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Comparative Studies on Oral Dispersible Tablet of Ondansetron Hydrochloride Marketed Products

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ABSTRACT:
The antiemetic effect of Ondansetron Hydrochloride (OS) is probably due to the selective antagonism of 5-HT_3 receptors on neurons located in either the peripheral or central nervous systems, or both. Comparative quality evaluation of oral dispersible tablets has prime importance among other oral drug-delivery system due to its improved patient compliance. They are also solid dosage forms, which disintegrate in the mouth within a minute in the presence of saliva due to super disintegrants present in the formulation. Thus this type of drug delivery system helps in improved peroral administration in pediatric and geriatric patients where swallowing is a matter of hurdle. The present study was carried out to assess the quality control parameters of four different brands of OS tablets marketed in Dindigul district. All the tablet brands were analysed for weight variation test, hardness, friability, wetting time, disintegration studies and percentage drug release by dissolution studies. The hardness of various brands of OS ranges from 5.5 kg/cm^2 to 8.0 kg/cm^2 and friability varies from 0.60 % to 0.88 %. The wetting time of four different marketed brands was ranges from 20.07 to 42.74 seconds and they had shown the disintegration time varies from 5.23 to 6.92 seconds. They showed 88.6% to 99.5% release of active drug within 30 minutes in dissolution studies. Hence, it was concluded that all the marketed formulations met the quality parameters as per Indian pharmacopeia to achieve optimum therapeutic efficacy.

KEY WORDS: Comparative study, In-Vitro quality evaluation, Wetting time, Disintegration studies.

I. INTRODUCTION

Ondansetron Hydrochloride (OS) is selective 5-HT3 antagonist. It acts both, peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema. It is indicated for the prevention of nausea and vomiting associated with cancer chemotherapy, radiotherapy or anesthesia and surgery.

Pharma industries are focusing on new drug delivery systems for existing drug with a revamped efficacy and bioavailability. Dispersible tablets are uncoated tablets intended to be dispersed in water before administration giving a homogeneous dispersion. Typically a dispersible tablet is dispersed in about 5-15 ml of water and the resulting dispersion is administered to the patient. It helps to increase user acceptance due to rapid disintegration, self-administration. It contains super disintegrant, that helps to disintegrate the dosage form rapidly in the mouth within few seconds[1,2].

The oral route of administration is the routine and most predominant method of administering drugs for systemic effects. Drug absorption is monitored by physicochemical properties of drugs, their formulations, and routes of administration, when drug is administered orally. So the dosage forms can have a significant effect on the quality control parameters such as weight variation, hardness, friability, wetting time, disintegration time, dissolution profile etc.

Also, these parameters are essential tools for maintaining batch to batch consistency during manufacturing process. This work mainly focus on the in-vitro quality control tests of four brands of OS marketed tablets and compared with pharmacopeial specifications[3,4].

II. MATERIALS AND METHODS:

Chemicals

Four brands of OS tablets of different manufacturers with labeled contents of 4 mg were obtained from various retail pharmacy shops of Dindigul district in Tamilnadu. All the samples were properly checked for their physical appearance, manufacturer's name, batch number,

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manufacturing date, expiration date, manufacturing license number, and the maximum retail price at the time of purchase. The samples were properly coded with OS-1, OS-2, OS-3 and OS-4.

Equipments

Equipments used in this work were mortar, pestle, Electronic Balance (Wensar), Hardness Tester (Vinsyst), Friability Test Apparatus (Rolex India), Disintegration Test Apparatus (Rolex India), Dissolution Test Apparatus USP (Ceyone) and UV Visible Spectrophotometer (Sytronics).

Table 1: Brands of Ondansetron Hydrochloride Tablets

Brand Name	Maufacturers	Sample Code	MRP (Rupees per strip)
Vomikind-MD4	Mankind	OS-1	40.65
Ondem-MD4	Alkem	OS-2	58.27
Onvin-MD4	Cadila	OS-3	56.99
Zofer-MD4	Sun pharma	OS-4	58.25

Preparation of the standard curve

About 100 mg of pure drug of ondanserton was accurately weighed and the volume was made up to the mark with 0.01N HCl acid in a 100 ml standard flask. It is said to be primary stock, 1ml of this solution was pipetted out and transferred to 100ml standard flask and the volume was made up to the mark with 0.1N HCl acid, named as secondary stock solution having the concentration of 10µg/ml.

From the secondary stock solution aliquots equivalent to 1,2,3,4,5,6,7,8,9 and 10 ml were pipetted out into a series of 10 ml standard flask and volume made up to the mark with 0.1N HCl acid.

The absorbance of all the above solutions was measured against 0.1NHCl acid as blank at 310nm using UV visible spectrophotometer. Then a calibration curve was plotted taking concentration inµg/ml on x axis and absorbance on y axis.

Evaluation of tablets[5-11]

Uniformity of weight (Weight Variation)

Ten tablets were selected at a random and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight (Wensar).

Weight Variation = (Iw -Aw)/Aw × 100%

Iw = Individual weight, Aw = Average weight

Table 2: Limit for Weight Variation

IP	Limit (%)
80 mg or less	± 10
80-250 mg	± 7.5
>250 mg	± 5

Hardness

The tablet crushing load, which is the force required to break a tablet by compression in the radial direction, was determined using a Monsanto hardness tester, VinSyst Manual Tablet Hardness Tester (Monsanto Type).

Limit: Oral tablets have a hardness of 4 to 10kg.

Friability

Friability of tablets was measured by using Roche Friabilator. Friability was evaluated from the percentage weight loss of 20 tablets tumbled in a friabilator at 25 rpm for 4 minutes. The tablets were dedusted, and the loss in weight caused by fracture or abrasion was recorded as the percentage weight loss (Rolex India).

Friability = (Iw -Fw) / Iw × 100%

Where , Iw = Initial weight and Fw =Final weight

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Limit: Friability below **1%** was considered acceptable.

Wetting time

The wetting time of the tablets was measured using a simple procedure. Five circular tissue papers of 10-cm diameter were placed in a Petri dish with a **10-cm diameter**. Ten millilitres of water containing eosin, a water-soluble dye, was added to the Petri dish. A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablets was noted as the wetting time.

Disintegration time

The process of breakdown of a tablet into smaller particles is called as disintegration. The in-vitro disintegration time of a tablet was determined using disintegration test apparatus as per I.P. specifications. Place one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using distilled water. The assembly should be raised and lowered between 30 cycles per minute. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

In vitro Dissolution Study

The dissolution study was performed for marketed OS tablets, by using digital dissolution apparatus. The dissolution medium used is distilled water (900 mL, 37 ± 0.5°C). The rate of agitation of the paddle was 50 rpm. Aliquot of dissolution medium was withdrawn at specific time interval of 5 minutes, it was filtered, diluted suitably and absorbance was measured spectro photometrically at 310 nm by UV spectrophotometer.

III. RESULTS AND DISCUSSION

Construction of Standard Curve

The OS pure drug was diluted suitably with 0.1N HCl acid to get the concentration of 1-10 mcg/mL and the analysis of the sample was done using 1cm sample cell and scanning at 310 nm using double beam UV-Visible spectrophotometer

Table 3: Data for Standard curve

Concentration (µg/ml)	Absorbance (at 310 nm)
0	0
1	0.045
2	0.082
3	0.115
4	0.151
5	0.182
6	0.217
7	0.243
8	0.263
9	0.292
10	0.330

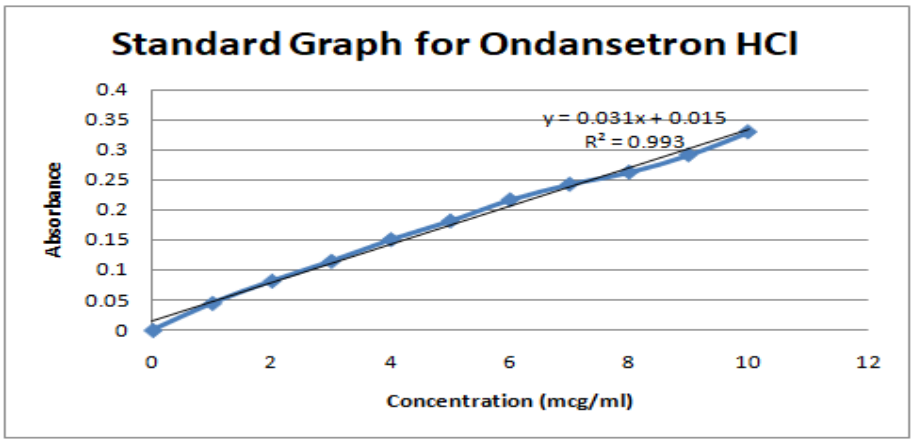

Fig 1: Standard Curve for Ondansetron Hydrochloride

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Comparative Study Data for Evaluation of Tablets[12-17]

The evaluation tests for all the brands of OS tablets were determined and the observed results are shown on Table 3 & 4.

Weight Variation

The weight variation of 4 different marketed brand were ranges from 0.3961% to 0.857%. Hence all brands have been complied with the weight variation test as per IP limit.

Hardness Test

The hardness of 4 different marketed brands were ranges from 5.5 kg/cm^2 to 8.0 kg/cm^{2}and all thebrands have been adhered to the IP limit.

Friability Test

The friability of 4 different marketed brands was ranges from 0.60 % to 0.88 %. So the above brand tablets have agreed the friability test as per IP limit.

Wetting Time

The wetting time of 4 different marketed brands was ranges from 20.07 to 42.74 seconds and all the brands were complied with the wetting time test as per IP limit.

Disintegration Test

The disintegration test of 4 different marketed brands was ranges from 5.23 seconds to 6.92 seconds and passed the disintegration test as per IP limit.

In vitro Dissolution study

Comparison of in vitro dissolution profiles of the four brands of OS tablets are illustrated in Figure 2. After 30 minutes, the release rate of different brands of OS tablets was satisfactory and ranged from 88.60 % to 99.50 % (Table 5). According to IP, the amount of Ondansetron Hydrochloride released within 30 min should not be less than 80% of the stated amount. From the dissolution test results, all the brands of CP tablets showed more than 80% of drug release within 30 min. Hence, all the products complied with the IP and BP dissolution tolerance limits.

Table 3: Comparative study data for Weight variation, Friability and Hardness

Our BrandName	Weight variation(%)	Friability(%)	Hardness(kg/cm^2)
OS-1	0.3961	0.60	5.5
OS-2	0.7777	0.69	5.5
OS-3	0.3304	0.78	8.0
OS-4	0.8571	0.88	7.0

Table 4: Comparative study data for Wetting Time, Disintegration and Dissolution

Our BrandName	Wetting Time(seconds)	Disintegration(seconds)	Dissolution(%)
OS-1	26.30	6.14	91.2
OS-2	20.51	5.54	95.3
OS-3	42.74	6.92	88.6
OS-4	20.07	5.23	99.5

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Table 5: Dissolution study data

TIME	% Release OS-1	% Release OS-2	% Release OS-3	% Release OS-4
0	0	0	0	0
5	4.2	4.8	4	5
10	17.2	18.5	16.5	20.2
15	32.2	35.3	30.1	40.5
20	51.1	54.6	45.6	60.8
25	72.9	74.8	68.7	81.6
30	91.2	95.3	88.6	99.5

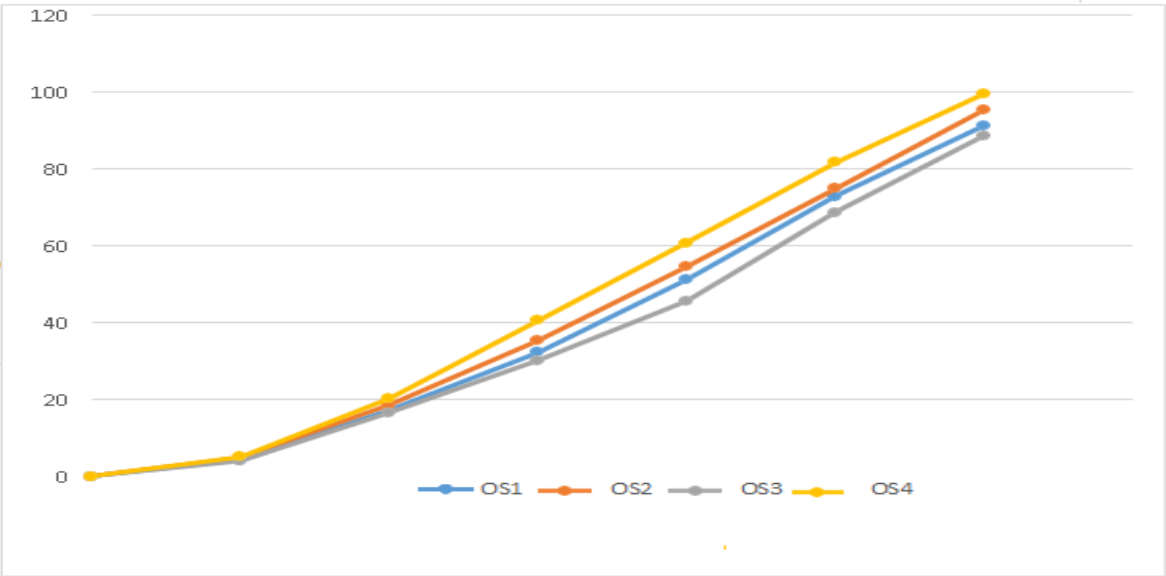

Fig 2: Graph for Dissolution Study

IV. CONCLUSION:

From the above investigation, it was concluded that all of the brands of OS tablet met the criteria laid in the official monographs for in-vitro evaluation tests. Highest percentage drug release on dissolution studies increased the therapeutic effectiveness of the product. The data reported in this study can help the manufacturers and researchers to concentrate and focus on quality to ensure better health of patients. It will be very useful and ultimately urge the pharmaceutical industry to invest more for quality control tests to provide better pharmaceutical formulations. The effectiveness of the drug products is based upon their analytical results which will force to achieve therapeutic and quality goals.

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