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Research Article

Quality Evaluation of Marketed Formulation of Mouth Dissolving Voglibose Tablets

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ABSTRACT

The main objective of this study was to compare the five brands of mouth dissolving tablets containing voglibose, an antidiabetic. 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 paediatrics, geriatric 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 drug content, friability test, hardness test, wetting time, weight variation test, and disintegration and in-vitro dissolution studies.

KEYWORDS

Mouth dissolving tablet, Voglibose, Quality evaluation,Marketed.

INTRODUCTION

Still today, oral drug delivery is the most favoured route for administration of various medications and is the most widely accepted [1, 2]. 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]

Recent advances in technology prompted researchers and scientists to develop oral disintegrating tablets (ODTs) with improved patient convenience and compliance. ODTs 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 Disintegration time, hardness, friability, dissolution, wetting time, and water uptake ratio, etc to judge the quality of MDT

MATERIALS AND METHODS

Following five different brands of marketed mouth dissolving tablets of voglibose 0.2 mg were collected and evaluated for In-vitro studies.

Marketed preparations used:-

Voglitor MD (Torrent Pharmaceuticals Ltd, Ahmadabad)
Voglistar MD (Mankind PharmaLtd,Delhi)
Vobit MD (Lupin Pharmaceuticals,Inc,Pune)
Prandial (Cipla Ltd, Mumbai)
Obiglo MD (Abbott, Mumbai)

EXPERIMENTAL DESIGN

Methodology:

The mouth dissolving voglibose tablets were collected from pharmacy outlet and evaluated for *in-vitro* (Content uniformity, friability, hardness, Disintegration time, and Dissolution
Studies).

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

1. 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 two times and the mean was noted.

2. Friabilitty:

The friability (FR) of the tablets was determined with a Roche friabilator and is expressed in percentage (%). Initially, twenty tablets were taken and weighed on a precision weighing balance and the weight of all the tablets was recorded. After that, the tablets were delivered into the drums 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) ---------- (01)

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

3. Weight variation test:
Randomly, 20 mouth dissolving tablets were selected from each brand of voglibose and were weighed individually to check for weight variation.

4. Disintegration Test [6]
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 (Veego India). The tablets were placed in each of the six tubes of the apparatus and the discs were added to each tube. The time in seconds required for the mouth dissolving tablets to get disintegrate was noted i.e. DT.

5. Content Uniformity:[4]
The twenty tablets of each brand of voglibose were weighed and powdered. About 0.2 g of voglibose was taken and was diluted with 50 ml of 0.1N HCL. The solution was shaken for 15 minutes and add sufficient amount of 0.1 N HCL was added to produce 200.0 ml. To 10.0 ml of the resulting solution added 10 ml of 0.1 N HCL and again, dilute to 100.0 ml with the same. The drug content was measured by UV spectro photometric method.

6. Wetting time and water absorption[9]
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, ---------- (02)
Where,
Wa is a weight of tablet before water absorption
Wb is a weight of tablet after water absorption

7. In-vitro Dissolution Studies:[4,7]
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 5min, 10 min, 15 min, 20 min, 25 and 30 min. The absorbance of the resulting solution was measured at the maximum at 282 nm.

Table No. 1:- Dissolution test conditions of mouth dissolving tablets of voglibose.

Sr.No	Parameters	Specifications
1	Apparatus	USP 2
2	Medium	Double distilled water
3	Volume of medium	900 ml
4	Temperature if medium	37 ± 0.5
5	Speed of paddle rotation	100
6	Time interval for sampling	5 minutes
7	Detection wavelength	282 nm.

RESULT AND DISCUSSION

The mouth dissolving tablets of voglibose of brands Voglitor MD, Voglistar MD, Vobit MD, Prandial, and Obiglo MD were studied for hardness, friability, weight variation test, disintegration time and content uniformity. As per the results, it was found that Voglitor MD, Voglistar MD, Vobit MD, and Obiglo MD had the disintegration time in the range of 99 to 121 seconds while the mouth dissolving tablet of Prandial showed higher disintegration time ie 150 seconds. Its hardness and friability was also found to be 5.2 kg/cm^2 and friability 0.09 % respectively, which was also comparatively high as compared to the other brands (Shown in **Table 2 A**). Wetting time for all marketed formulation showed significant similarity except that of Prandial. Same results were obtained for water absorption ratio.it was found to in the range of 35% and for Prandial it was 40% (Shown in **Table 2 B**) .The drug release study showed that for Prandial drug release was found to be 69% in 30 minutes while other brands of volglibose showed the release in the range of 84 to 92%.(Shown in **Fig 1**)

Table 2A: Weight, hardness, friability, disintegration time, Percentage Drug Content and Friability of Five MDT Marketed Voglibose Preparations:

Sr.No	Formulation Name	Weight mg	Friability (%)	Disintegration Time (seconds)	Hardness Kg/cm^2	Drug content
1	Voglitor MD	85±0.54	0.11±0.04	99±2.40	3.2±0.42	92.2± 0.23
2	Voglistar MD	74±0.45	0.12±0.21	105±1.54	3.6±0.51	94.1± 0.31
3	Vobit MD	75±0.41	0.19±0.13	114±1.48	3.0±0.47	90.1±0.19
4	Prandial	109±0.34	0.09±0.14	150±2.71	5.2±0.64	94.01±0.20
5	Obiglo MD	80±0.41	0.16±0.11	121±1.54	3.3±0.44	93.6±0.32

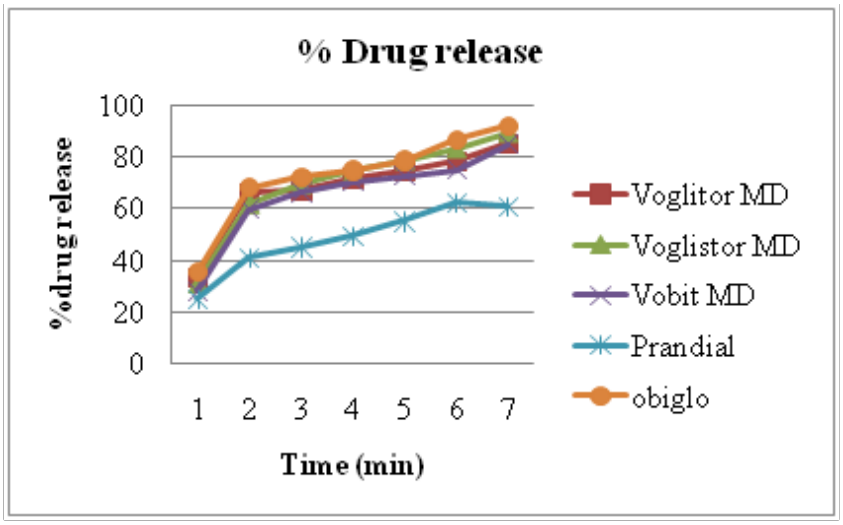
n =20

Table 2 B: Wetting time and Water absorption ratio Five MDT Release Marketed Voglibose Preparations

Sr.No	Formulation Name	Wetting time (sec)	Water absorption ratio (%)
1	Voglitor MD	15 ± 0.57	35.40± 0.58
2	Voglistar MD	13± 0.47	29.45±0.46
3	Vobit MD	18±0.15	32.64±0.31
4	Prandial	30± 0.23	40.28±0.28
5	Obiglo MD	18± 0.23	32.28±0.49

n=3

Fig.1: In-vitro release profile of MDT of Various Brands of Voglibose



CONCLUSION

The mouth dissolving tablets VoglitorMD, Voglistar MD, Vobit MD, Prandial, and Obiglo were found to be in the satisfactory range but Prandial was found to be on the higher side in terms of hardness test, friability and drug release.

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