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STUDY OF IDENTICAL CURATIVE FORMULATION OF DIFFERENT BRANDS OF VILDAGLIPTIN

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Abstract:

The main objective of the research is to identify the various brands of vildagliptin having identical pharmaceutical formulation. 02 different brands, which were having identical active salt of vildagliptin, were taken for this study and different physiochemical analysis was performed to ensure the quality and therapeutic level. Various test including heaviness distinction, diameter assessment, breadth, crumbling, dissolution, and consequences compared with the standard. All standard took from USP (United States Pharmacopeia). All the parameters were according to the measured or specified standards as mentioned in USP. All parameters for the physicochemical evaluation of vildagliptin tablets of 02 altered brands were performed they were weight variation test, thickness test, diameter test, disintegration test and dissolution. The 02 different variety of vildagliptin salt were having similar curative agent and all results were according to mentioned criteria of USP which was not exceed than ±1%. Only the time of disintegration was quietly differ but that was not altered the chemical or therapeutic property of that brand.

Key words: *Vildagliptin, Weight variation, Dissolution, Disintegration, Pharmacopeia*

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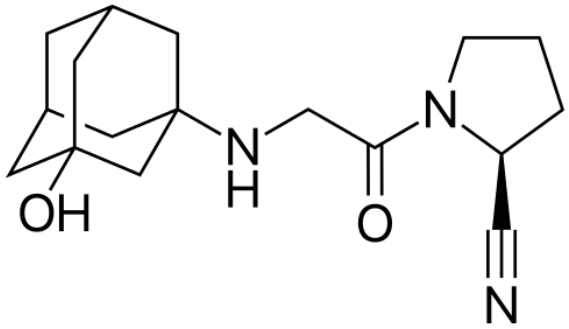
INTRODUCTION:

Vildagliptin is the active salt which is used to decrease the hyperglycemic level among diabetic people;[1]it belongs to DPP-4 inhibitors (dipeptidyl peptidase-4) class of anti-diabetic drugs. [2]It is having chemical formula (S)-[(3-Hydroxyadamantanl-yl) amino] acetyl pyrrolidin-2-carbonitril. Vildagliptin works as secretagogue as it enhances the action the action of pancreases to dischargeinsulin and also accelerate the working capacity of beta cells.[3]this active salt is having bets therapeutic results when it is used alone or in the amalgamation with other anti-diabetic drugs. Low weight gain and very minute episodes of hypoglycemic events is the main quality of vildagliptin, which is observed by the diabetic patients who consume this salt [4]. The main purpose of this research to know the identical curative agents as of vildagliptin brands available in the khairpur city.[5]



Chemical Structure of Vildagliptin[2]

METHODOLOGY:

Tablet Specification: All parameters for the physicochemical evaluation of vildagliptin tablets of 02 altered brands were performed they were weight variation test, thickness test, diameter test, disintegration test and dissolution.

Weight distinctionassessment: According to standards of the United States Pharmacopeia, there will be no more than 02 tablets out of 20 tablets should exceed the perimeter of ± 7.5% deviation. In the same case the statistical control chart (Shewart chart) shown in table 01. From each marque 20 tablets were assessed on the Electronic Balance and results were resolute that weight of each tablet was according to the standards of USP.

BreadthAssessment: Thickness of (vildagliptin) tablets with average, standard deviation, superior and inferiorparameters were intended.

WidthAssessments: Diameter of two numerousproducts of vildagliptin tablets as well as average, standard deviation, higher and inferior limits were considered.

Crumbling Test (Disintegration): Period of disintegration of the both brands were observed and the test was performed on (Curro Model no DS-0702) apparatus. Six tablets form each brand was put in the carrier and roofed with the disk on maintained temperature of 35c' to 39c' using distilled water tablets were not disintegrate than test was repeated on 12 tablets and test was positive and meet the expectation as 16 tablets from 18 tablets were disintegrated and it was clearly mentioned in the USP that tablet should disintegrate within 30 minutes in water for film layered tablets.

RESULTS:

Various physicochemical evaluation tests were performed including thickness, weight variation and diameter of two different brands of vildagliptin and the results are mentioned in table number 01.

TABLE NO 01: Weight (mg), Thickness (mm) and Diameter of 20 tablets of different brands of Vildagliptin

	Weight		Thickness		Diameter	
Tablet	**Vilget**	**Vildos**	**Vilget**	**Vildos**	**Vilget**	**Vildos**
1	203	226	3.4	4.5	8.1	8.5
2	202	231	3.4	4.5	8.2	8.6
3	199	224	3.4	4.5	8.1	8.5
4	197	225	3.1	4.6	8.1	8.5
5	210	231	3.4	4.6	8.1	8.6
6	199	224	3.3	4.5	8.1	8.6
7	201	226	3.4	4.5	8.1	8.7
8	202	225	3.5	4.6	8.1	8.5
9	198	224	3.1	4.6	8.2	8.5
10	200	226	3.4	4.5	8.2	8.5
11	204	227	3.5	4.5	8.1	8.5
12	206	227	3.5	4.5	8.1	8.5
13	207	226	3.5	4.5	8.1	8.6
14	201	225	3.4	4.5	8.1	8.5
15	204	220	3.4	4.6	8.1	8.5
16	203	223	3.5	4.6	8.1	8.6
17	206	229	3.5	4.6	8.2	8.6
18	204	230	3.5	4.5	8.1	8.5
19	201	227	3.4	4.5	8.1	8.5
20	200	225	3.4	4.5	8.1	8.5

The average weight variation along with its standard deviation was performed and with the use of specific formula the lower limit and upper limit weight was calculated as mentioned in table no 02

TABLE NO 02: Statistical Weight Variations

Tablets	**Average (mg)**	**Standard Deviation**	**Upper Limit (X+3S)**	**Lower Limit (X-3S)**
Vilget	202.1	2.57	209.81	194.38
Vildos	231.35	2.34	238.38	224.31

After analysis of weight of all tablets individually the compression was made with the standard as described in USP and all the tablets of two different brands meet with the specification as mentioned in table no 03

Table No 03: Weight Variation Test

Tablets	Results (mg)	USP Specification	Deviation from USP Specifications
Vilget	202.1	Deviation should be ±7%	Within the specified Limit
Vildos	231.35	Deviation should be ±7%	

The same criteria was repeated with the thickness test and result were compared with the standard as mentioned in United States of Pharmacopeia (USP) and all the results were under given range as in table 04

Table No 04: Statistical Thickness

Tablet	Average (mm)	Standard Deviation	Upper Limit (X+3S)	Lower Limit (X-3S)
Vilget	3.425	0.04426	3.55778	3.29222
Vildos	4.505	0.022361	4.57208204	4.43791796

The same test was again performed for the diameter of each tablet of two different brands and lower and upper limit was also calculated with application of standard deviation formula as mentioned in table no 05

Tablet No 05: Statistical Diameter

Tablet	Average (mm)	Standard Deviation	Upper Limit (X+3S)	Lower Limit (X-3S)
Vilget	8.16	0.05	8.31	8.00
Vildos	8.57	0.04	8.71	8.42

after physical test of weight variation, thickness and diameter the in vitro test for dissolution and disintegration was also performed and results were matched with the standard as described in USP and time was noted for all tablets as given in table no 06

Table No 06: Disintegration Test

Tablet	Disintegration Time	Limits	Deviation from USP
Vilget	4 min 22 sec	NMT 30 Min	Pass
Vildos	2 min 45 sec	NMT 30 Min	Pass

DISCUSSION:

The motive of this research to analyze the standards of 02 altered products of vildagliptin pills. All physicochemical parameters including weight distinction, breadth, and diameter and crumbling test were performed on two different brands of vildagliptin. The result of weight variation test was according to the standards of USP and meets the requirement as mentioned in tables below. Thickness of all pills of vildagliptin such as Standard deviation, average mass, greater and lesserparameters were in accord with the standards of United States Pharmacopeia as shown in Table. Diameter of all pills of vildagliptin tablets such as standard deviation, average weight, higher and lesser limits were also the specification of USP as mentioned in table 05. Disintegration time was also observed for the both brands of vildagliptin tablets, Vilget (Brand) crumbled in 4 min and 22 secwhereas Vildos (Brand) disintegrate in 2 min and 45 sec. The results and limits were according to the standards as mentioned in USP and data is specified in table 06.

CONCLUSION:

The 02 different variety of vildagliptin salt were having similar curative agent and all results were according to mentioned criteria of USP which was not exceed than ±1%. Only the time of disintegration was quietly differ but that was not altered the chemical or therapeutic property of that brand.

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