Review Article

# REVIEW ON PREPARATION TECHNIQUES FOR DOMPERIDONE RAPID DISSOLVING TABLETS



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Email ID: purushotam3012@gmail.com **DOI:** https://doi.org/10.59551/IJHMP/25832069/2025.6.2.106

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Received: 18 Sept, 2025, Decision for Acceptance: 16 Oct, 2025

#### **Abstract**

Domperidone is a widely used antiemetic and prokinetic drug, but its poor water solubility and extensive first-pass metabolism limit its bioavailability and onset of action. This review focuses on the development of Domperidone rapid dissolving tablets (RDTs) as an effective strategy to overcome these challenges. Various formulation techniques such as direct compression, wet granulation, freeze drying, melt granulation, and sublimation are discussed, along with suitable excipients like super disintegrants, binders, and fillers. The review also highlights evaluation parameters including disintegration time, dissolution rate, hardness, moisture content, and stability. RDTs offer faster drug release, improved bioavailability, and enhanced patient compliance, especially among pediatric, geriatric, and dysphagic populations. The article provides insights for researchers to develop efficient, patient-friendly dosage forms.

**Keywords:** Domperidone, Rapid Dissolving Tablets (RDTs), Formulation Techniques, Bioavailability Enhancement, Disintegration and Dissolution Studies.

### 1. Introduction

Domperidone is a well-known pharmaceutical agent widely used as an antiemetic and prokinetic drug. Chemically, it is classified as a benzimidazole derivative, and its molecular structure is characterized by the presence of aromatic rings that contribute to its pharmacological activity. Domperidone primarily functions by blocking dopamine D2 receptors located in the chemoreceptor trigger zone and gastrointestinal tract, which helps in controlling nausea, vomiting, and gastric motility disorders[1]. It is commonly prescribed for conditions such as postoperative nausea, gastroparesis, functional dyspepsia, and

other gastrointestinal disturbances. Despite its established therapeutic benefits, Domperidone presents significant challenges when formulated in conventional dosage forms such as tablets or capsules. One of the major limitations is its poor water solubility, which leads to limited dissolution in the gastrointestinal fluids, thereby reducing the extent and rate of absorption. Additionally, it undergoes extensive first-pass metabolism, which further decreases its bioavailability. These factors contribute to a delayed onset of action, requiring higher doses or frequent administration, which may increase the risk of side effects[1-3]. Given these

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challenges, there is a growing interest in developing novel drug delivery systems that can enhance the performance of Domperidone. Among these, rapid dissolving tablets (RDTs) have emerged as a promising approach. RDTs are solid dosage forms designed to disintegrate and dissolve quickly in the oral cavity without the need for water, thereby facilitating faster drug release and absorption[2].

Figure 1: Domperidone structure<sup>2</sup>

The quick disintegration and rapid onset of action make RDTs particularly useful in situations where immediate relief from symptoms is required. This formulation strategy can significantly improve patient adherence, especially among specific populations such as pediatric patients, elderly individuals, and those with swallowing difficulties (dysphagia). For pediatric patients, liquid formulations are often inconvenient or inaccurate in dosing, whereas RDTs offer a stable, palatable, and easily administered alternative. In geriatric patients, reduced saliva production and swallowing difficulties often hinder effective medication intake, which RDTs can overcome by enabling fast dissolution in the mouth. Similarly, patients with neurological disorders or those recovering from surgery benefit from the ease of administration without the need for water or complex swallowing techniques[3,4].

The advantages of RDTs extend beyond ease of use. These formulations help enhance the bioavailability of poorly soluble drugs like Domperidone by promoting faster dissolution in the oral cavity and subsequent absorption through the buccal mucosa or gastrointestinal tract. They reduce the need for higher doses, thereby minimizing the risk of adverse effects. Furthermore, RDTs contribute to better patient compliance, particularly in outpatient settings

where patients may forget or skip medication due to swallowing difficulties or lack of access to water. Additionally, RDTs offer convenience in emergency or travel situations, where immediate relief from symptoms such as nausea is essential[5].

The importance of this review is to provide an in-depth understanding of formulation strategies and preparation techniques used to develop Domperidone rapid dissolving tablets. It explores various excipients, super disintegrants, solubilizers, and processing methods employed to enhance the solubility, stability, and therapeutic efficacy of Domperidone in RDT form. Moreover, the review emphasizes the relevance of these formulations in modern pharmaceutical development and patient care, highlighting their role in improving treatment outcomes and ensuring patient-centric healthcare solutions[3-4].

## 2. Objectives of this Review

This review aims to explore various formulation techniques and excipients used in Domperidone rapid dissolving tablets to enhance solubility and patient compliance and to summarizes key evaluation parameters like disintegration time, dissolution rate, stability, and bioavailability.

# 3. Methodology of Review

A. Literature Search Strategy: A systematic literature search was conducted using reputable scientific databases such as PubMed, Google Scholar, ScienceDirect, and Scopus to gather information on Domperidone rapid dissolving tablets (RDTs). Keywords including "Domperidone rapid dissolving tablet," "formulation techniques," "super disintegrants," "bioavailability enhancement," and "evaluation methods" were used in different combinations to retrieve relevant articles. This approach ensured that the search covered a wide range of research studies, formulation strategies, and evaluation techniques associated with enhancing the solubility, absorption, and patient compliance of Domperidone<sup>6</sup>.

B. Inclusion and Exclusion Criteria: The review

included studies published within the last 10 to 15 years to ensure that the findings reflected the latest advancements in pharmaceutical technology. Only peer-reviewed research articles, review papers, and pharmaceutical guidelines were considered, as they provided verified and reliable data. Articles in languages other than English, incomplete studies, or those not directly related to Domperidone RDTs were excluded to maintain the focus and relevance of the review. This filtering process helped ensure that only high-quality and scientifically valid research contributed to the analysis [6-8].

C. Data Extraction and Synthesis Approach: After identifying the relevant studies, data extraction was performed by compiling information on formulation techniques, excipient compositions, preparation methods, and evaluation outcomes. Parameters such as disintegration time, dissolution rate, stability, and bioavailability were recorded and grouped according to formulation methods and their observed effects<sup>7,8</sup>. The collected data was then synthesized to identify common trends, challenges, and effective strategies used in the development of Domperidone RDTs. This structured approach enabled the review to offer a thorough and up-to-date analysis, providing valuable insights for researchers and formulators seeking to develop efficient and patient-friendly dosage forms[9-12].

## 4. Findings of this Review

Various preparation techniques such as direct compression, wet granulation, freeze drying, melt granulation, and sublimation have been explored, each offering distinct advantages and challenges. The role of excipients, including super-disintegrants, binders, fillers, lubricants, and taste-masking agents, is highlighted for their impact on tablet performance and patient acceptability[8,9]. Evaluation parameters like disintegration time, dissolution rate, hardness, moisture content, and stability are essential in assessing the effectiveness and quality of the final product. The review also emphasizes bioavailability

enhancement and sensory evaluation as critical factors for patient adherence.

### 3.1 Techniques for Preparation of Domperidone RDTs

A. Direct Compression: Direct compression involves blending the active drug with excipients and compressing the mixture directly into tablets without prior granulation or drying steps. This method is simple, fast, and cost-effective, making it suitable for large-scale production while maintaining consistent tablet quality. Super disintegrants promote rapid disintegration, while binders and fillers provide tablet integrity and bulk[9].

Example excipients: Super disintegrants (crospovidone, croscarmellose sodium, sodium starch glycolate), binders (PVP, gelatin), fillers (lactose, microcrystalline cellulose)[9].

B. Wet Granulation: Wet granulation involves mixing the active drug with excipients, adding a suitable solvent to form a wet mass, and passing it through a sieve to produce granules, which are then dried using methods like tray drying, fluidized bed drying, or vacuum drying before compression. This technique improves uniformity and flow properties of the powder but has challenges such as stability concerns and moisture sensitivity, which can affect the drug's efficacy[9,10].

Example excipients: Binders (PVP, gelatin), fillers (lactose, microcrystalline cellulose), solvents (water, ethanol).

C. Freeze Drying (Lyophilization): Freeze drying involves dissolving or dispersing the drug in a suitable solvent, freezing the solution, and then sublimating the frozen solvent under low pressure to produce highly porous tablets. This method creates ultra-fast disintegrating tablets with rapid drug release but is limited by high cost and scalability issues[10-11].

Example excipients: Cryoprotectants (mannitol, trehalose), solvents (water)[11].

D. Melt Granulation: Melt granulation uses a binder that melts upon heating to form granules, which are cooled and compressed into tablets. Temperature control is crucial to prevent drug degradation. This method enhances tablet hardness and mechanical strength, but excessive binder or heat may slow dissolution, affecting rapid action[12].

Example excipients: Meltable binders (PEG, fatty acids), fillers (microcrystalline cellulose)[13].

E. Sublimation Technique: In sublimation, sublimable agents such as camphor or ammonium bicarbonate are incorporated into the tablet, which are later removed by heating or vacuum drying, leaving a porous structure. This high porosity reduces disintegration time, enabling faster drug release and improved absorption in RDT formulations[14-15].

Example excipients: Sublimable agents (camphor, ammonium bicarbonate), binders (PVP, gelatin).

Table 1: comparison of the dissolution profiles for each technique based on reviewed data<sup>9-16</sup>

Sr. No.	Time (min)	Direct Compression (%)	Wet Granulation (%)	Freeze Drying (%)	Melt Granulation (%)	Sublimation (%)
1	0	0	0	0	0	0
2	5	40	30	60	35	50
3	10	70	60	85	65	80
4	15	85	80	95	82	90
5	20	92	88	98	90	95
6	25	96	93	99	94	98
7	30	98	95	100	97	99

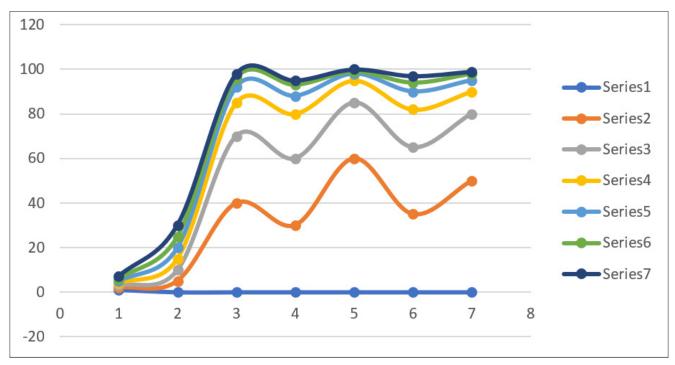


Chart 1: Comparison of the dissolution profiles for each technique<sup>9-16</sup>

Here is the chart comparing the dissolution profiles of Domperidone RDTs prepared using different techniques. It illustrates how each method impacts the rate of drug release over time, with freeze drying and sublimation showing the fastest dissolution, while direct compression and wet granulation are comparatively slower.

#### 3.1 Evaluation Parameters

A. Disintegration Time: Disintegration time is a critical parameter for rapid dissolving tablets, reflecting how quickly the tablet breaks down in the oral cavity or gastrointestinal fluids. For Domperidone RDTs, a shorter disintegration time ensures rapid release and absorption of the drug, leading to faster therapeutic action. Standard testing is performed using USP disintegration apparatus in simulated saliva or water at 37°C, with ideal disintegration typically within 30–60 seconds[10].

B. Wetting Time: Wetting time measures the ability of a tablet to absorb moisture and begin the disintegration process. It indicates the hydrophilicity of excipients and the efficiency of super disintegrants. A lower wetting time is preferred for RDTs to ensure quick dissolution in the oral cavity, enhancing patient compliance [12].

C. Dissolution Studies: Dissolution testing evaluates the rate and extent of drug release from the tablet into a suitable medium. For Domperidone RDTs, rapid dissolution is essential to improve bioavailability, especially given the drug's poor water solubility. Dissolution profiles are typically measured using USP apparatus I or II, with samples analyzed at predetermined intervals using UV spectroscopy or HPLC[13].

D. Hardness and Friability: Tablet hardness and friability assess the mechanical strength and durability of the dosage form. Adequate hardness ensures that tablets can withstand handling and transportation, while low friability (<1%) prevents excessive crumbling. Maintaining a balance is critical in RDTs to allow rapid disintegration without compromising tablet integrity[13-14].

E. Moisture Content: Moisture content influences tablet stability and dissolution. High moisture can lead to softening, reduced shelf life, or premature disintegration. Moisture is usually measured by loss on drying or using Karl Fischer titration to ensure optimal stability and performance of Domperidone RDTs.

F. Stability Studies: Stability studies evaluate how environmental factors such as temperature, humidity, and light affect the tablet over time. Accelerated and long-term stability tests are performed according to ICH guidelines to ensure that Domperidone RDTs maintain their physical, chemical, and therapeutic properties during storage[11].

G. In Vivo Bioavailability Enhancement: In vivo studies assess the absorption and pharmacokinetic profile of Domperidone from RDTs compared to conventional tablets. Enhanced bioavailability is a major objective of RDTs, achieved through rapid disintegration, improved solubility, and possible pre-gastric absorption via the oral mucosa[14].

H. Sensory Evaluation (Taste, Mouthfeel): Since RDTs dissolve in the mouth, taste and mouthfeel significantly impact patient acceptance and compliance. Taste-masking agents, sweeteners, and flavors are evaluated through sensory panels to ensure that the tablets are palatable and comfortable for patients, particularly pediatric and geriatric populations[16].

#### 5. Discussion

This review highlights the importance of developing Domperidone rapid dissolving tablets (RDTs) to overcome limitations such as poor solubility and delayed drug action in conventional forms. By exploring various preparation techniques—like direct compression, wet granulation, freeze drying, melt granulation, and sublimation—along with suitable excipients, researchers can enhance drug disintegration, dissolution, and bioavailability. The evaluation parameters ensure that tablets are stable, effective, and patient-friendly. Overall, RDTs offer a promising solution to improve therapeutic outcomes

and patient compliance, especially among vulnerable populations like pediatric and elderly patients. These advancements support more efficient and accessible pharmaceutical care.

### 6. Acknowledgement

I sincerely thank my mentors, faculty members, and the management of Dr. K. N. Modi University, Newai, for their guidance and support throughout this review. I also acknowledge the use of research databases and scientific resources that greatly assisted in gathering information and completing this work.

#### 7. Conflict of Interest: None

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Cite this article Yadav P et al., Review on Preparation Techniques for Domperidone Rapid Dissolving Tablets. Indian Journal of Health Care, Medical & Pharmacy Practice. 2025;6(2):43-48.