



Development and Evaluation of Dimenhydrinate Orally Disintegrating Tablets for Rapid Relief of Motion Sickness - A Novel Approach to Conventional Dosage Forms

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ABSTRACT

Motion sickness is a common condition characterized by nausea, vomiting and dizziness requiring rapid therapeutic intervention. Oral disintegrating tablets (ODTs) provide a convenient, patient-friendly dosage form that disintegrates quickly in the oral cavity without water, ensuring faster onset of action and improved compliance, especially in paediatric and geriatric populations. Dimenhydrinate, an effective antiemetic, is commonly used for motion sickness, but conventional tablets may have delayed onset due to slower disintegration and dissolution. In this study, Dimenhydrinate ODTs were prepared by the direct compression method using varying concentrations of super disintegrants, crospovidone and croscarmellose sodium. Seven formulations (F1–F7) were evaluated for pre- and post-compression properties, *in vitro* disintegration, wetting time and dissolution. The optimized formulation F4 showed the shortest wetting time (24 ± 1.0 s), attributed to a higher crospovidone concentration (7.5%), promoting capillary action and rapid water penetration. The *in vitro* disintegration times ranged from 28.4 ± 0.23 to 45.3 ± 0.12 seconds, well within pharmacopeial limits. Among the formulations, F6 exhibited superior performance, containing 7 mg croscarmellose sodium and 7.5 mg crospovidone, which synergistically enhanced rapid disintegration through swelling, wicking and capillary action. Dissolution studies showed that F6 released 69.46% of the drug within 5 minutes and 98.78% within 30 minutes, significantly faster than the marketed formulation (10.12% and 61.01%, respectively). These findings demonstrate that the optimized Dimenhydrinate ODT prepared by direct compression offers rapid disintegration and drug release, ensuring fast onset of action and improved patient compliance in the management of motion sickness.

Keywords: Dimenhydrinate, Orodispersible Tablets, Rapid Disintegration, Synergistic Superdisintegrants, Fast-Onset Anti-Motion Sickness, Direct Compression

1.INTRODUCTION

Motion sickness, also known as kinetosis, is a neurophysiological disturbance that arises due to repetitive motion or conflicting sensory signals between the visual and vestibular systems. It is characterized by nausea, vomiting, dizziness and general discomfort. Dimenhydrinate is a well-established first-generation antihistamine and antiemetic agent widely employed for the prevention and management of motion sickness. It is a salt of diphenhydramine and 8-chlorotheophylline, which acts synergistically to suppress vestibular stimulation and inhibit labyrinthine function. ODTs rapidly disintegrate in the oral cavity within seconds upon contact with saliva, eliminating the need for water [1]. This feature ensures a quicker onset of pharmacological action and is particularly advantageous for patients who have difficulty swallowing, such as paediatric, geriatric and traveling individuals. The formulation of Dimenhydrinate as an ODT offers several advantages over conventional dosage forms, including faster relief from motion sickness symptoms, ease of administration during travel, improved patient compliance and better stability compared to liquid formulations. Through the application of super disintegrants and direct compression technology, it is possible to develop robust ODTs with excellent mechanical strength, rapid disintegration and acceptable palatability [2].



2. ORAL DISINTEGRATING TABLET

Orally Disintegrating Tablets (ODTs) are innovative solid dosage forms that disintegrate or dissolve rapidly in the mouth within seconds, without the need for water. They are designed to improve patient convenience, compliance and therapeutic efficacy especially in populations who experience difficulty swallowing conventional tablets or capsules [3]. ODTs combine the advantages of both solid and liquid dosage forms, offering stability like tablets and fast onset of action like solutions. The formulation of ODTs involves the incorporation of super disintegrants such as croscarmellose sodium, sodium starch glycolate, or crospovidone, which facilitate rapid tablet disintegration upon contact with saliva [4]. The saliva then aids in dissolving the drug, allowing for immediate absorption either through the buccal mucosa or after swallowing. This results in faster therapeutic onset, which is particularly beneficial in conditions requiring quick symptom relief, such as motion sickness, migraine, and allergic reactions [5].

3. MATERIALS AND METHODS

3.1 Materials

Dimenhydrinate was obtained as a gift sample from BL Pharmaceuticals, India. Superdisintegrants such as Croscarmellose sodium and Crospovidone were procured from PharmaFabricon Pvt. Ltd., India. All other excipients, including microcrystalline cellulose, mannitol, sucrose, magnesium stearate and talc were of analytical grade and were obtained from the college laboratory premises. Distilled water was used throughout the experimental work.

3.2 Methods

Direct compression

The ODTs of Dimenhydrinate were prepared by the direct compression method. The accurately weighed quantities of all ingredients were passed through a #60 mesh sieve to obtain uniform particle size. The required quantity of Dimenhydrinate, superdisintegrants (Croscarmellose sodium and Crospovidone), diluents (such as mannitol and microcrystalline cellulose) and sweetening agent (aspartame) were transferred into a clean mortar and mixed thoroughly for 10–15 minutes using geometric dilution to ensure uniform blending [6,11]. To the above blend, magnesium stearate and talc were added as lubricant and glidant, respectively and the mixture was gently blended for an additional 2–3 minutes to avoid overwriting the compressibility of the powder. The prepared uniform powder blend was then subjected to precompression studies such as angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio to assess flow properties [7]. After confirming satisfactory flow characteristics, the powder blend was compressed into tablets using a rotary tablet compression machine equipped with flat-faced punches. The compression force was adjusted to obtain tablets of uniform hardness and weight. The prepared tablets were stored in airtight containers until further evaluation [8-10].

Table 1: Formulation table of Oral Disintegrating Tablet- Dimenhydrinate

INGREDIENTS	F1	F2	F3	F4	F5	F6	F7
Dimenhydrinate(mg)	50	50	50	50	50	50	50
Croscarmallose sodium	7	3.5	5.25	5.25	7	7	3.5
Crospovidone	5.25	5.25	3.0	7.5	3	7.5	3.0
Microcrystalline cellulose (MCC)	30	30	30	30	30	30	30
Sucrose	5	5	5	5	5	5	5
Mannitol	100.75	104.25	104.25	100.25	103	98.5	106.5
Magnesium stearate	2	2	2	2	2	2	2



4. Preparation of standard calibration curve

Drug: Dimenhydrinate

Solvent: Phosphate buffer pH 6.8.

Procedure

100 mg dimenhydrinate was weighed accurately and dissolved in 100 ml of phosphate buffer pH 6.8 in volumetric flask. Flask was shaken for 5 minutes to dissolve drug properly. Flask was labelled as Stock Solution I containing concentration of 1000 μ g/mL. 1 ml of stock solution I was further diluted into 100 ml of phosphate buffer pH 6.8 to get stock solution II (10 μ g/mL). From this stock solution 5ml, 10ml, 15ml, 20ml and 25ml are taken and diluted to 25ml with phosphate buffer pH 6.8. respectively, so that the final concentration of 2-10 μ g/ml is obtained. The above solutions are analysed by Ultraviolet-spectrophotometer. A graph will be drawn with concentration on X axis, absorbance on Y axis [12, 13].

4.1 Estimation of Absorption Maxima

Dimenhydrinate 10 μ g/mL stock solution II was analysed by Ultraviolet-spectrophotometer at 279nm for the estimation of Absorption maxima [14].

5.DRUG EXCIPIENT COMPATABILITY STUDIES

FTIR STUDIES

FTIR spectroscopy is an essential analytical tool used to identify functional groups and detect possible interactions between the drug and excipients. It provides detailed information about the molecular structure based on characteristic absorption bands. The obtained spectra were analyzed to confirm the presence of principal peaks corresponding to functional groups of the pure drug and to check for any shifts or disappearance of peaks indicating chemical interactions [15-17].

6. PREFORMULATION STUDIES

Preformulation studies were conducted to evaluate the physicochemical compatibility and properties of Dimenhydrinate and excipients prior to tablet formulation. Parameters such as appearance, solubility, melting point, and flow characteristics (angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio) were determined. These studies help in selecting suitable excipients, optimizing the formulation process and predicting potential stability issues [19].

6.1 Organoleptic Properties

The colour, odour and texture of the drug were evaluated through direct visual and sensory examination under adequate lighting. Any characteristic features such as crystalline form, taste, or odour were noted to ensure identity and consistency of the sample [18].

6.2 Solubility Profile

An excess amount of drug was added to various solvents such as distilled water, ethanol, methanol and phosphate buffer (pH 6.8). The mixtures were shaken at room temperature for 24 hours, filtered and the dissolved drug concentration was determined spectrophotometrically [11].

6.3 Melting Point

A small amount of drug was filled into a sealed capillary tube and placed in a melting point apparatus. The temperature range at which the sample began and completed melting was recorded to evaluate purity and thermal stability [18].

6.4 pH Determination

A 1% w/v aqueous solution of the drug was prepared using distilled water. The pH of the solution was measured at room temperature using a calibrated digital pH meter to assess its acidic or basic nature [6].

6.5 Partition Coefficient

Equal volumes of n-octanol and water were taken, and a known quantity of drug was added. The system was shaken for 24 hours, allowed to equilibrate, and the concentration in each phase was analyzed spectrophotometrically. The partition coefficient was calculated as the ratio of drug concentration in n-octanol to that in water [1].

7.EVALUATION PARAMETERS

7.1 PRE-COMPRESSION EVALUATION

Bulk Density

Bulk density is the mass of a powder divided by its bulk volume, including the void spaces between particles. It provides an estimate of the packing and flow behaviour of the powder. Lower bulk density indicates poor flow, whereas higher values suggest better packing. It is measured by pouring the powder into a graduated cylinder and recording the volume. This parameter is crucial for uniform die filling during compression [20].

$$\text{BULK DENSITY} = \frac{\text{WEIGHT OF THE POWDER}}{\text{BULK VOLUME OF THE POWDER}}$$

Tapped Density

Tapped density is the powder density after mechanically tapping a graduated cylinder containing the powder. It helps in understanding how the powder consolidates under vibration or compression. The difference between tapped and bulk density indicates the compressibility of the powder. Higher tapped density usually signifies better compressibility. It is used in combination with bulk density to calculate Carr's index and Hausner ratio [11].

$$\text{TAPPED DENSITY} = \frac{\text{WEIGHT OF THE POWDER}}{\text{TAPPED VOLUME OF THE POWDER}}$$

Carr's Index (Compressibility Index)

Carr's Index measures the ease of powder flow and compressibility using bulk and tapped densities. It is calculated as: $((\text{Tapped density} - \text{Bulk density}) / \text{Tapped density}) \times 100$. A lower Carr's Index (<15%) indicates excellent flow, while higher values (>25%) suggest poor flow. It helps predict tableting behavior and risk of weight variation. This is a simple and widely used pre-compression evaluation [21].

$$\text{CARR'S COMPRESSIBILITY INDEX} = \frac{\text{TAPPED DENSITY} - \text{BULK DENSITY}}{\text{TAPPED DENSITY}} \times 100$$

Hausner Ratio

Hausner ratio is the ratio of tapped density to bulk density. It provides an indirect measure of powder flowability. A ratio close to 1.0 indicates good flow, while values above 1.25 suggest poor flow properties. It complements Carr's Index in pre-compression analysis. This parameter helps in designing formulations with uniform die filling and reduced capping issues [20].

$$\text{HAUSNER'S RATIO} = \frac{\text{TAPPED DENSITY}}{\text{BULK DENSITY}}$$



Angle of Repose

The angle of repose is the maximum angle formed between the surface of a powder heap and the horizontal plane. It indicates the flow characteristics of the powder blend. Smaller angles ($<30^\circ$) suggest good flow, while larger angles indicate cohesive or poorly flowing powders. It is measured using a funnel method or fixed-height cone method. This test is essential for predicting problems during tablet compression [18].

$$\text{ANGLE OF REPOSE } (\tan\theta) = \frac{\text{HEIGHT}(h)}{\text{RADIUS}(r)}$$

7.2 POST-COMPRESSION EVALUATION

General Appearance

General appearance assesses the visual quality of the tablets, including shape, color, surface texture and presence of cracks or chips. It helps in ensuring patient acceptability and consistency in manufacturing. Defects can indicate poor formulation or compression issues. Uniform appearance is a sign of good manufacturing practices. This evaluation is qualitative but crucial for market-ready tablets [21, 28].

Weight Variation Test

Weight variation ensures uniformity of mass in individual tablets. A sample of tablets is weighed individually and compared with the average weight. This test detects problems in powder flow or dies filling. Tablets should comply with pharmacopeial limits to pass the test. It ensures accurate dosing and patient safety.

Table 2: Evaluation of Weight Variation in Accordance with IP Specifications

Average weight of tablet (According to IP/BP)	Limit	Average weight of tablet (According to USP)
80 mg or less	$\pm 10\%$	130mg or less
More than 80mg or Less than 250mg	$\pm 7.5\%$	130mg to 324mg
250mg or more	$\pm 5\%$	More than 324mg

Thickness and Diameter

Measurement of tablet thickness and diameter ensures uniform size and shape. Variations can indicate compression problems or die issues. Thickness affects disintegration and drug release, while diameter ensures consistency in packaging and patient acceptability. It is measured using vernier calipers or micrometers. Maintaining uniform dimensions is important for mechanical stability [20].

Hardness Test

Hardness testing measures the mechanical strength of a tablet to withstand handling, packaging, and transportation. It is performed using a hardness tester or Monsanto tester. Ideal hardness ensures tablets are neither too soft (fragile) nor too hard (delayed disintegration). Hardness affects friability, disintegration, and dissolution. It is an important parameter for quality control. ODTs are generally softer than conventional tablets, with an acceptable hardness range of approximately 2–5 kg/cm², depending on formulation and excipients [21].

Friability Test

Friability test evaluates the tendency of tablets to crumble or break under mechanical stress. Tablets are rotated in a friabilator and the weight loss is measured. Acceptable weight loss is usually $<1\%$. High friability indicates poor mechanical strength or formulation issues. This test complements hardness and ensures tablets can endure handling and shipping. According to the Indian Pharmacopoeia, friability measures the ability of tablets to resist chipping, cracking, or breaking during handling and transportation. For all tablets, including ODTs, the acceptable friability limit is generally not more than 1% weight loss after the specified number of rotations in a friabilator [11, 27].

$$\% \text{ Friability} = \frac{\text{INITIAL WEIGHT} - \text{FINAL WEIGHT}}{\text{INITIAL WEIGHT}} \times 100$$

***In vitro* Disintegration Time**

Disintegration time measures how quickly a tablet breaks down into smaller fragments in a suitable medium. It is crucial for tablets like ODTs where rapid action is desired. Tested using a disintegration apparatus under standard conditions. Faster disintegration ensures prompt drug release and onset of action. It is a key quality control parameter for patient compliance. As per the Indian Pharmacopoeia, the *in vitro* disintegration test measures the time required for an orally disintegrating tablet to break down into smaller particles in a suitable liquid medium. ODTs are designed to disintegrate rapidly in the mouth without water, and the acceptable disintegration time is generally within 3 minutes [27].

***In vitro* Dispersion Time**

Dispersion time is specifically important for orally disintegrating tablets (ODTs). It measures the time taken for the tablet to completely disperse in a medium. Faster dispersion enhances patient acceptability, especially in children and elderly. It is performed by placing the tablet in a small volume of liquid. This test complements disintegration studies [22].

Wetting Time

Wetting time indicates the ability of a tablet to absorb moisture and begin disintegration. A shorter wetting time is preferred for ODTs and fast-dissolving formulations. It is measured by placing a tablet on wetted tissue paper and recording the time for complete wetting. Wetting time affects disintegration, dissolution, and patient experience. This test ensures the tablet's readiness for immediate action [25].

Water Absorption Ratio

Water absorption ratio measures the capacity of a tablet to absorb water relative to its weight. It is important for predicting disintegration and swelling behaviour. Calculated as ((Weight of wet tablet – initial weight)/initial weight) × 100. Higher water absorption generally results in faster disintegration. This test is useful for evaluating ODTs and hydrophilic tablets [25, 26].

- Weigh the swollen tablet immediately and record as W_b.
- W_a = Weight of tablet before water absorption
- W_b = Weight of tablet after water absorption

$$\text{Water Absorption Ratio} = \frac{W_b - W_a}{W_a} \times 100$$

Drug Content Uniformity Test

This test ensures that each tablet contains the intended amount of active pharmaceutical ingredient (API). A sample of tablets is assayed using UV, HPLC, or other suitable methods. Uniform drug content is essential for therapeutic efficacy and patient safety. It also detects problems in mixing or compression [24]. Pharmacopeial limits define acceptable variation in drug content. As per the Indian Pharmacopoeia, drug content uniformity ensures that each orally disintegrating tablet contains the intended amount of active ingredient. The acceptable limit is that the drug content should be within 85–115% of the labelled claim, with a relative standard deviation (RSD) ≤6%.

***In vitro* Dissolution - Drug Release Study**

Dissolution testing measures the rate and extent of drug release from the tablet into a suitable medium. It simulates the drug release in the gastrointestinal tract. Data helps predict in-vivo performance and bioavailability. Common methods include USP dissolution apparatus I (basket) or II (paddle). It is critical for regulatory approval and quality assurance. *In vitro* dissolution measures the rate and extent of drug release from orally disintegrating tablets in a specified medium under controlled conditions. According to the Indian Pharmacopoeia, generally not less than 75% of the labelled drug should dissolve within 30 minutes for immediate-release formulations, including ODTs [23, 24].

8. RESULTS

Construction of dimenhydrinate calibration curve

Standard calibration of Dimenhydrinate

The absorbance of solution (2µg/ml-10µg/ml) was measured in UV- spectrophotometer at 276 nm.

Table 3: Calibration Data of Dimenhydrinate by UV Spectrophotometry

S. NO	CONCENTRATION (µg/ml)	ABSORBANCE
1	2	0.09
2	4	0.16
3	6	0.23
4	8	0.29
5	10	0.35

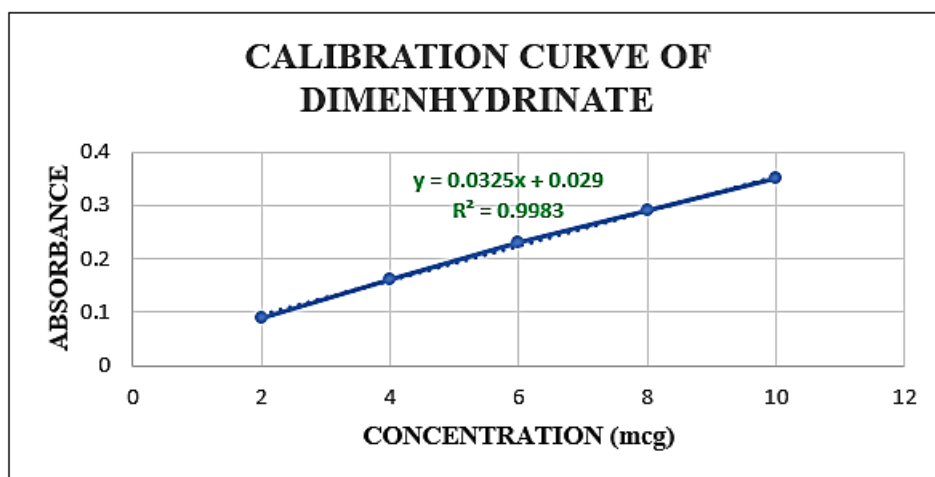


Figure 1: Calibration curve of Dimenhydrinate

Determination of Absorption maxima of Dimenhydrinate

The Absorption maxima of Dimenhydrinate was determined by scanning (10µg/ml) solution of drug in phosphate buffer pH 6.8 in the range of 200nm to 400nm by UV- Spectrophotometer and it was found to be 276 nm.

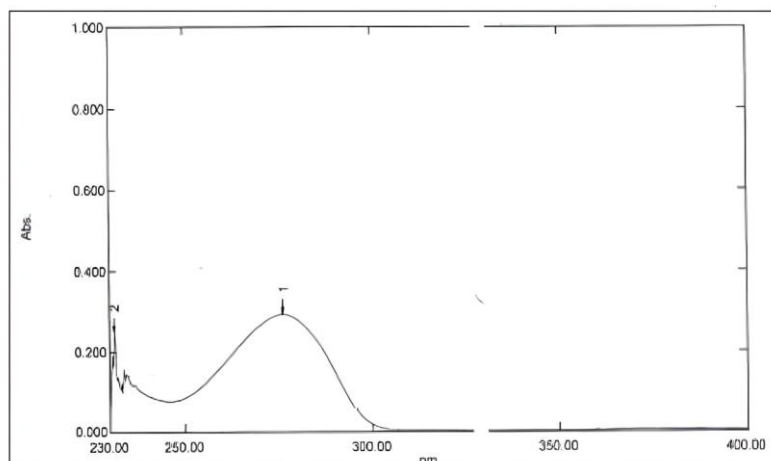
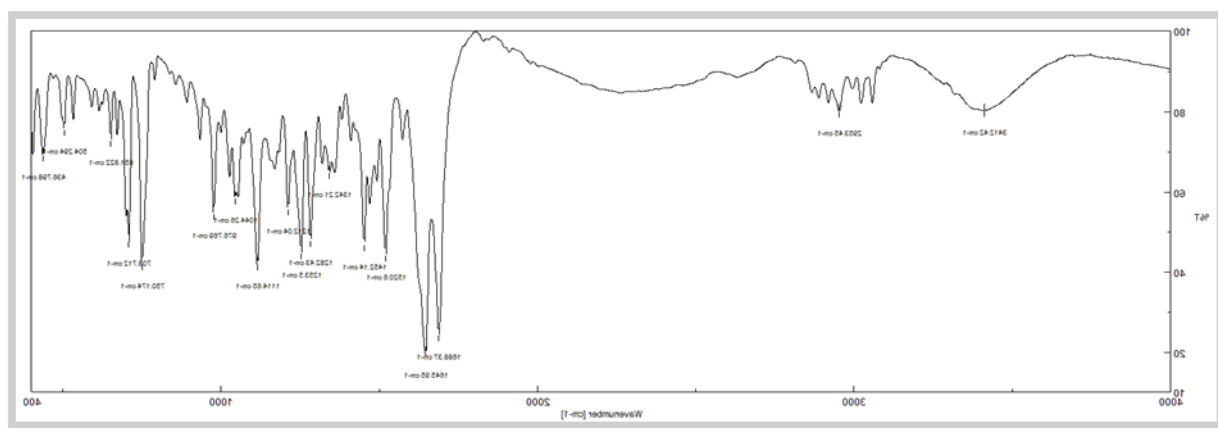


Figure 2: Absorption maxima of Pure Dimenhydrinate

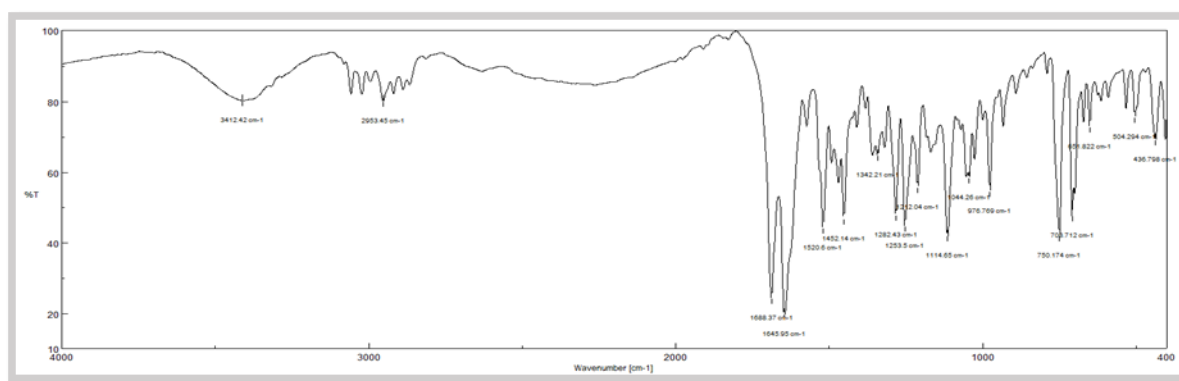
Compatibility studies for drug and excipients

Fourier transform infrared spectroscopy (FTIR)

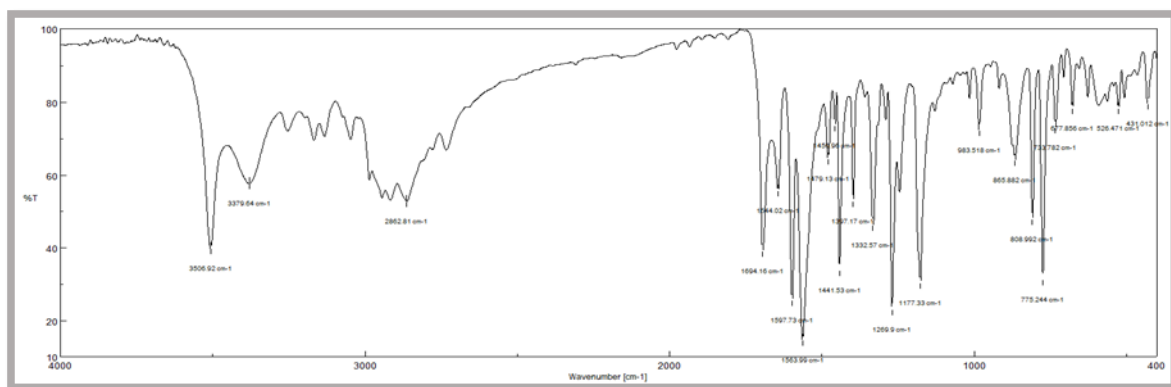
Infrared (IR) spectroscopic studies were carried out to confirm the compatibility between drug and excipients used for the preparation of orally disintegrating tablets. The IR studies were performed for Dimenhydrinate (pure drug), croscovidone, croscarmallose sodium, and physical mixture of drug and excipients. The spectra studied at 4000cm^{-1} to 400 cm^{-1} .



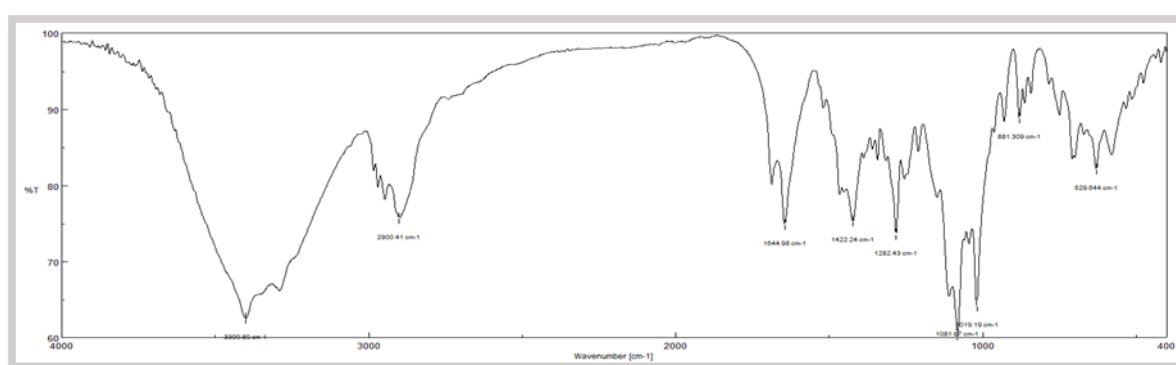
a]



b]



c]



d]

Figure 3: FTIR Spectra of a) Pure drug b) Croscarmellose sodium c) Crospovidone d) Physical mixture of Pure drug, croscarmellose sodium, crospovidone.

FTIR analysis was used to conduct research on drug-excipient compatibility. FTIR spectroscopy was performed on pure medications of Dimenhydrinate, Croscarmellose sodium, Crospovidone, and Physical mixture. FTIR spectra of the medication was perceived as a wide peak spanning 4000-400 cm. The results were displayed after the peaks from formulations were contrasted with the peaks of pure medications and excipients.

Preformulation studies

Organoleptic evaluation

The drug was white crystalline, odourless powder and compiled as per the manufacturer's Certificate of Analysis.

Table 4: Organoleptic evaluation of Dimenhydrinate

S.NO	PROPERTY	INFERENCE
1	Appearance	White crystalline powder
2	Odour	No odour
3	Taste	Bitter

Solubility studies

Dimenhydrinate has been studied for its solubility in various solvents, including water, chloroform, ethanol and phosphate buffer pH 6.8 solution. Dimenhydrinate was found to have solubility in water.

Table 5: Solubility data of dimenhydrinate in various solvents

S.NO	SOLVENT	SOLUBILITY
1	Purified water	Soluble
2	Phosphate buffer PH 6.8	Soluble
3	Ethanol	Freely soluble
4	Choloroform	Freely soluble

Determination of melting point

The procured drug specimen's melting point was determined, since it provides a strong initial indicator of sample purity because a decrease in melting point or an increase in melting point range can both indicate the existence of very modest amounts of impurity. The drug sample melting point ranged from 123°C to 131°C.

pH

The pH of a saturated solution of Dimenhydrinate in water is between 6.8 and 7.4.

Partition coefficient

The partition coefficient (log P) of Dimenhydrinate has been experimentally determined to be 0.63. This value indicates that Dimenhydrinate has a moderate balance between hydrophilicity and lipophilicity, suggesting potential for both water and lipid solubility. This property is relevant for its absorption and distribution in the body.

Precompression evaluation of powder blend

Determination of flow properties

Bulk density

Bulk density was used to measure the flow properties of the powder. The bulk density of the powder blend was in the range of **0.58±0.03 gm/ml to 0.64±0.01 gm/ml**. The results of bulk density for all the formulations were shown in table 19. It is within the acceptable limits.

Tapped density

Tapped density was used to measure the flow properties of the powder. The tapped density of the powder blend was in the range of **0.65±0.04 gm/ml to 0.68±0.06 gm/ml**. The results of tapped density for all the formulations were shown in table 19. It is within the acceptable limits.

Carr's compressibility index

Determination of carr's index, the ratio of bulk and tapped density, was used to measure the flow property of all formulations. The decreased value of CI% would indicate the better flow Properties of the powder. The carr's index of all formulation was found to be in the range of **5.8 %to 11.6 %**. It was less than 25%, which indicates that the powder blend has required flow property for compression of tablets. The results of carr's index of all formulations were shown in the table19.

Hausner's ratio

The hausner's ratio of all formulations were found to be in the range of **1.06 to 1.13**, If the Hausner ratio lies between 1.00-1.27, it indicates good flow behavior of the granules or powder. The results indicate the powder blend possess good flow property. The results were shown in the table 19.



Angle of repose

The angle of repose is a characteristic of the internal friction or cohesion of the particles, the values will be low, if the powder is non-cohesive and high if the powder is cohesive. All the prepared formulations were in the ranges from **24.67° to 28.36°**, which indicates the good flow properties of powder blend.

Table 6: Precompression Evaluation of Powder Blend

FORMULATION	BULK DENSITY (gm/ml)	TAPPED DENSITY (gm/ml)	CARR'S INDEX	HAUSNER RATIO	ANGLE OF REPOSE (θ°)
F1	0.59±0.03	0.66±0.03	10.6	1.11	24.67
F2	0.64±0.01	0.70±0.04	8.5	1.09	26.5
F3	0.62±0.02	0.67±0.01	7.4	1.09	25.5
F4	0.58±0.03	0.65±0.02	10.7	1.12	28.36
F5	0.60±0.01	0.68±0.06	11.6	1.13	25.89
F6	0.63±0.04	0.67±0.01	5.8	1.06	27.73
F7	0.62±0.07	0.68±0.04	8.8	1.09	26.96

POST COMPRESSION EVALUATION OF ORALLY DISINTEGRATING TABLET OF DIMENHYDRINATE

Tablets of different formulations were evaluated for the postcompressional parameters such as general appearance, weight variation, hardness, thickness, friability, wetting time, water absorption ratio, in-vitro disintegration time, drug content, in-vitro dissolution test.

General Appearance

The formulated tablets were white colour, round shaped. All tablets were elegant in appearance.

Weight Variation Test

The weight was used to ensure the uniformity of the tablet in all formulations. All the formulated tablets pass the weight variations within the acceptable limits as per IP.

Thickness and Diameter

The thickness of all the tablet formulations was used to determine the uniformity of size and shape of the tablets. All the prepared tablet formulations were measured by Vernier caliper and were found to be in the range of **3.01±0.53 to 3.12±0.63 mm**. The results indicated that all the formulations had uniform size and shape.

Hardness Test

Hardness of tablet was used to determine the resistance to withstand mechanical shakes of handling in manufacture and packing. All the prepared tablets were determined using Monsanto hardness tester. The hardness of the formulation was found to be in the range of **3.31±0.57 to 3.60±0.24**, which indicates that all tablet formulations had good mechanical strength.

1 Friability Test

The friability of tablets was determined using roche friabilator and used to determine the mechanical strength of tablets the percentage friability of all the tablet formulation was found to be in the range of. It was less than 1% the results indicated that all the tablets formulation had a good mechanical resistance of tablets.

In vitro dispersion time

In vitro dispersion time of all formulated tablets lies in the range of 21 ± 0.9 - 52 ± 1.8 .

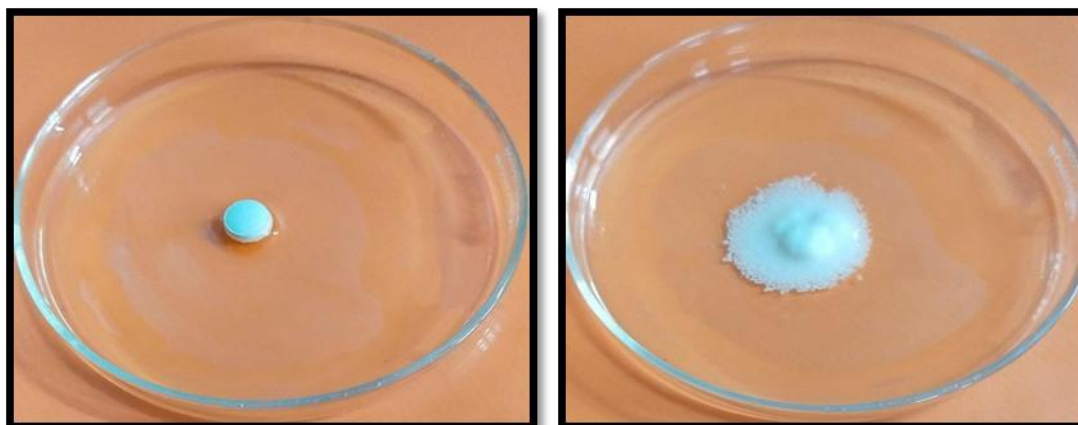


Figure 4: *Invitro* dispersion time of Oral Disintegrating Tablet at 0 and 25 seconds

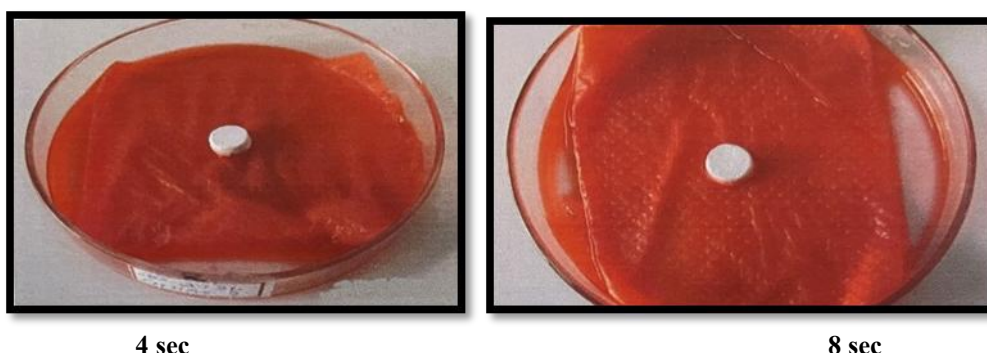
Table 7: Evaluation of Weight variation, Thickness, Hardness, Friability and *in vitro* dispersion of formulations F1-F7

Formulation code	Weight variation	Thickness and diameter (mm)	Hardness (Kg/cm ²)	Friability (%)	<i>In vitro</i> dispersion time (sec)
F1	202±0.51	3.04±0.15	3.35±0.38	0.514±0.21	52 ± 1.8
F2	205±0.42	3.06±0.64	3.41±0.57	0.571±0.19	46 ± 1.4
F3	201±0.46	3.03±0.42	3.65±0.42	0.475±0.25	33 ± 1.2
F4	203±0.52	3.07±0.61	3.60±0.24	0.567±0.17	26 ± 0.9
F5	202±0.36	3.01±0.53	3.55±0.43	0.589±0.13	28 ± 1.0
F6	203±0.49	3.06±0.95	3.81±0.28	0.465±0.29	25 ± 1.1
F7	204±0.55	3.12±0.63	3.49±0.38	0.395±0.15	41 ± 1.3

Wetting time

The wetting time of all formulations was within the range of 24–48 seconds, indicating excellent hydrophilicity and rapid water uptake. A faster wetting time corresponds to a shorter disintegration and dispersion time, improving patient compliance and rapid onset of action.

2 The optimized formulation (F4) showed the shortest wetting time (24 ± 1.0 s), attributed to the higher concentration of Crospovidone (7.5%), which promotes capillary action and enhances water penetration into the tablet matrix.



4 sec

8 sec

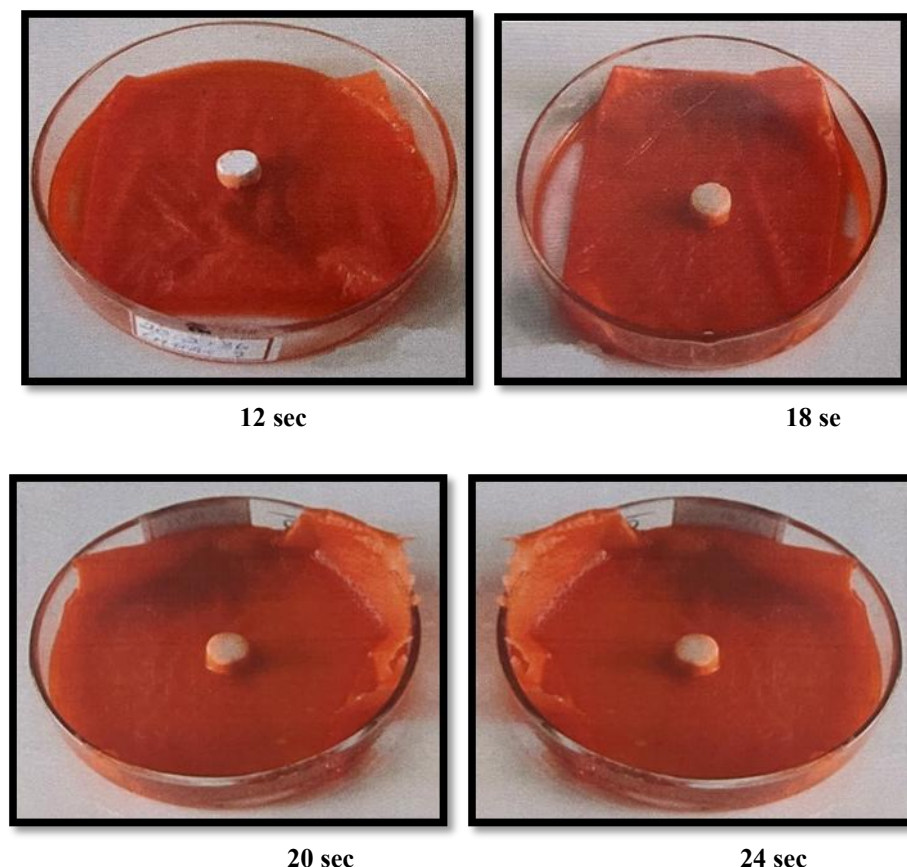


Figure 5: Wetting time for Formulation F4

Water absorption ratio

The water absorption ratio of all formulations ranged from 56.4% to 81.2%, demonstrating good hydrophilic properties and porous nature of tablet. The optimized formulation (F6) exhibited the highest R value (81.2%), which can be attributed to the enhanced capillary and wicking action of Crospovidone (7.5%) and Croscarmellose sodium (5.25%). The high R value correlates with shorter wetting and disintegration times, indicating superior water uptake and rapid tablet breakdown in the oral cavity.

Drug content Uniformity

The drug content of all formulations (F1–F7) was found in the range of **96.8% to 100.1%**,

which complies with the Indian Pharmacopoeia.

***In vitro* Disintegration time**

The disintegration time is defined as the minimum time required for the tablet to break down into smaller particles. The disintegration of the tablet reduces the particle size and consequently increases the total surface area available for dissolution of the drug at the site of disintegration. A shorter disintegration time indicates that the drug will dissolve and be absorbed rapidly from the site of administration, thereby producing a quicker onset of action. According to pharmacopoeial standards, the prescribed limit for disintegration of orally disintegrating tablets (ODTs) is 30 seconds, and in certain cases of fast-dissolving tablets, it may extend up to 3 minutes. In the present study, all the *in vitro* disintegration time values of the formulations ranged from **28.4 ± 0.23 to 45.3 ± 0.12 seconds**, which are well within the acceptable limits.

Table 8: Evaluation of Water absorption ratio, Wetting time, Drug content uniformity, *In vitro* disintegration time of formulations F1-F7

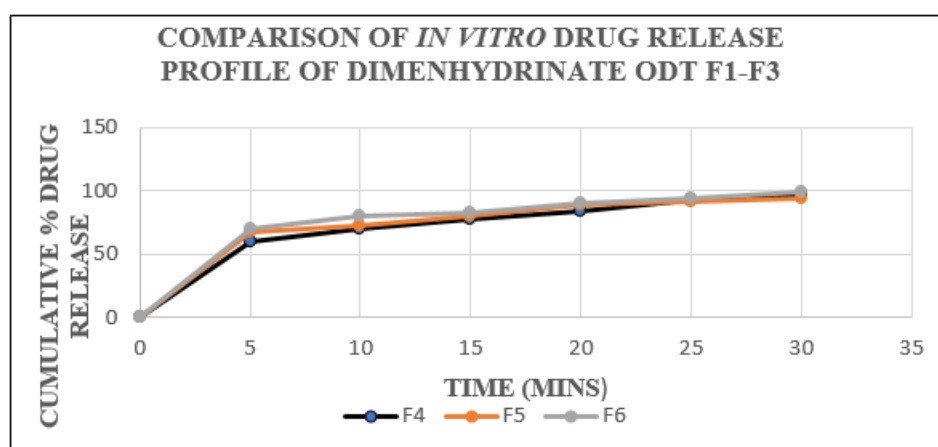
Formulation code	Water absorption ratio (%)	Wetting time (sec)	Drug content uniformity (%)	<i>In vitro</i> disintegration time (sec)
F1	56.4 ± 1.2	48 ± 1.6	96.8 ± 0.8	40.3±0.12
F2	62.3 ± 1.0	42 ± 1.4	98.2 ± 0.6	42.3±0.35
F3	74.5 ± 0.9	33 ± 1.2	99.4 ± 0.7	42.3±0.36
F4	79.1 ± 0.8	24 ± 1.0	98.1 ± 0.5	35.2±0.23
F5	77.3 ± 0.9	29 ± 1.1	99.2 ± 0.9	33.2±0.12
F6	81.2 ± 1.1	27 ± 1.0	98.7 ± 0.8	28.4±0.23
F7	64.1 ± 1.0	40 ± 1.5	97.3 ± 0.7	45.3±0.19

In vitro dissolution study

The *in vitro* drug release study of all Dimenhydrinate ODT formulations (F1–F7) was carried out using a USP Type II (paddle) dissolution apparatus. The dissolution medium, temperature, and paddle speed were maintained according to standard pharmacopeial conditions to simulate physiological conditions in the oral cavity and gastrointestinal tract. Among the seven ODT formulations (F1–F7) of Dimenhydrinate, F6 demonstrated superior performance based on the *in vitro* drug release profile. The formulation contains an optimized combination of superdisintegrants, with 7 mg of croscarmellose sodium and 7.5 mg of crospovidone, which act synergistically to promote rapid tablet disintegration through swelling, wicking, and capillary action. The release data indicate that F6 achieved 69.46% drug release within 5 minutes, reflecting a rapid onset of action, and reached 98.78% release at 30 minutes, (As per USP, ODT should release atleast 80% of drug within 30 minutes) representing nearly complete drug availability. This release behaviour surpasses that of the other formulations, which either exhibited slower initial release or lower cumulative release.

Table 9: Comparative *In Vitro* Drug Release Profile of Dimenhydrinate ODT Formulations (F1–F7)

Time (min)	F1	F2	F3	F4	F5	F6	F7
0	0	0	0	0	0	0	0
5	63.10	56.19	59.53	59.76	66.89	69.46	58.31
10	75.81	63.10	63.10	69.68	72.24	79.72	63.44
15	85.51	71.46	72.13	78.04	80.61	82.56	71.80
20	89.19	80.61	80.61	83.28	88.41	89.91	80.61
25	92.98	87.41	89.19	93.32	91.98	94.43	83.06
30	95.44	92.98	94.21	96.89	94.43	98.78	91.98


Figure 6: Comparison of *in vitro* drug release profile of Dimenhydrinate ODT F1-F3.

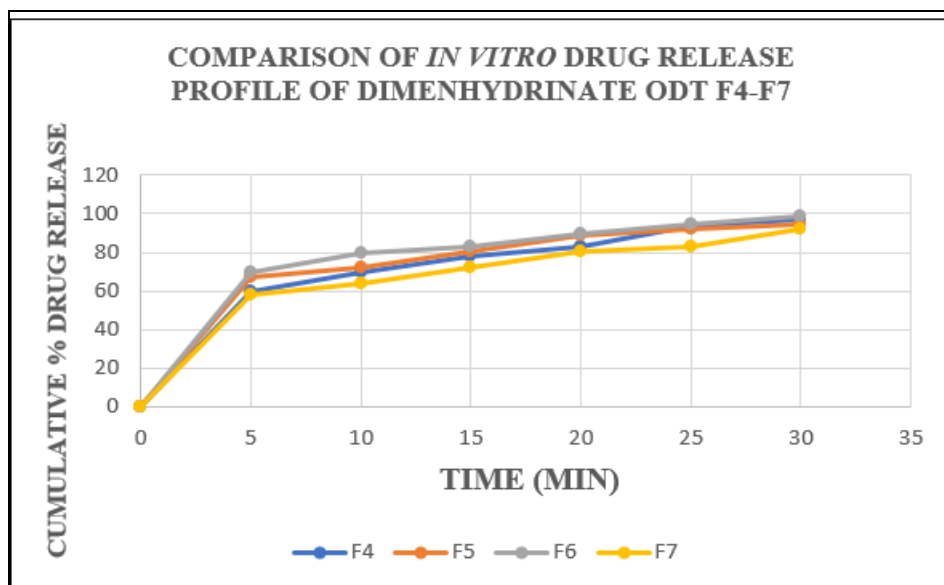


Figure 7: Comparison of in vitro drug release profile of dimenhydrinate ODT (F4-F7)

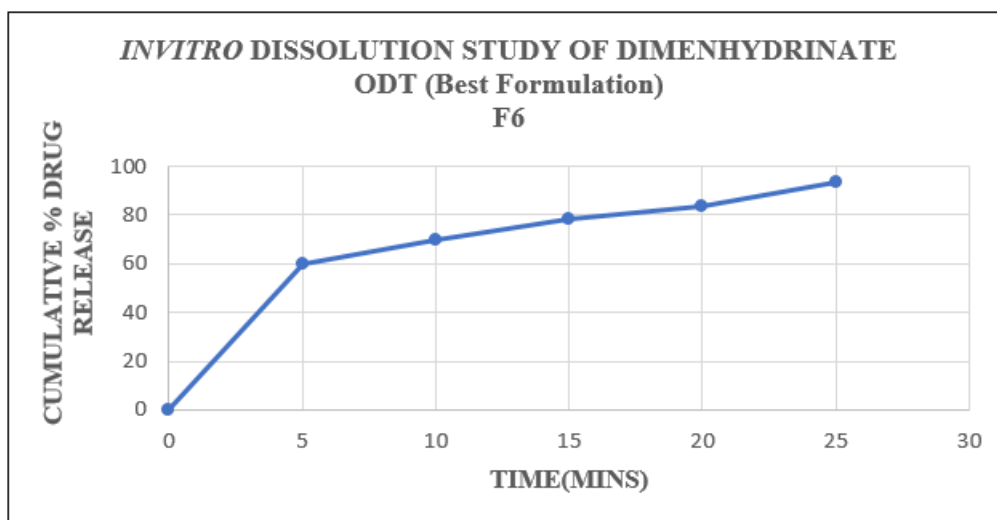


Figure 8: In vitro Drug Release profile of Best formulation F6

Table 10: In vitro Drug Release of Orally Dissolving Tablet VS Marketed Formulation

S.NO	TIME IN MINS	ODT- F6	MARKETED FORMULATION
1	0	0	0
2	5	69.46	10.12
3	10	79.72	21.54
4	15	82.56	32.96
5	20	89.91	41.78
6	25	94.43	52.14
7	30	98.78	61.01
8	35	-	70.39
9	40	-	79.15
10	45	-	81.79
11	50	-	88.54
12	55	-	91.52
13	60	-	95.32

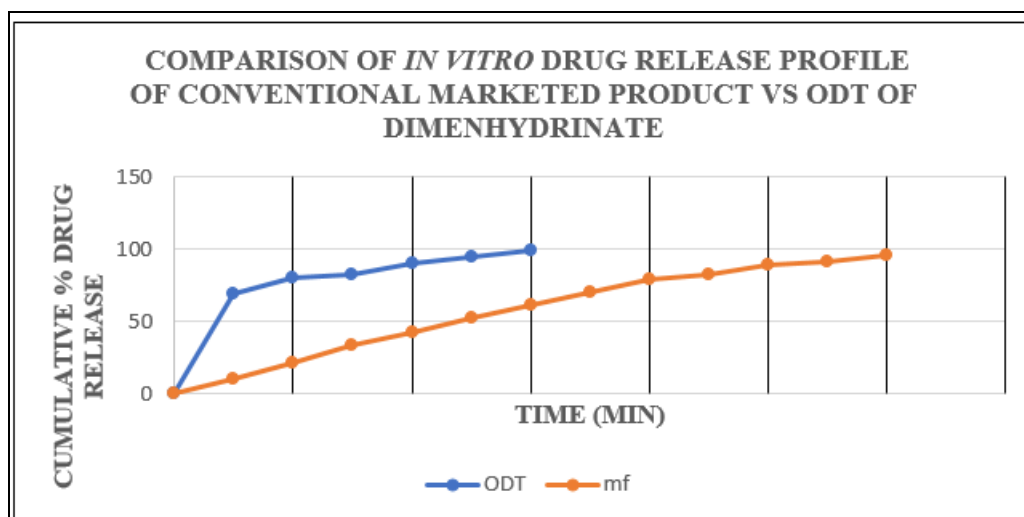


Figure 9: *In vitro* Drug Release of Dimenhydrinate ODT VS Marketed conventional tablet

9. DISCUSSIONS

The Dimenhydrinate ODTs were successfully formulated using direct compression, and the pre-compression evaluation of the powder blend indicated good flow properties, compressibility, and uniformity, making them suitable for tablet preparation. Post-compression parameters, including weight uniformity, thickness, hardness, friability, and drug content, were all within acceptable limits, confirming the mechanical integrity and dose accuracy of the tablets. The tablets exhibited rapid disintegration in simulated saliva, which is essential for fast onset of action in motion sickness management. High water absorption and wettability further supported the quick disintegration, ensuring patient-friendly administration, especially for pediatric and geriatric populations. In vitro dissolution studies showed complete and reproducible drug release, demonstrating that the ODTs can achieve efficient bioavailability comparable to conventional tablets. The study also highlighted the importance of optimized excipient selection, particularly superdisintegrants, in balancing mechanical strength and rapid disintegration. Overall, the formulated Dimenhydrinate ODTs provide a convenient, fast-acting, and effective dosage form that enhances patient compliance and therapeutic efficacy.

10. CONCLUSION

The present study successfully formulated and evaluated oral disintegrating tablets (ODTs) of Dimenhydrinate for the effective management of motion sickness. Pre-compression evaluation of the powder blends indicated good flow properties, compressibility and uniformity suggesting suitability for direct compression. Post-compression parameters, including weight uniformity, thickness, hardness, friability and drug content, were within pharmacopeial limits, confirming the tablets' mechanical integrity and dose accuracy.

Importantly, the ODTs exhibited rapid disintegration in simulated saliva, ensuring quick onset of action, which is essential for motion sickness management. In vitro dissolution studies demonstrated complete and reproducible drug release, indicating that the ODTs can provide efficient bioavailability compared to conventional oral dosage forms. The study also highlighted the critical role of excipients and formulation techniques in achieving desirable disintegration and mechanical properties. Overall, the formulated Dimenhydrinate ODTs offer a patient-friendly, fast-acting and effective alternative to conventional tablets, making them particularly suitable for pediatric, geriatric and dysphagic patients. The successful development of these ODTs demonstrates the potential of direct compression and modern excipient selection in enhancing patient compliance and therapeutic efficacy.

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Conflict of Interest Statement:

The authors have no conflicts of interest to declare.

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