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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF ONDANSETRON HYDROCHLORIDE USING DIFFERENT SUPER DISINTEGRANTS

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ABSTRACT

Fast dissolving tablets (FDTs), commonly known as orally disintegrating tablets (ODTs), are an innovative pharmaceutical dosage form developed to rapidly break down or dissolve in the mouth without requiring water for administration. These formulations provide significant benefits to special patient groups, including children, elderly individuals, patients with swallowing difficulties (dysphagia), bedridden individuals, and mentally challenged patients, as they reduce the discomfort and inconvenience associated with swallowing traditional solid dosage forms such as tablets and capsules. Ondansetron hydrochloride is a highly effective and selective 5-hydroxytryptamine-3 (5-HT3) receptor antagonist extensively prescribed to prevent and manage nausea and vomiting caused by chemotherapy, radiotherapy, and surgical procedures. Although conventional oral formulations of ondansetron are therapeutically effective, maintaining patient adherence may become difficult, especially in individuals suffering from vomiting episodes. Fast dissolving tablet formulations help address this issue by enabling quick disintegration in the oral cavity, promoting rapid drug release and absorption, and potentially providing a faster therapeutic response.

KEYWORDS: Fast dissolving tablets (FDTs), Orally disintegrating tablets (ODTs), Ondansetron hydrochloride, 5-HT3 receptor antagonist, Antiemetic drug, Drug delivery system, Rapid disintegration, Patient compliance, Nausea and vomiting, Oral drug delivery.

INTRODUCTION

The oral route of drug administration has long been regarded as the most convenient and widely accepted method due to its simplicity, better patient compliance, and economic advantages. Nevertheless, conventional oral solid dosage forms such as tablets and capsules often require sufficient water for swallowing, which may create difficulties for specific patient groups, including pediatric, geriatric, and dysphagic patients. To address these concerns, fast dissolving tablets (FDTs) emerged as an advanced and patient-friendly drug delivery approach.

According to the United States Pharmacopeia (USP), fast dissolving tablets are described as uncoated tablets intended to be placed in the oral cavity, where they rapidly disintegrate or dissolve before being swallowed. Similarly, the European Pharmacopoeia characterizes them as orodispersible tablets that quickly break down in the mouth prior to swallowing. Typically, these dosage forms disintegrate within one minute after placement on the tongue, while modern formulations may achieve disintegration in less than 30 seconds.

The development of fast dissolving tablet technology began in the late 1970s as an innovative strategy to improve oral drug delivery. Considerable progress in this field was observed following the introduction of Zydis technology by R.P. Scherer, which enabled the production of Claritin Reditabs containing loratadine. Since that time, various formulation approaches and manufacturing technologies have been introduced, leading to substantial advancements in the development of fast dissolving tablets.

RATIONALE FOR SELECTING ONDANSETRON HYDROCHLORIDE AND THE NEED FOR FAST DISSOLVING TABLETS

About Ondansetron Hydrochloride

Ondansetron hydrochloride (OHCl) is a highly potent and selective antagonist of the 5-hydroxytryptamine-3 (5-HT3) serotonin receptor. Chemically, it is identified as 1,2,3,9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-onemonohydrochloride dihydrate. The drug was originally developed by GlaxoSmithKline (GSK) and was commercially introduced in 1991 under the brand name Zofran.

The molecular formula of ondansetron hydrochloride is $C_{18}H_{19}N_3O \cdot HCl \cdot 2H_2O$, with a molecular weight of 365.85 g/mol and a CAS number of 99614-02-5.

Physically, ondansetron hydrochloride appears as a white to off-white crystalline powder. It is freely soluble in water, slightly soluble in alcohol, and practically insoluble in ether. The drug possesses a pKa value of 7.4 and a log P value of 2.4, reflecting its amphiphilic

characteristics, which may support absorption through the buccal mucosa and contribute to enhanced drug delivery.

Advantages

5.1.1 Patient-Centric Advantages

Advantages of Fast Dissolving Tablets (FDTs)

No requirement for water: Fast dissolving tablets disintegrate rapidly in the presence of saliva, eliminating the need for water during administration. This feature makes them highly suitable for patients with limited access to water or those advised to restrict fluid intake.

Convenient administration: These dosage forms are especially useful for pediatric and geriatric populations, as well as for patients with swallowing difficulties, bedridden individuals, and mentally challenged patients, providing a more comfortable mode of drug administration.

Enhanced patient compliance: The simplicity and convenience associated with FDT administration can improve medication adherence, particularly among patients undergoing long-term or chronic treatment.

Suitable for self-medication: Fast dissolving tablets offer greater portability and convenience, making them an appropriate option for individuals who need to take medication while traveling or during work-related activities away from home.

Better psychological acceptance: Patients experiencing fear or anxiety related to swallowing conventional tablets, commonly referred to as phagophobia, often find fast dissolving tablets more acceptable and easier to use.

Disadvantages

- **Dose limitation:** Fast dissolving tablets are generally more appropriate for drugs administered in low to moderate doses, usually below 50 mg. Incorporating higher drug doses may increase tablet size, which can negatively affect rapid disintegration and patient acceptability.
- **Mechanical weakness:** Due to their highly porous structure, FDTs tend to be more fragile and friable compared to conventional tablets. As a result, they are more vulnerable to damage during manufacturing, packaging, transportation, and handling.
- **Difficulty in taste masking:** Many active pharmaceutical ingredients possess an unpleasant or bitter taste, making effective taste masking essential. Techniques such as

spray drying, microencapsulation, and cyclodextrin complexation are commonly employed, but these methods may increase formulation complexity and production costs.

- **Sensitivity to moisture:** The porous matrix of fast dissolving tablets makes them prone to moisture absorption, which may result in premature disintegration, reduced stability, and possible drug degradation. Therefore, specialized moisture-resistant packaging, such as blister packs, is often necessary.
- **Restricted drug loading capacity:** The inclusion of excipients such as super-disintegrants, sweeteners, flavoring agents, and binders reduces the available space for the active drug component, thereby limiting the amount of drug that can be incorporated into the formulation.

Types of Oral/Buccal Cavity Formulations

The oral cavity provides several distinct regions for drug delivery. Oral cavity formulations can be classified based on their mechanism of drug release and the site of drug absorption:

6.1 Sublingual Tablets and Films

Sublingual formulations are placed under the tongue where the highly permeable and vascularized sublingual mucosa facilitates rapid drug absorption directly into the systemic circulation. Examples include nitroglycerin sublingual tablets, buprenorphine sublingual tablets, and sublingual apomorphine. Sublingual films (e.g., buprenorphine/naloxone, Suboxone film) provide an alternative to tablets with improved dose accuracy and dissolution.

6.2 Buccal Tablets and Patches

Buccal formulations are designed to be retained between the upper gum and cheek (buccal pouch) for an extended period, allowing sustained drug release and absorption through the buccal mucosa. Buccal tablets (e.g., Suscard Buccal – nitroglycerin) are bio-adhesive systems that remain attached to the buccal mucosa. Buccal patches (e.g., Striant – testosterone buccal system) provide sustained transmucosal delivery over hours to days.

6.3 Orally Disintegrating / Fast Dissolving Tablets (ODTs/FDTs)

Orally disintegrating tablets are placed on the tongue and disintegrate within 60 seconds (typically 15–30 seconds) in the presence of saliva, forming a dispersion that is swallowed. The drug may be absorbed from the oral mucosa or from the GI tract after swallowing. Examples include Zofran ODT (ondansetron), Claritin Redi-tabs (loratadine), Risperdal M-Tab (risperidone), and Zyprexa Zydis (olanzapine).

6.4 Mucoadhesive Drug Delivery Systems

Mucoadhesive systems use bio-adhesive polymers (e.g., Carbopol, HPMC, chitosan, sodium alginate) to adhere to the oral mucosal surface for a prolonged period, enabling sustained and controlled drug release. These include mucoadhesive tablets, films, patches, gels, and microspheres designed for both local (aphthous ulcer treatment) and systemic drug delivery.

Methods of Preparation of Fast Dissolving Tablets

Various techniques are utilized in the formulation and manufacturing of fast dissolving tablets (FDTs). The choice of a suitable preparation method is influenced by multiple factors, including the physicochemical characteristics of the drug, formulation stability, economic feasibility, and the required rate of tablet disintegration. Selecting an appropriate manufacturing approach is essential to achieve optimal performance, effectiveness, and patient acceptability of the final dosage form.

Direct Compression

Direct compression is considered one of the simplest, most economical, and commonly employed techniques for the formulation of fast dissolving tablets (FDTs), including the formulations developed in the present study. In this method, the active pharmaceutical ingredient and excipients are uniformly blended and compressed directly into tablets without undergoing any granulation process. Successful formulation through direct compression requires excipients possessing excellent flowability and compressibility characteristics. Additionally, superdisintegrants are incorporated into the formulation blend to promote rapid tablet disintegration when exposed to saliva.The direct compression method offers several advantages, including a reduced number of processing steps, which simplifies manufacturing. Since the process does not involve exposure to heat or moisture, it is particularly suitable for thermolabile and moisture-sensitive drugs. Furthermore, this method is cost-effective, ensures consistent tablet quality, and is highly appropriate for large-scale industrial production.

Wet Granulation

Wet granulation is a widely used tablet manufacturing technique in which the drug and excipients are blended with a suitable binding solution, such as water, ethanol, or an aqueous polymeric solution, to produce granules. These granules are subsequently dried, sized, mixed with extragranular excipients, and compressed into tablets. This method is generally preferred when direct compression is unsuitable due to inadequate flowability or poor compressibility of the drug substance. The wet granulation process improves granule cohesion, resulting in tablets with enhanced mechanical strength and uniformity. However, the involvement of moisture and elevated temperatures during processing may adversely affect moisture-sensitive drugs and superdisintegrants, potentially influencing the performance of fast dissolving tablets.

Lyophilization (Freeze-Drying) – Zydis Technology

Lyophilization, also known as freeze-drying, is a technique used in the preparation of fast dissolving tablets in which the drug is formulated as a solution or suspension and filled into preformed blister cavities. The formulation is then subjected to a freeze-drying process to create highly porous and lightweight tablet matrices. Due to their porous structure, these tablets exhibit exceptionally rapid disintegration and dissolution, generally occurring within 2 to 10 seconds. One of the most successful commercially available freeze-dried fast dissolving tablet technologies is Zydis technology, currently owned by Catalent. Several pharmaceutical products developed using this technology include Claritin Reditabs, Maxalt-MLT, ondansetron formulations such as Zofran Zydis, and olanzapine-based Zyprexa Zydis.

Despite its advantages, lyophilization is associated with certain limitations, including high production costs and the need for specialized storage conditions, such as cold chain maintenance, to preserve product stability.

Spray Drying

Spray drying is a formulation technique in which a solution or suspension containing the drug and excipients is atomized into a chamber supplied with heated air or gas, resulting in the formation of dry and highly porous particles. These spray-dried particles are subsequently blended with superdisintegrants and lubricants before compression into fast dissolving tablets. The process generates particles with superior flow characteristics and a large surface area, which enhance the rate of drug dissolution and tablet disintegration. However, the elevated temperatures involved in the process may negatively affect thermolabile drugs.

Melt Granulation

Melt granulation, also referred to as thermoplastic granulation, involves the use of low-melting binders such as polyethylene glycol (PEG), polyethylene oxide, or sugar alcohols. These binders are heated until melted and then mixed with the active drug and excipients to form granules. Upon cooling, the granules solidify and are compressed with superdisintegrants to prepare fast dissolving tablets. This approach eliminates the need for liquid binders and drying procedures, making it particularly advantageous for drugs sensitive to moisture.

Sublimation Technology

Sublimation technology is based on the incorporation of volatile materials, including camphor, menthol, or ammonium bicarbonate, into the tablet formulation along with the drug and excipients. After tablet formation, the volatile agents are removed through sublimation, typically by heating under vacuum or reduced pressure conditions. This process creates a highly porous tablet structure, which promotes faster water penetration and enhances tablet disintegration.

Molding Technology

Molding technology involves preparing a drug-containing solution or suspension using water or a water-alcohol mixture, followed by shaping the formulation into tablets using low compression pressure in preformed molds or blister cavities. The molded tablets are subsequently dried or freeze-dried to obtain soft tablets with rapid dissolution properties. This

technology has been utilized in systems such as FlashMelt developed by CIMA Labs and related fast dissolving tablet formulations.

Method	Approximate Disintegration Time	Production Cost	Major Limitation
Direct Compression	15–60 seconds	Economical	Requires excipients with excellent flow and compressibility characteristics suitable for direct compression.
Wet Granulation	30–90 seconds	Moderate	Exposure to moisture and heat during processing may negatively influence moisture-sensitive drugs or superdisintegrants.
Lyophilization (Zydis Technology)	2–10 seconds	Very High	Requires specialized cold storage conditions and produces relatively fragile tablets.
Spray Drying	20–60 seconds	Moderate	Elevated processing temperatures may not be suitable for heat-sensitive (thermolabile) drug substances.
Sublimation Method	15–45 seconds	Moderate	Requires an additional step for removal of volatile materials from the formulation.
Molding Technology	10–30 seconds	Moderate to High	Tablets generally exhibit lower mechanical strength and are usually limited to lower drug doses.

Evaluation Parameters for Fast Dissolving Tablets

The assessment of fast dissolving tablets (FDTs) includes both pre-compression and post-compression evaluation parameters. Pre-compression studies are performed to examine the characteristics of the powder blend, while post-compression studies focus on the quality attributes of the compressed tablets. A thorough evaluation process is essential to ensure the formulation meets the required standards of quality, safety, stability, and therapeutic effectiveness.

11.1 Post-Compression Tablet Evaluation

11.1.1 Weight Variation Test

In the weight variation test, twenty tablets are selected randomly and weighed individually using an analytical balance to determine their average weight. The percentage deviation of each individual tablet from the calculated mean weight is then evaluated. According to the standards specified by the Indian Pharmacopoeia (IP) and United States Pharmacopeia (USP), for tablets weighing between 80 mg and 250 mg, not more than two tablets should show a deviation greater than ±7.5% of the average weight, while no tablet should exceed a deviation of ±15%. This evaluation is performed to ensure uniformity in tablet weight and to confirm the consistency and reliability of the manufacturing process.

11.1.2 Tablet Thickness and Diameter

The thickness and diameter of tablets are determined using a Vernier caliper or a suitable thickness gauge, typically by evaluating at least ten tablets. Measurement of tablet dimensions is an important quality control parameter in the development of fast dissolving tablets (FDTs), as it influences factors such as disintegration time, patient comfort during administration, and packaging suitability. Tablets intended for oral disintegration should possess dimensions that allow comfortable placement within the oral cavity while maintaining structural integrity. For fast dissolving tablets, the recommended thickness generally ranges between 2.5 mm and 5.0 mm, whereas the tablet diameter is usually maintained within the range of 8 mm to 13 mm to ensure ease of administration and acceptable performance characteristics.

11.1.3 Tablet Hardness (Crushing Strength)

Tablet hardness refers to the mechanical strength or crushing resistance of a tablet and is evaluated using instruments such as the Monsanto hardness tester, Pfizer hardness tester, or Erweka hardness tester. In this test, a tablet is positioned diametrically between two jaws of the instrument, and pressure is gradually applied until the tablet fractures. The hardness value is generally expressed in kilograms per square centimeter (kg/cm^2) or Newtons (N). For fast dissolving tablets (FDTs), maintaining an appropriate hardness level is essential to ensure both adequate mechanical stability and rapid disintegration. An optimal hardness range of approximately 3–5 kg/cm^2 is commonly considered suitable. Excessive hardness may prolong tablet disintegration time, whereas insufficient hardness can result in fragile tablets that are prone to breakage during handling, packaging, and transportation. Therefore, achieving a

balance between tablet strength and rapid disintegration remains a major consideration in the formulation of FDTs.

11.1.4 Friability Test

The friability test is conducted to assess the ability of tablets to withstand mechanical stress, including abrasion and attrition, that may occur during handling, packaging, transportation, and storage. This test evaluates the physical durability of the tablet formulation.

In the procedure, twenty tablets are initially weighed collectively to obtain the initial weight (W_1) and then placed in a Roche friabilator operated at 25 revolutions per minute (rpm) for 4 minutes, equivalent to 100 rotations. After completion of the test, the tablets are removed, dedusted, and reweighed to determine the final weight (W_2). Friability is calculated using the following formula:

Friability (%) = $[(W_1 - W_2) / W_1] \times 100$

According to pharmacopeial standards such as the United States Pharmacopeia (USP), the acceptable friability limit should not exceed 1.0%. Due to their porous and fragile nature, fast dissolving tablets may exhibit slightly higher friability compared to conventional tablets; however, values within the acceptable range are considered satisfactory.

11.1.5 Disintegration Time – Standard Method

Disintegration time is a critical evaluation parameter for fast dissolving tablets (FDTs), as it determines the speed at which the tablet breaks down after administration. The test is commonly performed using the USP Disintegration Apparatus (Type I, basket-rack assembly). In this method, six tablets are placed individually into the apparatus, generally with the use of discs, and immersed in a suitable medium such as simulated saliva (phosphate buffer pH 6.8) or distilled water maintained at a temperature of 37 ± 2°C.

11.1.6 Wetting Time

Wetting time is an important evaluation parameter used to estimate the duration required for a tablet to absorb moisture when placed in the oral cavity. This test indirectly reflects the tablet's ability to disintegrate rapidly in saliva. In the procedure, a piece of tissue paper is placed inside a Petri dish containing approximately 6 mL of water, and the tablet is carefully positioned on the tissue surface. The time required for complete wetting of the tablet, indicated by uniform water penetration throughout the tablet matrix, is recorded. Wetting time is considered closely associated with in vivo mouth feel and disintegration performance.

For fast dissolving tablets (FDTs), a wetting time of less than 60 seconds is generally regarded as acceptable, while shorter wetting times suggest superior disintegration efficiency.

11.1.7 Water Absorption Ratio (WAR)

The water absorption ratio (WAR) is determined to evaluate the ability of a tablet to absorb moisture relative to its initial dry weight. This parameter provides insight into tablet wettability and hydration behavior, which are directly related to disintegration performance. The water absorption ratio is calculated using the following equation:

WAR (%) = [(Ww − Wd) / Wd] × 100

Where, **Ww** represents the weight of the tablet after wetting and **Wd** indicates the initial dry weight of the tablet. A higher WAR value indicates enhanced water uptake, suggesting improved wettability and potentially faster tablet disintegration. In general, fast dissolving tablets exhibiting WAR values greater than 100% demonstrate favorable disintegration properties.

11.1.8 Drug Content Uniformity

Drug content uniformity testing is conducted to confirm the consistent distribution of the active pharmaceutical ingredient throughout the tablet batch. In this method, twenty tablets are weighed and finely powdered. A quantity of powder equivalent to the dose of one tablet is accurately measured, dissolved in 0.1 N hydrochloric acid or another suitable solvent, filtered, and appropriately diluted. The prepared sample solution is then analyzed using UV spectrophotometry at the λmax of ondansetron hydrochloride (310 nm). Drug content is determined using either a standard calibration curve or absorptivity values. According to pharmacopeial standards, the acceptable drug content range should typically remain between 90% and 110% of the labeled claim, ensuring formulation consistency and dosage accuracy.

11.1.9 In Vitro Disintegration Time in Simulated Saliva

To achieve a more clinically relevant evaluation of tablet performance, disintegration studies may be performed under conditions simulating the oral environment. One approach involves recording the time required for tablet disintegration on the tongue of healthy volunteers (in vivo evaluation). Alternatively, an in vitro procedure may be performed by placing the tablet in a limited quantity (approximately 2 mL) of simulated saliva solution, such as mucin-containing phosphate buffer at pH 6.8, in a Petri dish. The duration required for complete

tablet disintegration is measured. This method more accurately replicates conditions within the buccal cavity and provides better prediction of in-mouth performance.

11.1.10 In Vitro Drug Dissolution Study

Drug dissolution studies are performed to assess the release pattern of the active ingredient from fast dissolving tablets. The study is commonly carried out using the USP Dissolution Apparatus Type II (paddle method) operated at 75 rpm in 900 mL of phosphate buffer (pH 6.8), maintained at 37 ± 0.5°C to simulate physiological conditions. At predetermined intervals (2, 5, 10, 15, 20, 25, and 30 minutes), aliquots of the dissolution medium are withdrawn and replaced with an equal volume of fresh medium to maintain sink conditions. The collected samples are filtered and analyzed spectrophotometrically at 310 nm. The cumulative percentage of drug release is subsequently calculated and plotted against time. Furthermore, dissolution data may be fitted into kinetic models such as zero-order, first-order, Higuchi, Hixson-Crowell, and Korsmeyer-Peppas models to better understand the drug release mechanism.

11.1.11 Dissolution Efficiency (DE%)

Dissolution efficiency (DE%) is calculated to evaluate the effectiveness of drug release within a specified period. It is determined from the area under the dissolution curve and expressed as a percentage of the total area representing complete (100%) drug dissolution over the same time interval. A higher dissolution efficiency value indicates a more effective and rapid dissolution profile. Statistical tools such as Student's t-test or analysis of variance (ANOVA) may be applied to compare dissolution efficiency values among different formulations and identify significant variations.

11.2 Stability Studies (ICH Guidelines Q1A(R2))

The optimized fast dissolving tablet formulation is subjected to stability testing in accordance with ICH Q1A(R2) guidelines to assess its long-term quality and performance. Accelerated stability studies are typically conducted at 40°C ± 2°C and 75% ± 5% relative humidity (RH) for three months, while long-term stability testing is carried out at 25°C and 60% RH for six months. Samples are periodically evaluated for parameters such as physical appearance, weight variation, hardness, friability, disintegration time, drug content, and dissolution profile. Due to their porous structure and moisture sensitivity, fast dissolving tablets require careful monitoring during storage stability assessments.

11.3 Organoleptic Evaluation and Mouth Feel

Organoleptic evaluation is conducted to assess sensory characteristics such as color, odor, taste, and texture of the tablet formulation. Mouth feel and palatability are particularly important for fast dissolving tablets, as these factors directly influence patient acceptability. Taste masking effectiveness may be assessed using a scoring scale, where lower scores indicate unacceptable bitterness and higher scores represent pleasant taste. Additional mouth feel parameters, including grittiness, smoothness, residue formation, and cooling sensation, are also evaluated. Ingredients such as mannitol and menthol may contribute to improved sensory perception. Mouth feel is often rated on a numerical scale ranging from very poor to excellent to assess overall patient acceptability.

RESULTS AND DISCUSSION

The present study was successfully carried out to formulate and evaluate fast dissolving tablets (FDTs) of ondansetron hydrochloride using different superdisintegrants, namely Croscarmellose Sodium (CCS), Crospovidone (CP), and Sodium Starch Glycolate (SSG), at concentrations of 2%, 4%, and 6% w/w by the direct compression method. A total of nine formulations (F1–F9) were prepared and systematically evaluated to identify the most effective formulation.

The pre-compression parameters of the powder blends, including bulk density, tapped density, angle of repose, Carr's compressibility index, and Hausner ratio, demonstrated acceptable flow and compressibility properties. The angle of repose values indicated good flowability of the powder blends, while the Carr's index and Hausner ratio confirmed suitable compressibility for direct compression. These findings suggested that all formulations possessed adequate flow characteristics for tablet manufacturing without significant processing difficulties. All prepared tablet formulations complied with official pharmacopeial standards for physical appearance, weight variation, hardness, thickness, friability, and drug content uniformity. The tablets showed acceptable mechanical strength with hardness values sufficient to withstand handling and packaging while maintaining rapid disintegration properties. Friability values remained within the permissible pharmacopeial limit of less than 1%, indicating adequate resistance to mechanical stress.

The wetting time and water absorption ratio studies revealed that formulations containing higher concentrations of superdisintegrants exhibited improved wettability and faster moisture penetration, which contributed to reduced disintegration times. Among all formulations, tablets containing Crospovidone demonstrated superior wetting behavior and

water absorption characteristics due to its porous and non-gelling nature. Disintegration time was considered one of the most critical parameters in evaluating fast dissolving tablets. The results demonstrated that increasing the concentration of superdisintegrants significantly reduced tablet disintegration time. Among all formulations, F6 containing 6% Crospovidone exhibited the shortest disintegration time of **18 seconds**, indicating excellent disintegration performance. The in vitro dissolution studies revealed rapid and efficient drug release from all formulations; however, formulation F6 showed the highest cumulative drug release of **98.7% within 20 minutes**, indicating superior dissolution behavior. The rapid dissolution profile of F6 may be attributed to the effective capillary action and rapid water uptake provided by Crospovidone, which facilitated quick tablet disintegration and drug release.

Crospovidone showed the best performance because of its efficient wicking mechanism and non-swelling, non-gelling characteristics, which enhanced water penetration and accelerated tablet breakup. Croscarmellose sodium also showed satisfactory results due to swelling and capillary action, whereas sodium starch glycolate exhibited comparatively slower disintegration due to gel formation at higher concentrations. From the obtained findings, formulation **F6 containing 6% Crospovidone** was identified as the optimized formulation among all developed batches. It demonstrated superior characteristics including rapid disintegration (**18 seconds**), excellent drug content (**99.2%**), acceptable hardness and friability, enhanced wetting properties, and maximum drug release (**98.7% within 20 minutes**). Therefore, the optimized fast dissolving tablet formulation of ondansetron hydrochloride may serve as an effective alternative to conventional oral tablets, offering improved patient convenience, faster onset of action, and better compliance, particularly in patients suffering from nausea and vomiting.

CONCLUSION

The present investigation successfully focused on the formulation and evaluation of fast dissolving tablets (FDTs) of ondansetron hydrochloride employing three different superdisintegrants, namely Croscarmellose Sodium (CCS), Crospovidone (CP), and Sodium Starch Glycolate (SSG), at varying concentrations of 2%, 4%, and 6% w/w through the direct compression technique. Among the developed formulations, the batch containing 6% Crospovidone (F6) was identified as the optimized formulation based on detailed pre-compression and post-compression evaluation parameters. The optimized formulation demonstrated a rapid disintegration time of 18 seconds, satisfactory drug content of 99.2%,

and an in vitro drug release of 98.7% within 20 minutes, meeting the required pharmacopeial standards for fast dissolving tablets.

The significance of the developed formulation lies in its ability to overcome the practical limitations associated with administering conventional oral tablets to patients experiencing nausea and vomiting. The fastly dissolving tablet of ondansetron hydrochloride offers a convenient dosage form that does not require water for administration, facilitates ease of use under emergency or difficult clinical conditions, and provides a rapid therapeutic response. Moreover, the possibility of partial transmucosal absorption may contribute to enhanced bioavailability and faster onset of antiemetic activity. Among all the formulations prepared, the batch containing 6% Crospovidone (F6) was identified as the most optimized formulation based on its superior overall performance. The formulation exhibited rapid tablet disintegration within 18 seconds, excellent drug content uniformity (99.2%), and a high cumulative drug release of 98.7% within 20 minutes. These findings indicate that the optimized formulation achieved the desired balance between mechanical integrity and rapid drug release, which is a major challenge in the formulation of fast dissolving tablets.

The findings of the study further established the relative effectiveness of superdisintegrants in improving tablet performance, with the order of efficiency observed as: Crospovidone > Croscarmellose Sodium > Sodium Starch Glycolate. The superior performance of Crospovidone may be attributed to its efficient capillary action and non-gelling characteristics, which promote rapid tablet disintegration. Further research may focus on evaluating the in vivo pharmacokinetic behavior of the optimized formulation in comparison with commercially available conventional tablets to determine differences in onset of action and bioavailability. In addition, advanced taste-masking strategies, including hot-melt extrusion and cyclodextrin complexation, may be investigated to improve palatability and enhance overall patient compliance.

The practical and clinical importance of the present work is particularly relevant in the treatment of emesis, where administering conventional oral tablets may become difficult or ineffective due to frequent vomiting episodes. The developed fast dissolving formulation of ondansetron hydrochloride addresses this therapeutic challenge by enabling administration without water, reducing swallowing difficulties, and providing a rapid onset of antiemetic action.

REFERENCES

1. Bhaskaran S, Narmada GV. Rapid dissolving tablets: A novel dosage form. Indian Pharmacist. 2002;1:9–12.
2. Chang RK, Guo X, Burnside BA, Couch RA. Fast-dissolving tablets. Pharmaceutical Technology. 2000;24(6):52–58.
3. Dobetti L. Fast-melting tablets: Developments and technologies. Pharmaceutical Technology Europe. 2000;(Suppl):32–42.
4. Fu Y, Yang S, Jeong SH, Kimura S, Park K. Orally fast disintegrating tablets: Developments, technologies, taste-masking and clinical studies.
5. Critical Reviews in Therapeutic Drug Carrier Systems. 2004;21(6):433–475.
6. Goel H, Rai P, Sharma V, Vyas SP. Orally self-emulsifying systems: A strategy to overcome oral delivery challenges for lipophilic drugs.
7. PDA Journal of Pharmaceutical Science and Technology. 2008;62(3):201–215.
8. Habib W, Khankari R, Hontz J. Fast-dissolve drug delivery systems: Critical developmentand considerations. Drug Delivery Technology. 2000;3:1–4.
9. Hirani JJ, Rathod DA, Vadalia KR. Orally disintegrating tablets: A review. Tropical Journal
10. Ondansetron hydrochloride Bhowmik D, Chiranjib B, Krishnakanth, Pankaj, Chandira RM. Fast Dissolving Tablet: An Overview. *Journal of Chemical and Pharmaceutical Research*. 2009;1(1):163–177.
11. Hirani JJ, Rathod DA, Vadalia KR. Orally Disintegrating Tablets: A Review. *Tropical Journal of Pharmaceutical Research*. 2009;8(2):161–172.
12. Fu Y, Yang S, Jeong SH, Kimura S, Park K. Orally Fast Disintegrating Tablets: Developments, Technologies, Taste-Masking and Clinical Studies. *Critical Reviews in Therapeutic Drug Carrier Systems*. 2004;21(6):433–476.
13. Seager H. Drug Delivery Products and the Zydis Fast Dissolving Dosage Form. *Journal of Pharmacy and Pharmacology*. 1998;50(4):375–382.
14. Kuchekar BS, Arumugam V. Fast Dissolving Tablets. *Indian Journal of Pharmaceutical Education*. 2001;35(4):150–152.
15. Bhagwati ST, Hiremath SN, Sreenivas SA. Comparative Evaluation of Disintegrants by Formulation and Evaluation of Orodispersible Tablets. *Indian Journal of Pharmaceutical Education and Research*. 2005;39(4):194–197.
16. Velmurugan S, Sundar V. Oral Disintegrating Tablets: An Overview. *International Journal of Chemical and Pharmaceutical Sciences*. 2010;1(2):1–12.

17. Shukla D, Chakraborty S, Singh S, Mishra B. Mouth Dissolving Tablets I: An Overview of Formulation Technology. *Scientia Pharmaceutica*. 2009;77(2):309–326.
18. Siddiqui N, Garg G, Sharma PK. Fast Dissolving Tablets: Preparation, Characterization and Evaluation. *International Journal of Pharmaceutical Sciences Review and Research*. 2010;4(2):87–96.
19. Deshmukh VN. Mouth Dissolving Drug Delivery System: A Review. *International Journal of PharmTech Research*. 2012;4(1):412–421.
20. Patel DM, Patel MM. Optimization of Fast Dissolving Tablets Containing Ondansetron Hydrochloride by Direct Compression Technique. *International Journal of Pharmaceutical Sciences and Research*. 2011;2(5):1257–1264.
21. Sharma S. New Generation of Tablet: Fast Dissolving Tablet. *Latest Reviews in Pharmaceutical Sciences*. 2008;6(1):1–8.
22. Mohanachandran PS, Sindhumol PG, Kiran TS. Superdisintegrants: An Overview. *International Journal of Pharmaceutical Sciences Review and Research*. 2011;6(1):105–109.
23. Pahwa R, Gupta N. Superdisintegrants in the Development of Orally Disintegrating Tablets: A Review. *International Journal of Pharmaceutical Sciences and Research*. 2011;2(11):2767–2780.
24. Chang RK, Guo X, Burnside BA, Couch RA. Fast-Dissolving Tablets. *Pharmaceutical Technology*. 2000;24(6):52–58.