.70±0.03	153±4	1.28±0.02	99.05±0.45
F3	3.6±3	0.65±0.04	149±3	1.26±0.04	99.60±0.63
F4	3.4±2	0.72±0.06	149±5	1.27±0.03	98.00±0.85
F5	3.5±3	0.68±0.03	153±8	1.29±0.02	97.20±0.74
F6	3.7±2	0.75±0.02	154±5	1.30±0.04	96.10±0.63

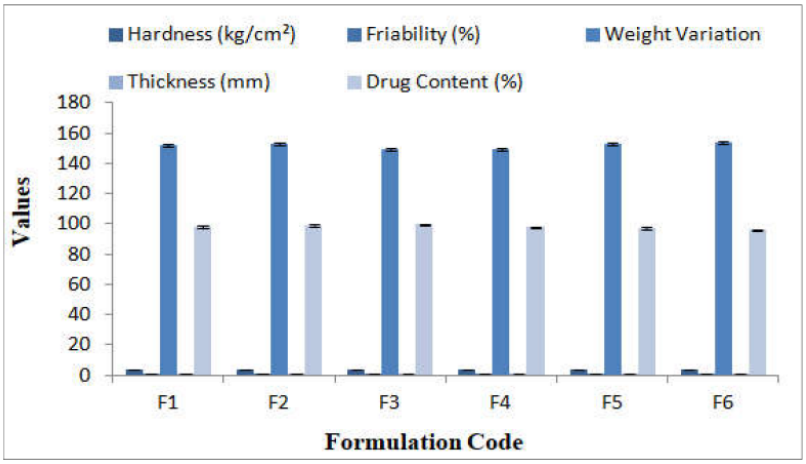

Figure 3: Results of post-compression parameters of all formulations.

Table 4: Results of disintegration time parameters of all formulations.

Formulation Code	Disintegration Time (sec) Mean ± SD
F1	72 ± 5
F2	60 ± 4
F3	45 ± 6
F4	88 ± 7
F5	80 ± 6
F6	70 ± 5

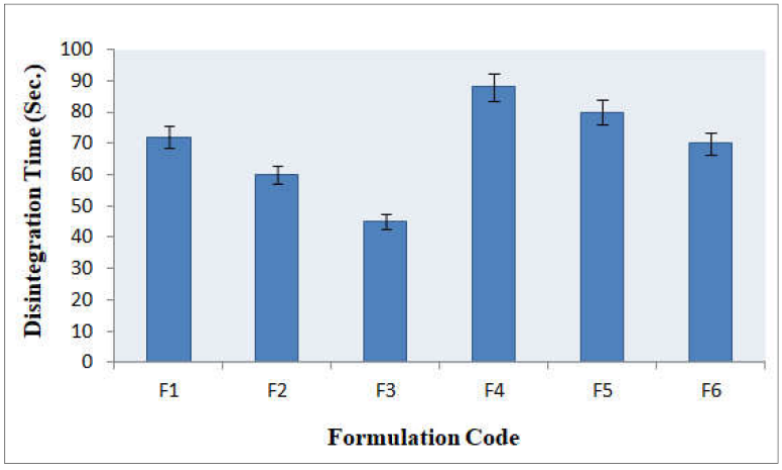

Figure 4: Results of disintegration time parameters of all formulations.

Table 5: *In-vitro* drug release data for optimized formulation F3.

Time (min)	Square Root of Time(h)$^{1/2}$	Log Time	Cumulative*% Drug Release	Log Cumulative % Drug Release	Cumulative % Drug Remaining	Log Cumulative % Drug Remaining
1	1	0	51.12	1.709	48.88	1.689
5	2.236	0.699	66.65	1.824	33.35	1.523
10	3.162	1	84.45	1.927	15.55	1.192
15	3.873	1.176	98.85	1.995	1.15	0.061

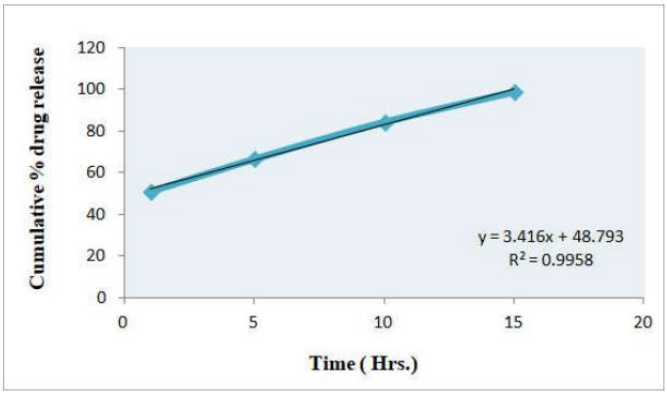

Figure 5: Graph of zero order release Kinetics of formulation F3.

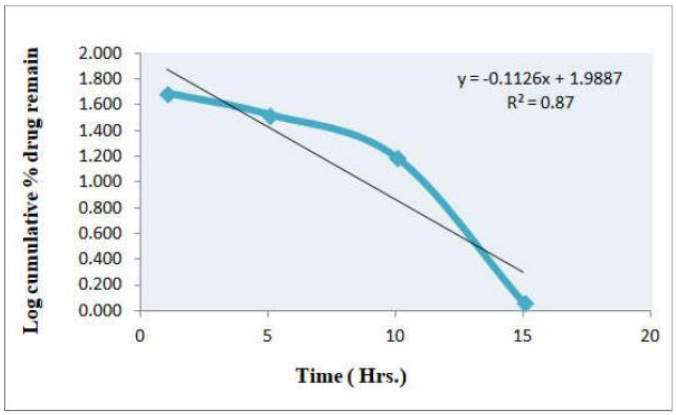

Figure 6: Graph of first order release kinetics of formulation F3.

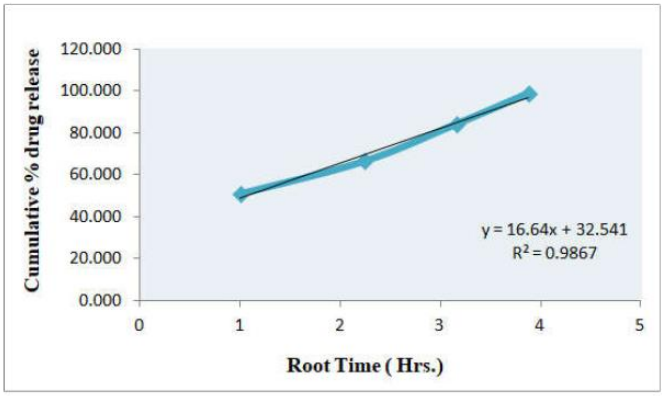

Figure 7: Graph of Higuchi release Kinetics of formulation F3.

Table 6: Regression analysis data of optimized formulation F3.

Batch	Zero Order	First Order	Higuchi	Korsmeyer peppas
	r^2			
F3	0.9958	0.870	0.9867	0.870

SUMMARY AND CONCLUSION

The physicochemical and sensory evaluation of Memantine indicated that the drug is a white to off-white fine powder with a characteristic bitter taste, consistent with its chemical properties. Solubility studies revealed that Memantine is freely soluble in water, 0.1 N HCl, and methanol, soluble in ethanol, phosphate buffer pH 6.8, and 0.1 N NaOH, and sparingly soluble in chloroform, which supports its suitability for immediate-release tablet formulations.

The melting point (152–154°C) closely matched the reported standard value (153°C), confirming the identity and purity of the drug. FT-IR analysis showed characteristic peaks corresponding to functional groups such as N–H stretching, C–H aliphatic stretching, and C–N stretching, confirming the structural integrity of Memantine. The loss on drying (0.157%) indicated minimal moisture content, which contributes to good stability of the drug.

The UV spectrophotometric calibration curve of Memantine in phosphate buffer pH 6.8 at 212 nm showed good linearity in the concentration range of 2–10 µg/mL with a correlation coefficient of 0.998, demonstrating the reliability of the analytical method.

Pre-compression evaluation of powder blends showed loose bulk density values of 0.36–0.39 g/mL and tapped bulk density values of 0.45–0.47 g/mL. The Carr's index (15.22–20%) and Hausner's ratio (1.179–1.250) indicated fair to good flow properties, confirming the suitability of the blends for direct compression.

Post-compression evaluation demonstrated that all tablet formulations had acceptable hardness (3.4–3.7 kg/cm²) and friability below 1%, indicating good mechanical strength. Weight variation (149–154 mg) and drug content (96.10–99.60%) were within pharmacopeial limits, confirming uniform drug distribution. Disintegration studies showed that tablets disintegrated within 45–88 seconds, with formulation F3 showing the fastest disintegration (45 seconds).

The in-vitro dissolution study of the optimized formulation F3 showed 98.85% drug release within 15 minutes, indicating rapid drug availability. Release kinetics analysis suggested that the formulation followed zero-order kinetics (r^2 = 0.9958) with a strong Higuchi correlation (r^2 = 0.9867), indicating a diffusion-controlled release mechanism. The Korsmeyer–Peppas model (r^2 = 0.870) indicated non-Fickian drug transport behavior.

Overall, formulation F3 exhibited optimal flow properties, good mechanical strength, rapid disintegration, and immediate drug release, making it the best formulation among all batches. The results confirm that the developed Memantine tablets are suitable as fast-acting immediate-release tablets, providing rapid onset of therapeutic action and consistent drug delivery.

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