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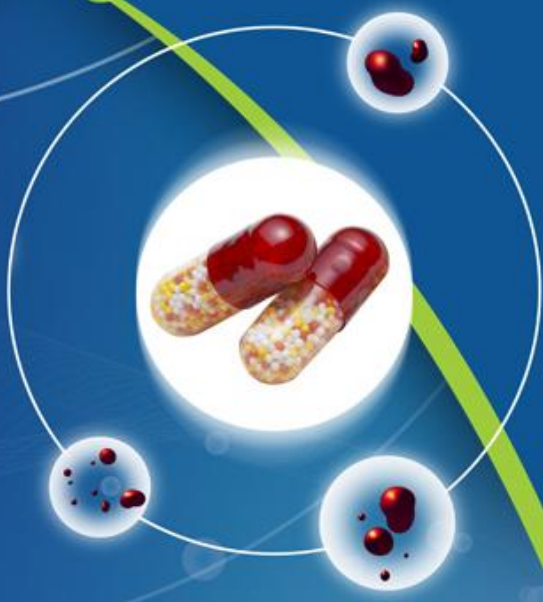

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Research Article

QUALITY EVALUATION OF MARKETED FORMULATION OF MOUTH DISSOLVING ONDANSETRON TABLETS

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ABSTRACT:

The main objective of this study was to compare the five brands of mouth dissolving tablets containing ondansetron, an antiemetic. Novel MDT technique provides the patient compliance and also meets the pharmaceutical needs such as improvement in the life cycle management over the convenient dosing especially for pediatrics, geriatrics and for psychiatric patients having difficulty in swallowing the conventional tablets and capsules dosage forms. For this study the mouth dissolving tablets were collected from market and were evaluated for hardness, friability, thickness, drug content, wetting time, weight variation test disintegration and in-vitro dissolution studies.

KEYWORDS: *Ondansetron, Mouth dissolving tablet, Quality evaluation, Marketed.*

INTRODUCTION:

Oral drug delivery is the most favoured route for administration of varrious medication and is the most widely accepted. This is an innovative tablet technology where the dosage form containing active pharmaceutical ingredients disintegrates rapidly, usually in a matter of seconds, without the need for water, providing optimal convenience to the patient. Innovators and inventor companies have given these tablets various names such as orally disintegrating tablets (ODT), mouth dissolving (MD), fast melting, fast dissolving or orodisperse.[3,4]

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Recent advances in technology prompted researchers and scientist to develop mouth dissolving tablets (MDTs) with improved patient compliance and convenience. MDTs are solid unit dosage form which dissolve or disintegrate rapidly in the mouth without water. It's important for all the tablet formulation to be evaluated for hardness, thickness, friability, disintegration time, dissolution, wetting time and water uptake ratio etc to judge the quality of MDT.

MATERIALS AND METHODS:

Following different brands of marketed mouth dissolving tablets of ondansetron 4 mg were collected and evaluated for in- vitro studies.

Marketed preparations used:-

Vomikind MD (Pharma Force Lab.)

Onsetrin MD (Akums Drug and Pharmaceutical Ltd.)

Ondamac MD (Macleods Pharmaceutical Ltd.)

Nuavomin MD (East African WHO Certified Lab.)

Zofer MD (Sun Pharma.)

EXPERIMENTAL DESIGN:

Methodology:

The mouth dissolving ondansetron tablets were collected from pharmacy outlet and evaluated for in-vitro (drug content, friability, hardness, disintegration time, wetting time, thickness, water absorption ratio and dissolution studies).

IN-VITRO Evaluation of Marketed Formulations[4,5,6]

Hardness:

Hardness is the force at which the tablet fractures and is expressed in kg/cm^2. The hardness of the MDT tablets taken was determined using a monsanto hardness tester. This test was repeated three times and the mean was noted.

Thickness:

The thickness of three randomly selected tablets from each formulation was determined in mm using vernier caliper. The average values were calculated.

Friability:

The friability of the tablets was determined with a Roche Friabilator and is expressed in percentage (%). Initially, twenty tablets were taken and weighed on a high precision weighing balance and the weight of all the tablets was recorded. After that, the tablets were delivered in to the drum of friabilator and the apparatus was set to rotate at 100 revolutions. Then the weight of mouth dissolving tablets after the test was taken and the difference in weight was expressed in terms of percentage of the initial weight of the tablets. The percentage friability was calculated by following formula.

Percentage of friability=

100(1-weight of tablets initially weighed/ weight of tablets weighed finally)

The tablets that loosing less than 1 percent of weight were considered to be compliant.

Weight variation test:

Randomly 20 mouth dissolving tablets were selected from each brand of ondansetron and were weighed individually to check for weight variation.

Disintegration Test:

Tablet disintegration time is the important characteristic required for the fast dissolving tablets. The MDT dosage forms are meant to disintegrate within a minute. Disintegration test was carried out in double distilled water. The disintegration time was determined using disintegration apparatus (Electrolab Ltd.). The tablets were placed in each of the six tubes of the apparatus and discs were added to each tube. The time in seconds required for the mouth dissolving tablets to get disintegrate was noted i.e. DT.

Content uniformity:

The ten tablets of each brand of ondansetron were weighed and powdered. About 4 mg of ondansetron was taken and was diluted with 50 ml of 0.1N HCL. The solution was shaken for 15 minutes and sufficient amount of 0.1N HCL was added to produced 200.0 ml. To 10.0 ml of the resulting solution added 10.0 ml of 0.1N HCL and again, dilute to 100.0 ml with the same. The drug content was measured by UV Spectrophotometric method at 249 nm.

Wetting time and water absorption:

Piece of tissue paper folded twice was placed in small petridish containing 6 ml of water. A tablet of known weight was put on the paper and time required for complete wetting of tablet was measured. The wetting tablet was then weighed; water absorption ratio was determined using following equation.

R= 100(Wa-Wb)/ Wb,
Where,
Wa is a weight of tablet before water absorption
Wb is a weight of tablet after water absorption

In-vitro Dissolution Studies:

Dissolution test of tablet is carried out by using water as the dissolution medium and rotating paddle as per Table no. 1. A suitable volume of the sample was withdrawn and filtered properly. First few ml of the filtrate were discarded and diluted to a suitable volume of the filtrate with the same solvent. The sampling was done at an interval of 2.5 min, 5 min, 7.5 min and 10 min. The absorbance of the resulting solution was measured at the maximum at 249 nm.

Table I: Dissolution test condition of mouth dissolving tablets of Ondansetron

Sr. No.	Parameters	Specification
1	Apparatus	USP-II
2	Medium	Phosphate buffer pH 6.8
3	Volume of medium	900 ml
4	Temperature if medium	37±0.5
5	Speed of paddle rotation	100
6	Time interval for sampling	2.5 minutes
7	Detection wavelength	249 nm

RESULT AND DISCUSSION:

The mouth dissolving tablet of ondansetron of brands Vomikind MD, Onsetrin MD, Ondamac MD, Nuavomin MD, and Zofer MD were studied for thickness, hardness, friability, weight variation, disintegration time and drug content. As per results, it was found that Vomikind MD, Onsetrin MD, Ondamac MD, and Zofer MD had the disintegration time in the range of 9 to 10 seconds while the mouth dissolving tablet of Nuavomin MD showed higher disintegration time i.e. 12 seconds. It's hardness and friability was also found to be 5.4 kg/cm^2 and 0.29% respectively, which was also comparatively high as compared to the other brands (shown in Table 2,3). Wetting time for all marketed formulation showed significant similarly except that of Nuavomin MD. Same results were obtained for water absorption ratio. It was found to in the range of 27-35% and for Nuavomin MD it was 40% (shown in Table 3). The drug release study showed that for Nuavomin MD drug release was found to be 80% in 10 min, while other brands of ondansetron showed the release in the range of 94 to 98 % (shown in Fig. 1).

Table II: Weight variation, Friability, Disintegration time and Hardness of Five MDT Marketed Ondansetron Preparations

Sr. No.	Formulation Name	Weight variation(mg)	Friability (%)	Disintegration time (sec)	Hardness (kg/cm^2)
1.	Vomikind MD	109±0.45	0.16±0.14	10±11	5.1±0.42
2.	Onsetrin MD	100±0.54	0.09±0.11	9±21	5.2±0.51
3.	Ondamac MD	57±0.41	0.19±0.21	10±15	4.9±0.47
4.	Nuavomin MD	140±0.34	0.29±0.04	12±18	5.4±0.44
5.	Zofer MD	61±0.41	0.12±0.13	10±20	4.8±0.61

Table III: Drug content, Wetting time and Water absorption ratio of Five MDT Marketed Ondansetron Preparations

Sr. No.	Formulation Name	Drug content (%)	Wetting time (sec)	Water absorption ratio (%)
1.	Vomikind MD	94.1±0.19	15±0.57	32.64±0.31
2.	Onsetrin MD	92.2±0.23	13±0.47	29.45±0.46
3.	Ondamac MD	96.1±0.31	18±0.15	27.28±0.28
4.	Nuavomin MD	97.5±0.25	20±0.23	40.28±0.49
5.	Zofer MD	94.3±0.22	18±0.23	35.17±0.58

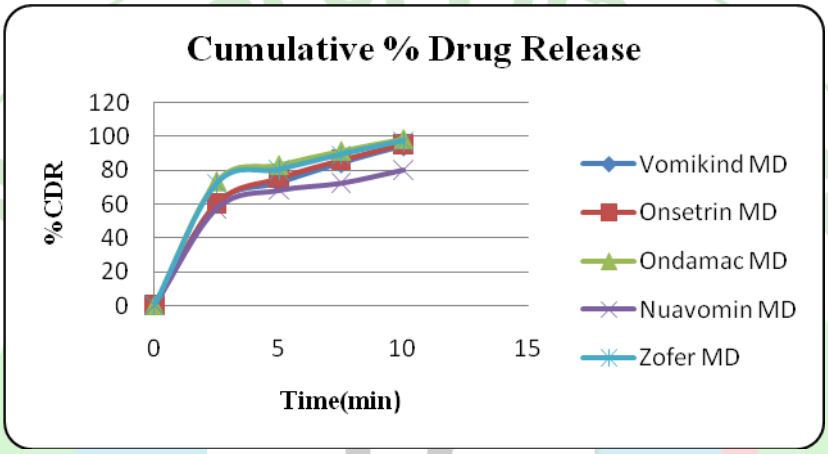

Figure 1: In-vitro release profile of various brands of Ondansetron MDT

CONCLUSION:

The mouth dissolving tablets Vomikind MD, Onsetrin MD, Ondamac MD, Nuavomin MD, and Zofer MD were found to be in the satisfactory ranges of result but Nuavomin MD was found to be on the higher side in terms of hardness, friability and drug release.

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