**IJPSR (2025), Volume 16, Issue 9** **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 03 April 2025; received in revised form, 25 April 2025; accepted, 25 August 2025; published 01 September 2025

# FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF VORTIOXETINE HBr

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**Keywords:**

Vortioxetine, Mouth Dissolving Tablets (MDTs), Orally Disintegrating Tablets (ODTs), Super disintegrants, Direct compression method

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**ABSTRACT:** Vortioxetine, a well-established antidepressant for major depressive disorder, faces limitations in traditional formulations regarding patient compliance and rapid onset of action. Mouth dissolving tablets (MDTs) offer a patient-friendly alternative, particularly beneficial for drugs with narrow therapeutic windows. This study aimed to formulate and evaluate MDTs of vortioxetine using super disintegrants (Cros povidone, Croscarmellose sodium, Sodium starch glycolate), effervescent agents, and sublimation techniques. Twelve formulations (F1–F9) were prepared *via* direct compression, each containing 4 mg vortioxetine. The tablets were evaluated for physical properties (hardness, friability, disintegration time), drug content, dissolution profiles, and stability. Results indicated rapid disintegration (85% within 10 minutes). Stability studies over 45 days showed no significant changes in drug content or disintegration time. The optimized formulation (F9) demonstrated superior performance, with 98.5% drug release at 10 minutes. MDTs of vortioxetine present advantages such as enhanced patient compliance, ease of administration, and potential for faster therapeutic effects. This study underscores the potential of MDTs as a viable alternative to conventional tablets, particularly for patients with dysphagia. Further clinical studies are warranted to validate these findings.

**INTRODUCTION:** The concept of mouth dissolving tablets, also known as orally disintegrating tablets (ODTs), represents a fascinating innovation in the pharmaceutical industry. These tablets have garnered significant attention and interest due to their unique characteristics and advantages [8]. Unlike traditional tablets or capsules that need to be swallowed whole, ODTs are designed to rapidly disintegrate in the mouth without the need for water.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.16(9).3635-41

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.16(9).3635-41

This groundbreaking formulation not only offers convenience for patients who may have difficulty swallowing pills but also provides potential benefits for drug absorption and onset of action. In this journal introduction, we will delve into the history, formulation, manufacturing processes, and various applications of mouth dissolving tablets, exploring how they have revolutionized drug delivery and patient compliance in the field of medicine [11].

Vortioxetine is an antidepressant medication used to treat major depressive disorder. While it is commonly available in standard tablet form, there may also be mouth-dissolving or orally disintegrating tablet (ODT) formulations of vortioxetine available in some regions or under certain brand names. Orally disintegrating tablets

are designed to dissolve rapidly in the mouth without the need for water or swallowing. This can be particularly useful for people who have difficulty swallowing pills or for those who prefer a more convenient way to take their medication [12]. The rapid dissolution in the mouth allows for faster absorption of the drug into the bloodstream. Patients prescribed vortioxetine in orally disintegrating tablet form should follow their healthcare provider's instructions for usage carefully. It's typically placed on the tongue, where it will dissolve quickly. You should avoid chewing or swallowing the tablet whole. It's important to note that specific instructions for vortioxetine MDT and its availability can vary by region and pharmaceutical manufacturer, so it's advisable to consult your healthcare provider or pharmacist for guidance specific to your prescription and location. Additionally, always follow the prescribed dosage and treatment plan provided by your healthcare professional when taking any medication [13-15].

**MATERIAL AND METHOD:** The compounds that were utilized in this research were purchased from several commercial sources, and they were utilized without undergoing any additional purification processes. Chemical and drug are – vortioxetine, Crospovidone, Croscarmellose sodium, Sodium starch glycolate, Sodium bicarbonate, Citric acid, Lactose monohydrate, Microcrystalline cellulose, Stevea, Magnesium stearate, Purified talc, Sodium chloride and Sodium Hydroxide [14].

**Formulation of Vortioxetine HBr MDTs:** Mouth dissolving tablets of selected drugs were prepared by direct compression method using three different approaches; superdisintegrant addition, effervescence and sublimation, in addition to combined approaches according to the formulae given. Mouth dissolving tablets of Vortioxetine contains 4mg of pure drug. Total weight of the tablet 100 mg were prepared for all the formulations. In all formulations lactose monohydrate and mannitol were used as diluents [15]. For tablets prepared by sublimation approach using camphor as a sublimating agent. For tablets prepared by the effervescence approach, sodium bicarbonate and citric acid were used. For tablets prepared by superdisinterant approach Crospovidone, Croscarmellose sodium and sodium starch glycolate were used as superdisintegrants [16].

The specified quantity of the drug and the other excipients were weighed accurately and passed through 40 # screen prior to mixing. The magnesium stearate was individually passed through #60 mesh. The blend was lubricated with magnesium stearate.

The resulting powder mixture was compressed into tablets using single punch tablet machine (Erweka, Germany) using 8 mm flat surface punches. The compression force was adjusted to give tablet hardness in the pharmacopeial range of mouth dissolving tablets (2–4 kg/cm$^3$). In all formulations the weighed amounts of drug and lactose were mixed first then other excipients were mixed thoroughly to load the drug on the surface of water-soluble carriers. Twelve formulations were designed for vortioxetine [18-20].

**TABLE 1: COMPOSITION OF VORTIOXETINE HBR MOUTH DISSOLVING TABLET FORMULATIONS**

| Ingredients (In mg) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| Vortioxetine HBr (eq) | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Citric Acid | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Sodium Starch Glycolate | 1 | 2 | 5 | - | - | - | - | - | - |
| Cross povidone | - | - | - | 1 | 2 | 5 | - | - | - |
| Croscarmellose | - | - | - | - | - | - | 1 | 2 | 5 |
| Lactose | 82 | 81 | 78 | 82 | 81 | 78 | 82 | 81 | 78 |
| Stevea | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Talc | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Magnesium Stearate | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Total | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |

**Evaluation:** A granule refers to a conglomeration of constituent particles that are bound together due to the existence of bonds possessing limited strength. The present investigation utilized the direct compression method. The dissolving rate of pharmaceuticals included in a heterogeneous

formulation can be considerably influenced by many physical features of granules, including specific surface area, shape, hardness, surface characteristics, and size. The granules of twelve distinct formulations were assessed for several physical properties, including angle of repose, loose bulk density (BD), tapped density (TD), compressibility index (CI), and Hausner's ratio. The findings were presented in Table 6.8. The powder exhibited a high level of cohesion, resulting in its inability to pass through the funnel. In contrast, the granules displayed angle of repose values ranging from 31.08°±0.032 to 39.36°±0.024. The Hausner's ratio values of the Vortioxetine granules that were produced were determined [21]. The values observed ranged from 1.12±0.05 to 1.36±0.04. The latter observation was believed to suggest favorable flow characteristics of the granules that were manufactured. The % compressibility, which is a metric devised by Carr to indirectly measure the flow ability of powder from its bulk densities. The study determined that the % compressibility of Vortioxetine was within the range of 11.11± 1.19 to 26.96±1.23. The obtained outcome exhibited a strong concurrence with the findings related to the angle of repose, hence substantiating the notion that granulation positively influenced both the flow characteristics and compressibility properties.

The bulk density of the granules exhibited a range of 0.65 ± 0.02 to 0.72 ± 0.03, while the tapped density of the granules ranged from 0.81 ± 0.01 to 0.89 ± 0.01. Ultimately, the levels and types of disintegration did not significantly impact the physical qualities of the granules. The obtained results were deemed to be satisfactory. Mannitol was employed as a diluent to enhance the flow characteristics of the granules. The superior compressibility of mannitol can be ascribed to its inherent nature. In order to reduce disintegration time and wetting time, three distinct methodologies were employed, namely the utilization of superdisintegrants, sublimation, and effervescent chemicals, each at varying concentrations. The results presented in this study also demonstrates that an elevated ratio of diluents to drug is associated with improved compressibility index of the granules in Vortioxetine formulations **Table 2.** All the formulation mixes exhibited favorable flow qualities, which therefore facilitated the preparation of tablets using the direct compression method. The direct compression method is primarily characterized by two critical features, namely, favorable flow properties and desirable compressibility. The flow characteristics of powder are influenced by interactions between particles [22-25].

**TABLE 2: FLOW PROPERTIES OF TABLET BLEND FOR VORTIOXETINE**

| S. no. | Bulk Density | Tapped Density | Hausner's Ratio | Carr's Index | Angle of Repose(θ) |
|---|---|---|---|---|---|
| F1 | 0.65±0.02 | 0.89±0.01 | 1.36±0.04 | 26.96±1.23 | 38.95±0.02 |
| F2 | 0.68±0.04 | 0.86±0.05 | 1.26±0.03 | 20.93±1.19 | 39.36±0.024 |
| F3 | 0.68±0.02 | 0.85±0.04 | 1.25±0.04 | 20.00±1.54 | 39.02±0.034 |
| F4 | 0.69±0.06 | 0.85±0.08 | 1.23±0.03 | 18.82±1.12 | 38.92±0.071 |
| F5 | 0.67±0.03 | 0.83±0.03 | 1.24±0.08 | 20.23±1.34 | 38.25±0.043 |

**Development of Vortioxetine HBr Mouth Dissolving Tablets:** Vortioxetine HBr mouth dissolving tablets were created using three distinct techniques, including superdisintegrant addition, sublimation, and effervescence. Table 6.9 presents the physical parameters of various batches of produced mouth dissolving tablets containing Vortioxetine Hbr. The investigation of these qualities was conducted by means of ascertaining. The study aimed to determine the mean weight, thickness, drug content, hardness, friability, disintegration time, and wetting time of the tablets that were manufactured [23]. The mean percentage of deviation for 20 tablets of each formulation is below 3%, indicating that all the formulations meet the official criteria for weight uniformity. The thickness of the Vortioxetine Hbr tablets that were manufactured exhibited a range of 1.84 ± 0.52 mm to 2.84 ± 0.16 mm. Furthermore, it was noted that the augmentation of disintegrant concentration did not lead to a noticeable modification in the thickness of the tablet formulation. The obtained results suggest that the disintegrant does not have a significant impact on the binding characteristics of the formulations. The tablets from various batches exhibit a high level of homogeneity in drug content, as evidenced by the fact that all measured values fall within the range of 87% to 98 % of the stated claim. Typically, an elevation in the concentration of the diluent is associated with an

augmentation in hardness values. Nevertheless, the measure of hardness does not serve as an unequivocal sign of strength. The hardness of the tablets that were manufactured exhibited a range of 3.5 ± 0.2 to 5.0 ± 0.26 kg/cm$^2$. The friability values of the produced tablets were observed to be within the range of 0.16 ± 0.02 to 0.83 ± 0.03. According to the European pharmacopoeia, a loss of up to 1% is deemed permissible. The disintegration time and wetting time of all formulations were observed to range from 49 ± 2.3 to 13 ± 1.4 and 45 ± 1.3 to 12 ± 0.9, respectively. Hence, these findings were deemed acceptable [24]. No significant variation in the friability was noticed among the tablets made utilizing varied concentrations of disintegrants. The obtained results from the thickness measurement were consistent with the findings, so providing support for the notion that the used disintegrant does not affect the binding capabilities. All tablet formulations exhibited satisfactory pharmaco-technical characteristics and adhered to the prescribed criteria for weight fluctuation, drug content, hardness, and friability. The findings were shown in **Table 3.**

**TABLE 3: PHYSICAL CHARACTERISTICS OF FORMULATED TABLETS OF VORTIOXETINE HBr**

| S. no. | Thickness (mm) | Hardness (Kg/cm2) | Friability (%) | DT (sec) | Weight Variation (mg) | Drug content (%) |
|---|---|---|---|---|---|---|
| F1 | 1.91±0.16 | 3.5±0.2 | 0.83±0.03 | 49±2.3 | 110±1.45 | 96 |
| F2 | 1.84±0.22 | 3.7±0.5 | 0.54±0.04 | 40±2.1 | 102±1.67 | 87 |
| F3 | 2.01±0.13 | 4.0±0.32 | 0.47±0.03 | 34±1.9 | 101±1.34 | 95 |
| F4 | 2.10±0.09 | 4.2±0.45 | 0.32±0.05 | 35±1.4 | 101±1.34 | 97 |
| F5 | 2.58±0.07 | 3.5±0.39 | 0.65±0.06 | 41±2.4 | 102±1.35 | 97 |
| F6 | 2.36±0.21 | 3.5±0.27 | 0.78±0.03 | 38±1.9 | 101±1.56 | 96 |
| F7 | 2.65±0.23 | 4.0±0.21 | 0.58±0.07 | 36±2.3 | 105±1.64 | 96 |
| F8 | 2.84±0.16 | 4.0±0.43 | 0.52±0.06 | 29±1.8 | 102±1.23 | 97 |
| F9 | 2.48±0.24 | 4.5±0.51 | 0.29±0.04 | 25±2.7 | 102±1.26 | 98 |

*The values were represented as Mean±SD; (n=3).

*In-vitro* release studies of developed Vortioxetine HBr mouth dissolving tablets an appropriate in vitro dissolving method is a crucial tool for quality control purposes, as it allows for the evaluation of batch-to-batch release performance and ensures the physiological availability of the drug. The utilization of the *in-vitro* dissolution test extends to the facilitation of formulation development and the surveillance of production operations.

The regulatory test is employed to evaluate and authorize small modifications in formulation, changes in manufacturing location, and the scaling up of the bio-batch to the production batch. All of the experimental groups have demonstrated that there is a positive correlation between the concentration of the disintegrant and the observed effects. The drug release rates pertaining to Vortioxetine HBr mouth dissolving tablets were presented in **Table 4** and **Fig. 1** [25]. However, it was observed that the release of the medication from these tablets exhibited an upward trend as the concentration of the disintegrant employed in the formulation increased. Moreover, the release rate was augmented through the incorporation of a subliming agent and an effervescent component.

The formulation exhibits a notable concentration of effervescent material, and the use of crospovidone demonstrates a favorable release rate within a 10-minute timeframe when compared to alternative formulations. Therefore, it may be inferred that the release of medicines in vitro is directly influenced by their solubility in the dissolving medium [25-26].

**TABLE 4: *IN-VITRO* DISSOLUTION STUDY FOR VORTIOXETINE HBr**

| Time (Min) | Cumulative % drug release | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 40.5 | 51.8 | 60.5 | 66.3 | 59.8 | 62.5 | 69.8 | 79.5 | 86.2 |
| 4 | 87.5 | 89.3 | 90.7 | 91.8 | 89.5 | 91.2 | 90.3 | 89.7 | 93.5 |
| 6 | 88.8 | 93.5 | 93.8 | 94.2 | 94.5 | 93.2 | 91 | 92.8 | 95.5 |
| 8 | 89.5 | 91.8 | 92.5 | 97.8 | 89.7 | 92.3 | 93.5 | 95.8 | 97.5 |
| 10 | 88.2 | 91.5 | 92 | 97.5 | 89.2 | 92 | 93 | 96.5 | 98.5 |

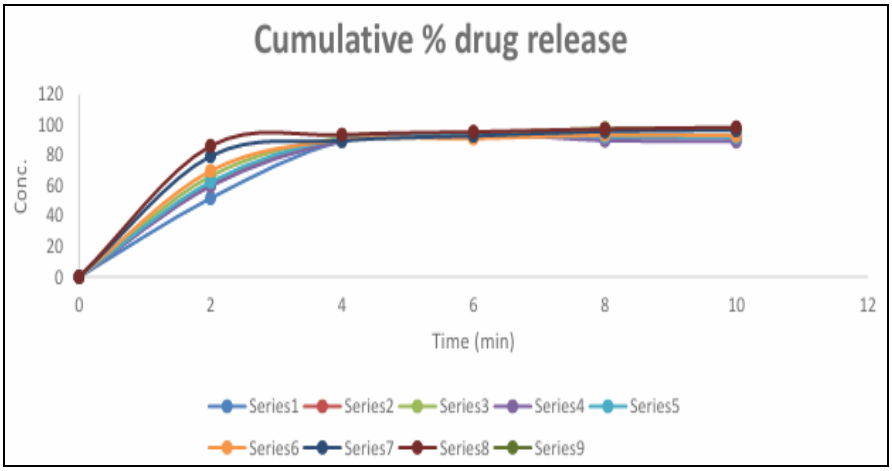


**FIG. 1: *IN-VITRO* RELEASE PROFILE OF F1-F12**

**Stability Study of Optimized Batch:** The optimized tablet formulations (F12) were stored in glass bottles with cotton placed at the headspace and securely sealed with closures. The optimized batches were held under ambient conditions of room temperature and 60% relative humidity, with variations in light exposure (dark and light) and container type (amber and light-colored glass vials). The maintenance of relative humidity was achieved by utilizing a saturated salt solution of ammonium nitrate (NH4NO3). The stability of the formulation was evaluated through a comparative analysis of the results obtained from *in-vitro* disintegration, percentage of drug content, and changes in color. The formulation was systematically sampled at consistent time intervals throughout a period of 45 days.

**TABLE 5: RESULTS OF STABILITY STUDIES ON COLOR OF OPTIMIZED PREPARATION AFTER 15, 30, AND 45 DAYS STORAGE AT ROOM TEMPERATURE AND 60% RELATIVE HUMIDITY**

| S. no. | Time (days) | Change in color | |
|---|---|---|---|
| | | Dark condition | Light Condition |
| 1 | 15 | * | * |
| 2 | 30 | * | * |
| 3 | 45 | * | * |

*Nochange, + Slightchange

**TABLE 6: RESULTS FROM STABILITY STUDIES OF OPTIMIZED BATCH AFTER 0, 15, 30, AND 45 DAYS STORAGE AT ROOM TEMPERATURE AND 60% RELATIVE HUMIDITY**

| S. no. | Time (days) | Evaluation Parameters | |
|---|---|---|---|
| | | Disintegration time (Sec.) | % Drug content |
| 1 | 0 | 4.84 ± 0.65 | 99.98 |
| 2 | 15 | 5.53 ± 0.72 | 98.79 |
| 3 | 30 | 6.08 ± 0.30 | 98.54 |
| 4 | 45 | 6.31 ± 0.5 | 98.42 |

*±SD (n=3).

Results of stability studies **Table 5** showed that there was no change in color of formulation. Result shown in **Table 6** indicated that no significant difference in the in vitro disintegration times and % drug content of the optimized formulation during storage for 45 days [28-30].

**CONCLUSION:** This research focuses on the preparation of mouth dissolving tablets of selected drugs using the direct compression method. The compounds used were obtained from various commercial sources and did not undergo any additional purification processes. The tablets were prepared using three different approaches: superdisintegrant addition, effervescence, and sublimation, as well as combined approaches. The tablets contained 4mg of pure drug and were prepared in batches of 100 mg. The granules were assessed for physical properties such as angle of repose, loose bulk density, tapped density, compressibility index, and Hausner's ratio.

The results showed that the granules exhibited a high level of cohesion and a high angle of repose value. Mannitol was used as a diluent to enhance the flow characteristics of the granules. To reduce disintegration time and wetting time, three distinct methodologies were employed: superdisintegrants, sublimation, and effervescent chemicals. The results also showed that an elevated ratio of diluents to drug was associated with improved compressibility index in Vortioxetine Hbr formulations. All formulation mixes exhibited favorable flow qualities, facilitating the preparation of tablets using the direct compression method.

The study aimed to determine the mean weight, thickness, drug content, hardness, friability, disintegration time, and wetting time of the manufactured tablets. The results showed that all formulations met the official criteria for weight uniformity, with a mean percentage of deviation below 3%.

The tablets from various batches showed high homogeneity in drug content, with all measured values falling within the range of 87% to 98 % of the stated claim. The disintegration time and wetting time were acceptable, with no significant variation in friability. The tablet formulations exhibited satisfactory pharmaco-technical characteristics and adhered to the prescribed criteria for weight fluctuation, drug content, hardness, and friability. The *in-vitro* dissolving method is crucial for quality control purposes, allowing for evaluation of batch-to-batch release performance and ensuring drug availability. The release of medication from the tablets exhibited an upward trend as the concentration of the disintegrant increased. The stability of the formulation was evaluated through a comparative analysis of *in-vitro* disintegration, percentage of drug content, and changes in color. Results showed no change in color or significant difference in *in-vitro* disintegration times and % drug content during storage for 45 days.

**ACKNOWLEDGEMENTS:** The authors acknowledge the Modern Institute of Pharmaceutical Science, Indore, for providing the necessary facilities and support to conduct this research. We also extend our gratitude to the laboratory staff for their technical assistance.

**CONFLICT OF INTEREST:** The authors declare no conflict of interest regarding the publication of this manuscript.

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**How to cite this article:**
Pathak S, Shaikh G, Malviya S and Kharia A: Formulation and evaluation of mouth dissolving tablets of vortioxetine HBr. Int J Pharm Sci & Res 2025; 16(9): 3635-41. doi: 10.13040/IJPSR.0975-8232.16(9).3635-41.