RESEARCH PAPER

Comparative in Vitro Evaluation of Selected Ondansetron Tablet Brands Marketed in Iraq

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ABSTRACT

Background: Ondansetron tablets are widely used for the management of nausea and vomiting associated with chemotherapy, radiotherapy, and postoperative conditions. The quality and performance of these tablets depend on their physicochemical properties, which may vary among different marketed brands.

Objective: This study aimed to evaluate and compare the physicochemical properties of selected ondansetron tablet brands marketed in Iraq.

Methods: Six commercially available brands of ondansetron tablets (8 mg) were evaluated using standard pharmacopeial methods. The tests included weight variation, friability, hardness, tensile strength, disintegration time, and in vitro dissolution. All experiments were performed using ERWEKA equipment, and the results were expressed as mean ± standard deviation.

Results: All tested brands complied with pharmacopeial limits for weight variation and friability (<1%). Significant differences were observed in hardness and disintegration time among the brands. Ondalek® showed the highest crushing strength, while Vomot® exhibited the fastest disintegration and dissolution rate. Variations in dissolution profiles were observed among the formulations, indicating differences in drug release behavior.

Conclusion: The evaluated ondansetron tablet brands demonstrated acceptable quality; however, variations in physicochemical properties and dissolution behavior were observed. These differences may influence drug performance and highlight the importance of routine in vitro evaluation of marketed pharmaceutical products.

Keywords: *Ondansetron; Tablets; Physicochemical evaluation; Dissolution test; Disintegration; Friability; Pharmaceutical quality; Iraq*

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INTRODUCTION

Solid dosage forms such as tablets and capsules are the most widely used pharmaceutical preparations due to their stability, convenience, and ease of administration. Among these, tablets are the most common, accounting for approximately 70% of pharmaceutical products worldwide. They offer several advantages, including accurate dosing, cost-effectiveness, ease of manufacturing, and improved patient compliance compared to other dosage forms [1, 2] . A tablet is defined as a compressed solid dosage form containing one or more active pharmaceutical ingredients, with or without excipients. The quality of tablets depends on several physicochemical properties such as weight uniformity, hardness, disintegration, and dissolution, which are essential to ensure consistent drug release and therapeutic effectiveness [2, 3].

Ondansetron is a widely used antiemetic drug that is effective in the treatment and prevention of nausea and vomiting of various etiologies, including chemotherapy-induced, radiotherapy-induced, and postoperative conditions [4]. Despite the advantages of tablet dosage forms, variations in formulation and manufacturing processes may lead to differences in physicochemical properties among different brands. These variations can affect drug performance, bioavailability, and therapeutic outcomes. Therefore, in vitro evaluation of tablet formulations is essential to ensure their quality, safety, and compliance with pharmacopeial standards [3, 5]. The aim of this study is to evaluate and compare the physicochemical properties of selected ondansetron tablet brands marketed in Iraq, with a particular focus on those available in Karbala.

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MATERIALS AND INSTRUMENTS

Six commercially available brands of ondansetron tablets (8 mg) marketed in Iraq were selected for this study, including Nixvom (N-Pharma), No Vomit (Pioneer), Zaferon (4CARE Lifescience Pvt. Ltd., India), Zomet (Lelle, Germany), Ondalek (Lekhim), and Vomot (Almotakadema Pharma).

All experiments were carried out using standard pharmaceutical testing equipment (ERWEKA, Germany), including an electronic balance for weight variation, a friability tester, a hardness tester, a disintegration apparatus, and a dissolution test apparatus. Additional laboratory accessories such as syringes and glassware were also used where required.

METHODS

WEIGHT VARIATION TEST

Twenty tablets from each brand were individually weighed using a calibrated electronic balance, and the average weight was calculated. The test was evaluated according to the United States Pharmacopeia (USP) requirements, where not more than two tablets may deviate from the average weight by more than the specified percentage, and no tablet may deviate by more than twice that percentage [6].

FRIABILITY TEST

Friability was determined using a friability tester (ERWEKA). A sample of tablets equivalent to approximately 6.5 g (usually 10 tablets for tablets ≥650 mg or fewer if heavier) was weighed and placed in the drum. The apparatus was operated at 25 rpm for 4 minutes (100 revolutions). The tablets were then dedusted and reweighed. The percentage weight loss was calculated, and a value not exceeding 1.0% was considered acceptable [6, 7]

HARDNESS TEST

Tablet hardness (crushing strength) was measured using a hardness tester. Tablets were placed between two anvils, and force was applied diametrically until fracture occurred. The breaking force was recorded in Newtons (N). Although no official USP limit is specified, hardness is evaluated to ensure adequate mechanical strength and resistance to handling during manufacturing and transportation [7, 8].

DISINTEGRATION TEST

Disintegration testing was carried out using a USP disintegration apparatus. Six tablets (or at least three for evaluation purposes) were placed individually in the tubes of the basket rack assembly with disks, if required. The assembly was immersed in simulated gastric fluid maintained at 37 ± 2°C. The basket was moved vertically at a frequency of 29–32 cycles per minute through a distance of 5–6 cm. The time required for complete disintegration of each tablet, with no palpable core remaining, was recorded. Immediate-release tablets should generally disintegrate within 15 minutes unless otherwise specified [6, 9].

DISSOLUTION TEST

Dissolution testing was performed using a USP dissolution apparatus (ERWEKA), typically Apparatus II (paddle method). The dissolution medium was maintained at 37 ± 0.5°C, and the paddle rotation speed was set according to pharmacopeial specifications (commonly 50–75 rpm). One tablet from each brand was placed in each vessel containing the dissolution medium.

Samples (5 mL) were withdrawn at predetermined time intervals (5, 10, 15, 20, and 25 minutes) using a syringe and filtered if necessary. After each sampling, an equal volume of fresh dissolution medium was added to maintain sink conditions. The samples were analyzed to determine the amount of drug released, and dissolution profiles were constructed. The test was evaluated according to USP dissolution requirements for ondansetron tablets [6, 10]

RESULTS

The physicochemical properties of the selected ondansetron tablet brands are presented in Table 1.

Table 1: Physical evaluation of ondansetron tablets

Test Parameter	Vomot®	Zaferon®	Ondalek®	Nixvom®	Zomet®	No-Vomit®
Weight variation (g ± SD)	0.201 ± 0.003	0.181 ± 0.0035	0.313 ± 0.002	0.102 ± 0.002	0.306 ± 0.010	0.246 ± 0.003
Friability (% ± SD)	0.3 ± 0.001	0.3 ± 0.012	0.9 ± 0.013	0.2 ± 0.003	0.5 ± 0.007	0.3 ± 0.001
Crushing strength (N ± SD)	3.6 ± 1.15	4.53 ± 0.78	11.9 ± 0.7	4.9 ± 0.66	4.6 ± 1.1	10.23 ± 0.064
Tensile strength (kg/cm²)	0.076	0.095	0.196	0.18	0.096	0.2
Disintegration time (min ± SD)	2 ± 0.04	7 ± 0.53	2.5 ± 0.021	8 ± 0.44	6.4 ± 0.06	7 ± 1.02

The results demonstrated variations among the tested brands in terms of weight variation, friability, hardness, tensile strength, disintegration time, and dissolution behavior.

All formulations showed relatively consistent weight variation, indicating acceptable uniformity. Friability values for all brands were below 1%, suggesting adequate mechanical resistance. Significant differences were

observed in hardness and tensile strength, with Ondalek® showing the highest crushing strength, while Vomot® showed the lowest. Disintegration time ranged between 2 ± 0.04 and 8 ± 0.44 minutes. Dissolution profiles (Figure 1) indicated variability in drug release among the tested brands, with Vomot® showing the fastest release.

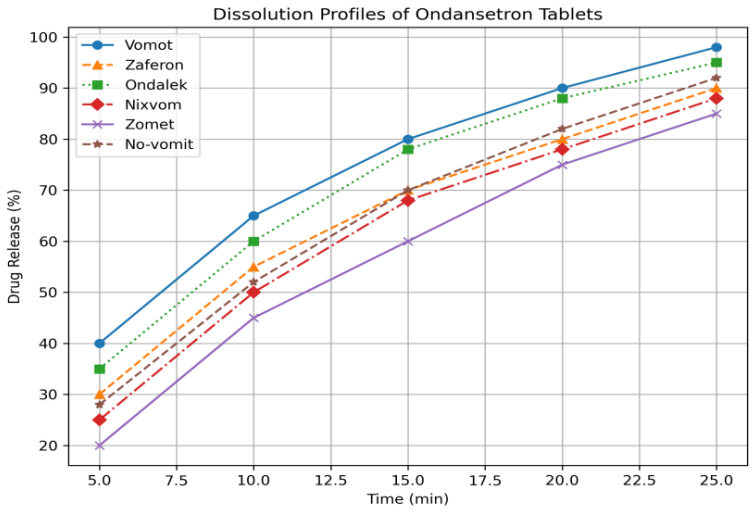

Figure 1: In vitro dissolution profiles of selected ondansetron tablet brands.

DISCUSSION

The present study evaluated the physicochemical properties of different brands of ondansetron tablets marketed in Iraq and revealed noticeable variations among formulations.

Weight Variation

All brands showed acceptable weight uniformity, indicating good manufacturing practices. Minor variations observed among the formulations may be attributed to differences in granulation techniques or tablet compression processes. Similar findings have been reported in previous studies, where marketed tablets demonstrated acceptable weight variation within pharmacopeial limits [1, 11]

Friability

All tested brands exhibited friability values below 1%, indicating adequate resistance to mechanical stress during handling, packaging, and transportation. Ondalek® showed the highest friability, whereas Nixvom® showed the lowest. These results are consistent with previous studies reporting that acceptable friability values (<1%) reflect good tablet durability and formulation integrity **[3]**

Hardness (Crushing Strength)

Significant differences in tablet hardness were observed among the brands. Ondalek® exhibited the highest hardness, indicating stronger mechanical integrity, while Vomot® showed the lowest hardness. Tablet hardness is influenced by formulation composition, compression force, and excipient type. Previous studies have shown that higher hardness improves mechanical stability but may delay disintegration and dissolution [12, 13]

Disintegration Time

Disintegration time varied among the tested brands, with Vomot® showing the fastest disintegration and Nixvom® the slowest. However, all formulations complied with pharmacopeial limits for immediate-release tablets. Faster disintegration generally enhances drug availability, which is particularly important for drugs like ondansetron used for rapid relief of nausea and vomiting. These findings agree with earlier studies indicating that disintegration time is a key factor influencing drug release and onset of action **[5, 14]**

Dissolution Test

The dissolution study revealed differences in drug release profiles among the brands. Vomot® showed the fastest drug release, while Zomet® and Zaferon® exhibited slower release profiles. These variations may be attributed to differences in formulation factors such as excipients, coating, and compression force. Previous studies have demonstrated that dissolution behavior is directly influenced by disintegration time, hardness, and formulation composition [12, 15]

CONCLUSION

The evaluated ondansetron tablet brands complied with pharmacopeial standards for weight variation and friability; however, differences were observed in hardness, disintegration, and dissolution behavior. Ondalek® showed the highest mechanical strength, while Vomot® exhibited the fastest disintegration and drug release. These variations may affect drug performance, highlighting the importance of routine in vitro evaluation to ensure consistent quality and therapeutic efficacy.

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