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RESEARCH ARTICLE

EXPLORING POST-COMPRESSION PARAMETERS IN MARKETED VILDAGLIPTIN TABLETS

Siva Krishna P[1]*, Eswarudu M.M[1], Santhi Priya N[2], Srinivasa Babu P[2], Hema Chowdary G[1], Madhurika Ch[1], Sowjanya Ch[1], Praveen Naik K[1], Deepika D[1].

[1]Department of Pharmaceutical Analysis, Vignan Pharmacy College, Vadlamudi, Guntur, Andhra Pradesh, India.

[2]Department of Pharmaceutics, Vignan Pharmacy College, Vadlamudi, Guntur, Andhra Pradesh, India.

***Corresponding Author:** P. Siva Krishna*

Abstract: This study investigates the post-compression parameters of tablets produced by five prominent pharmaceutical brands. Tablets play a crucial role in drug delivery, and their quality is essential for ensuring therapeutic efficacy. The post-compression phase is a critical step in tablet manufacturing, influencing key parameters such as weight variation, hardness, friability, and disintegration. This research aims to assess and compare these parameters for tablets from five selected brands, confirming their adherence to quality standards. The tablets from Brand A, Brand B, Brand C, Brand D, and Brand E underwent a rigorous testing protocol to evaluate hardness using a calibrated hardness tester, friability through Roche friabilator, and disintegration employing a disintegration tester. The study utilized standardized testing methods to ensure consistency and reliability across all assessments. Results revealed that all five brands successfully met benchmarks for weight variation, hardness, friability, and disintegration time. The tablets demonstrated robust mechanical strength, minimal friability, and prompt disintegration of active pharmaceutical ingredients.

Keywords: *Post-compression, Hardness, Friability, Disintegration.*

INTRODUCTION

Vildagliptin (LAF237) selectively inhibits dipeptidyl peptidase-4 (DPP-4) in the body, aiming to regulate blood sugar levels. Prescribed for the management of type II diabetes mellitus, this drug acts by inhibiting GLP-1 secretion and insulinotropic effects. Vildagliptin's inhibition of DPP-4 results in the preservation of glucose-dependent insulinotropic polypeptide (GIP), an incretin hormone responsible for stimulating insulin secretion and regulating blood sugar levels.

As a consequence, elevated levels of both GLP-1 and GIP contribute to improved glycemic control. Notably, clinical trials indicate that the risk of hypoglycemia associated with vildagliptin is relatively low, further emphasizing its potential as an effective and well-tolerated treatment option for diabetes [1].

In 2008, the European Medicines Agency approved the oral use of vildagliptin in the treatment of adults diagnosed with type II diabetes mellitus, either as a standalone therapy or in combination with metformin, sulfonylureas, or thiazolidinediones, particularly for those individuals who did not attain sufficient glycemic control with monotherapy. It has been Marketed under the brand name Galvus, this drug offers a versatile approach to diabetes management.

Additionally, a fixed-dose formulation combining vildagliptin with metformin, known as Eucreas, is available for adults whose glycemic control remains inadequate with vildagliptin alone. As of now, vildagliptin is undergoing investigation in the United States, signifying its potential for broader accessibility in the future. The drug profile of vildagliptin is shown in Table 1.

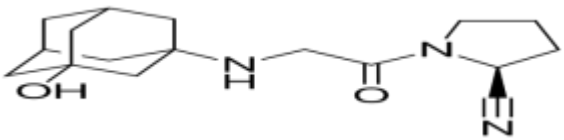

Figure 1: Chemical structure of vildagliptin

Table 1: Drug profile of vildagliptin

Drug	Vildagliptin
IUPAC Name	(2S)-1-{2-[(3-hydroxyadamantan-1-yl) amino] acetyl) pyrrolidine -2-carbonitrile
Chemical Formula	C l7H25N3O2
Molecular Mass	303.3993 g/mole
Melting Point	153-l55°C
Physical State	Solid
Solubility	Soluble in Water and Methanol
pKa	14.71 and 9.03 Strongest acidic and basic respectively
t1/2	90 minutes
Therapeutic Use	Used to reduce hyperglycemia in type II diabetes mellitus.

Post-Compression Parameters for Tablets

Hardness Test [2]

Hardness refers to the tablet's ability to resist applied force until it reaches the point of breakage. The tablet's hardness and strength are crucial factors in protecting it from the stresses encountered during manufacturing and transportation. This property is typically quantified in units of kg/cm^2.

Factor Affecting Hardness

- Amount of binder.
- Granulation preparing method.
- Compressive force.

Table 2: Types of tablets and standard hardness values [3]

Type of tablets	Standard hardness values (kg/cm^2)
Uncoated tablets	3-5
Coated tablets	3
Fast dissolving tablets	3.0-4.2
Conventional tablets	2.5-5
Extended-release tablets	5-7.5
Chewable tablets	2.25-2.
Sustained release tablets	10-20

Friability Test

This phenomenon involves the surface of the tablet being damaged or broken due to mechanical shock. The testing procedure involves utilizing a Roche friabilator, which is rotated at 25 rpm for a total of 100 revolutions.

F = Initial wt. – Final wt. / Initial wt. x 100

Weight Variation [4]

This test is conducted to assess the uniformity of tablet weight. Tablets are randomly chosen from each batch, and their weights are measured to identify any weight variation. According to pharmacopeia standards, not more than two individual weights should deviate from the average weight by a percentage specified in IP, BP, and USP. The prescribed limits for tablet weight variation are outlined below in the respective pharmacopeia.

Table 3: Pharmacopeial limits for tablet weight variation

USP	Max. % difference allowable	IP/BP
130 mg > or less	±10%	80 mg > or less
130 mg – 324 mg	±7.5%	80 mg – 250 mg
324 mg < or less	± 5 %	0 < or more

Disintegration Time

DT Apparatus [5]

The study of the *in-vitro* disintegration time of the tablet is determined by using a disintegration test apparatus as per USP.

The apparatus consists of 6 glass tubes. Mesh aperture: 2 mm, cycles: 28-32 cycles/min, 50-60 mm distance from top and bottom, temperature of water $37^0C \pm 2^0C$. If 1 or 2

tablets fail, repeat the test for another 12 tablets. Place one tablet in every tube disc upload in each tube and apparatus run by using pH 6.8. Temperature maintained at 37 ±2^0 C. in 1000 ml vessel.

Table 4: Standard disintegration time for various types of tablets [6]

Tablet	Time (min)	Temperature conditions	Solvent used
Uncoated tablets	NMT 15	37 ^{0}C ± 2 ^{0}C	Water
Dispersible / Soluble tablets	3	25 ^{0}C ±1 ^{0}C (IP), 15 – 25 ^{0}C (BP)	Water
Oro dispersible tablets	Within 1 min	-	-
Effervescent tablets	5, 5	20-30 ^{0}C (IP), 15-25 ^{0}C (BP)	Water (200 mL), Water (200 mL)
Chewable tablets	5	-	-
Sugar-coated tablets	60	-	Water
Coated tablets (Film-coated tablets)	NMT 30	-	-
Coated tablets (Other than film-coated tablets)	NMT 60	-	-
Enteric-coated tablets	120, 60	-	0.1 N HCl Phosphate buffer solution, pH 6.8
Delayed-release tablets	120, 60	-	0.1 N HCl Phosphate buffer solution, pH 6.8
Buccal & Sublingual	15-30	-	-

MATERIALS AND METHODS

A selection of precision instruments for quality control and testing has been curated, featuring renowned brands in the field. The digital vernier caliper from Perfect Sales India provides accurate measurements, ensuring precision in various applications. Essae's AJ-220E weighing balance, designed for milligram precision, offers reliable and consistent results.

Sisco's Monsanto Hardness tester is included in the lineup, guaranteeing the assessment of material hardness with efficiency. The Roche friabulator, model EI 902 from EI, is dedicated to assessing the friability of tablets, ensuring their robustness. Additionally, the disintegration apparatus EI 1901, also from EI, is part of the selection, facilitating the evaluation of the disintegration time of pharmaceutical formulations.

This assortment of instruments reflects a commitment to quality assurance and meticulous testing across diverse aspects of pharmaceutical and industrial applications.

In the pursuit of ensuring the quality and consistency of pharmaceutical formulations containing vildagliptin, five distinct brands with identical strengths have been carefully chosen for comprehensive post-compression testing. These selected brands represent a diverse array of manufacturers, each renowned for their commitment to excellence in pharmaceutical production. The post-compression tests aim to assess various critical parameters such as tablet hardness, friability, and disintegration time.

By subjecting these vildagliptin formulations to rigorous testing, the goal is to discern any variations in product attributes and performance among the different brands. This meticulous evaluation process is vital for maintaining pharmaceutical standards, ensuring patient safety, and facilitating informed choices for healthcare professionals and consumers alike.

A group of pharmaceutical brands, each offering vildagliptin formulations at a consistent strength of 50 mg, has been identified. These brands, namely Zukanorm (A), Intaglip (B), Vildagile (C), Vildanex (D), and Vildader (E) contribute to the diverse landscape of medications available in the market. Their alignment in terms of strength emphasizes a shared potency level, allowing healthcare professionals and consumers to choose from a range of trusted brands while ensuring consistent dosage for the treatment of various medical conditions.

Table 5: formulations Details of the selected products of vildagliptin

Brand name	A	B	C	D	E
Manufacturing date	6/2023	2/2023	5/2023	6/2022	5/2023
Batch no	M2AGW008	N2300321	IS23091	5/202252GIB701	IS23091
Composition	Vildagliptin-50mg Excipients-qs	Vildagliptin- IP-50 mg Excipients-qs	Vildagliptin-IP-50 mg excipients-qs	Vildagliptin-IP-50 mg Excipients-qs	Vildagliptin-IP-50 mg Excipients-qs
Manufacture license No	MNB/06/335	M/717/2016	JK/01/05-06182	27/UA/2018	JK/01/05-06/82
Storage	Not exceeding 30^0C	Not exceeding 30^0C	Below 25^0C	Not exceeding 50^0C	Below 25^0C
Manufactured by	Next ware India	Intas Pharmaceuticals Ltd.	India by Ind-Swift Ltd.	Synokem Pharmaceuticals Ltd.	In India by Ind-Swift Ltd.
Expiry date	5/2025	1/2025	4/2025	5/2024	4/2025

RESULTS AND DISCUSSION

Thickness

The thickness of various brands of Vildagliptin are shown in Table 6

Table 6: Thickness of marketed vildagliptin products

Brand	**Label claim(mg)**	**Thickness ***
A	50	3.426
B	50	3.437
C	50	3.641
D	50	4.055
E	50	3.707

**Average thickness of 20 tablets*

Weight Variation

The weight variation of various brands of vildagliptin is shown in Table 7.

Table 7: Weight variation studies of marketed vildagliptin products

Brand	**Label claim(mg)**	**Weight (g) ***	**% Deviation**	**Results**
A	50	0.201	0.864	Pass
B	50	0.2031	1.460	Pass
C	50	0.1999	0.909	Pass
D	50	0.2019	0.4415	Pass
E	50	0.199	0.844	pass

**Average weight of 20 Tablets*

Friability

The friability of various brands of vildagliptin is shown in Table 8.

Table 8: Friability data of marketed vildagliptin products

Brand	**Label claim(mg)**	**Friability (%)**	**Results**
A	50	0.185	Pass
B	50	0.323	Pass
C	50	0.312	Pass
D	50	0.417	Pass
E	50	0.282	Pass

Disintegration

The disintegration of various brands of vildagliptin is shown in Table 9.

Table 9: Disintegration data of studies of marketed vildagliptin

Brand	Label claim(mg)	Disintegration time (mL)	Results
A	50	2.42	Pass
B	50	1.11	Pass
C	50	1.55	Pass
D	50	0.45	Pass
E	50	4.50	Pass

Hardness

The hardness of various brands of vildagliptin is shown in Table 10

Table 10: Hardness of marketed vildagliptin products

Brand	Label claim(mg)	Hardness (kg/cm²)	Results
A	50	3.0	Pass
B	50	3.0	Pass
C	50	3.5	Pass
D	50	5	Pass
E	50	4	Pass

CONCLUSION

The comprehensive assessment of post-compression parameters affirms that the tablets from Brands Zukanorm, Intaglip, Vildagile, Vildanex, and Vidader consistently meet stringent quality criteria. This study provides valuable insights into the manufacturing processes of these pharmaceutical brands, instilling confidence in the reliability and effectiveness of their tablet formulations.

Further research may explore additional parameters or variations in manufacturing conditions to enhance our understanding of tablet quality across different production scenarios.

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