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Pharmaceutical Equivalent study of Vildagliptin Formulation

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ABSTRACT

The aim of this study is to check pharmaceutical equivalence of different brands of vildagliptin tablets available in Karachi, Pakistan. Two different brands of vildagliptin tablets were investigated in the study. Four quality control (QC) parameters: weight variation, Diameter test, thickness, disintegration and dissolution test were carried out specified by BP/USP (British and United States pharmacopeia). The results of the study revealed that the parameters such as weight variation, Diameter test, thickness, disintegration test are in accordance with BP/USP limits.

Keywords: vildagliptin, weight variation, hardness, thickness disintegration and dissolution test.

INTRODUCTION

Vildagliptin is a oral anti diabetic drug that increase pancreatic islet cell responsiveness to glucose.[1] Vildagliptin belongs to the dipeptidyl peptidase-4 (DPP-4) inhibitors.[2] Vildagliptin has been widely studied in multiple clinical studies, including various populations with type 2 diabetes mellitus T2DM.[3] The drug has verified its efficacy as mono therapy or when given in combination with other anti diabetic medicines or insulin.[4-5] The drug is well tolerated and has a low risk of hypoglycemia and weight gain. [6] Chemically the drug is (S)-[(3-Hydroxyadamantan-1-yl) amino] acetyl pyrrolidin-2-carbonitril as shown in fig: 1. [7]

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The aim of this study is to evaluate pharmaceutical equivalents of drug vildagliptin tablets available in Karachi, Pakistan.

METHODOLOGY

Tablet specifications

All parameters (wt. variation, thickness, diameter, disintegration and dissolution) of two different brands of vildagliptin are carried out.

Weight variation test:

According to the BP/USP requirements that not more than two tablets out of 20 tablets should cross ± 7.5 % deviation. Similarly their statistical control chart

(shewart chart) shown in table-1 For this 20 tablets of each brand were weighed on Electronic Balance FX-400 and determined that weight of each capsule must be within BP/USP limits.

Thickness test:
Thickness of vildagliptin tablets including average, standard deviation, upper and lower limits is calculated.
Diameter test:
Diameter of vildagliptin tablets including average, standard deviation, upper and lower limits is calculated.

Disintegration test:
Disintegration time of both the brands of vildaglipitn is observed. Disintegration apparatus (Curro model no DS-0702) was used to perform disintegration test. Six Tablets of each brand were placed in the basket and then covered with the disk. Temperature is maintained at 35°C to 39°C using water or another liquid as the immersion fluid. After a specified time examine whether all the tablets have been disintegrated completely. If 1 or 2 tablets do not disintegrate, the test is repeated on 12 tablets. Out of 18 tablets 16 tested are disintegrated the requirements is met. Follow the same procedure for each brand.
According to USP, tablet should disintegrate in not more than 30 minutes in water for film coated tablets.

RESULTS AND DISCUSSION

The aim of this study is to evaluate and compare the quality standards of two different brands of vildagliptin tablets. All parameters (wt. variation, thickness, diameter, disintegration) of two different brands of vildagliptin are carried out. Weight variation test of vildagliptin tablets proved statistically that all the tablets were in accordance to the BP/USP requirements as shown in Table 1, 2 & 3. Thickness of all tablets of vildagliptin including standard deviation, average weight, upper & lower limits are in accordance with BP/USP as shown in Table 1 & 4. Diameter of all tablets of vildagliptin including standard deviation, average weight, upper & lower limits are in accordance with BP/USP as shown in Table 1 & 5. Disintegration time of both the brands of vildaglipitn is observed. Galvus disintegrated in 4 minutes and 22 seconds, while vildos disintegrated in 2 minutes and 45 seconds. The disintegration time of both the brands was in limits as specified in USP. Its data is given in as shown in Table 6.

CONCLUSION

Both the two brands of Vildagliptin are Pharmaceutical equivalents. All the results shows that there is no difference exist between the two brands except slight variation is observed in disintegration testings.

Table I: Weight (Mg), Thickness (Mm) And Diameter Of 20 Tablets (Randomly Selected) Of Different Brands

	Weight		Thickness		Diameter	
tablet	Galvus	vildos	Galvus	vildos	Galvus	vildos
1	202	228	3.4	4.5	8.1	8.6
2	203	231	3.4	4.5	8.1	8.6
3	199	233	3.4	4.5	8.1	8.6
4	200	228	3.5	4.5	8.2	8.6
5	208	232	3.4	4.5	8.1	8.6
6	202	229	3.5	4.5	8.2	8.5
7	199	234	3.4	4.5	8.2	8.6
8	204	235	3.4	4.5	8.2	8.5
9	202	232	3.4	4.5	8.2	8.6
10	202	231	3.5	4.5	8.2	8.5
11	202	228	3.4	4.6	8.2	8.6
12	203	231	3.4	4.5	8.1	8.5
13	199	233	3.5	4.5	8.1	8.5
14	200	228	3.4	4.5	8.1	8.6
15	202	232	3.4	4.5	8.2	8.6
16	208	229	3.5	4.5	8.2	8.6
17	204	234	3.4	4.5	8.2	8.6
18	199	235	3.4	4.5	8.1	8.5
19	202	232	3.4	4.5	8.2	8.6
20	202	232	3.4	4.5	8.2	8.6

Table II: Statistical Weight Variations

Tablets	Average	Standard deviation	Upper limit	Lower limit
	(mg)		(X+3S)	(X-3S)
Galvus	202.1	2.57	209.81	194.38
Vildos	231.35	2.34	238.38	224.31

Table III: Weight Variation Test

Tablets	Result(mg)	USP specifications	Deviation from USP specifications
Galvus	202.1	Deviation should be ±7.5%	Within the specified limit
Vildos	231.35	Deviation should be ±7.5%	

Table IV: Statistical Thickness

Tablets	Average (mm)	Standard deviation	Upper limit (X+3S)	Lower limit (X-3S)
Galvus	3.425	0.04426	3.55778	3.29222
Vildos	4.505	0.022361	4.57208204	4.43791796

Table V: Statistical Diameter

Tablets	Average (mm)	Standard deviation	Upper limit (X+3S)	Lower limit (X-3S)
Galvus	8.16	0.05	8.31	8.00
Vildos	8.57	0.04	8.71	8.42

Table VI: Disintegration Test

Tablets	Disintegration time	Limits	Deviation from USP
Galvus	4 min 22sec	NMT 30 Min	PASS
Vildos	2 min 45 sec	NMT 30 Min	PASS

REFERENCES

1. Chantal Mathieu and Evy Degrande Vildagliptin: a new oral treatment for type 2 diabetes mellitus Vasc Health Risk Manag. 2008 Dec; 4(6): 1349–1360.

2. Cornelia B Landersdorfer, Yan-Ling He and William J Jusko Mechanism-based population pharmacokinetic modelling in diabetes: vildagliptin as a tight binding inhibitor and substrate of dipeptidyl peptidase IV Br J Clin Pharmacol. 2012 Mar; 73(3): 391–401.

3. Keating GM. Vildagliptin: a review of its use in type 2 diabetes mellitus. Drugs. 2010;70:2089–2112

4. Fonseca V, Baron M, Shao Q, Dejager S. Sustained efficacy and reduced hypoglycemia during one year of treatment with vildagliptin added to insulin in patients with type 2 diabetes mellitus. Horm Metab Res. 2008;40:427–430

5. Matthews DR, Dejager S, Ahren B, et al. Vildagliptin add-on to metformin produces similar efficacy and reduced hypoglycaemic risk compared with glimepiride, with no weight gain: results from a 2-year study. Diabetes Obes Metab. 2010;12:780–789.

6. Ahren B, Foley JE, Bosi E. Clinical evidence and mechanistic basis for vildagliptin's action when added to metformin. Diabetes Obes Metab. 2011;13:193–203.

7. Kleppinger EL, Helms K. The role of vildagliptin in the management of type 2 diabetes mellitus. Ann Pharmacother. 2007; 41:824–32.

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