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A COMPARATIVE STUDY FOR THE EVALUATION OF FOUR DIFFERENT BRANDS OF ORAL ANTI DIABETIC DRUG "GLIMEPIRIDE 1 MG"

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ABSTRACT

The objective of this research work was to formulate and comprehensively evaluate glimepiride tablets utilizing the uncoated tablets. Tablets represent the most widely prescribed solid oral dosage form owing to their dosing accuracy, physical stability, and ease of manufacturing. Post-compression metrics evaluated included weight variation, thickness, diameter, mechanical hardness, friability, disintegration profile. Glimepiride is a widely prescribed oral anti-diabetic sulfonylurea used to manage type 2 diabetes mellitus (T2DM). Due to its highly hydrophobic nature and Biopharmaceutical Classification System (BCS) Class II categorization, ensuring batch-to-batch quality and strict compliance with pharmacopoeial standards is crucial for maintaining optimal therapeutic efficacy and bioavailability. This study aimed to evaluate quality control considerations for commercial glimepiride tablets in Indian. The different brands of glimepiride 1mg tablets were obtained from private pharmacies. Four brands of glimepiride tablets were used in the study. The four marketed brands of glimepiride tablet were tablet A, B, C, D respectively.

1. INTRODUCTION

Diabetes mellitus is a chronic condition that affects the metabolism of carbohydrates, fats, and proteins. A hallmark of diabetes mellitus is an inadequate or absent insulin secretion response, leading to compromised utilization of carbohydrates (glucose) and subsequent hyperglycemia. Often known simply as "sugar," diabetes mellitus (DM) is the most prevalent endocrine disorder, typically arising from either a lack of insulin or, in rare cases, a reduction in insulin efficiency (insulin resistance). The complications associated with diabetes include kidney failure, nerve damage, and peripheral vascular disease, which may result in limb amputations, vision loss due to retinopathy, and a heightened risk of heart disease and stroke, all of which are linked to poor diabetes management. Diabetes mellitus can be divided into different categories; however, the two main types are type 1 and type 2.

The term type 1 has traditionally been used to describe insulin-dependent diabetes mellitus (IDDM). The term juvenile-onset diabetes has sometimes been used to refer to IDDM. it is caused by ß-cell destruction with little or no endogenous, insulin secretory capacity, Autoimmune (90%) is stem from autoimmune destruction of pancreatic β cells leading to insulin deficiency, Idiopathic (10%) is which lacks evidence of autoimmunity. It is chronic illness.

The term type 2 has traditionally been used to describe non-insulin-dependent diabetes mellitus (NIDDM). Ranges from relative insulin deficiency to disorders of insulin secretion and insulin resistance. Type 2 diabetes has been predominantly found in individuals aged over 40. It is often linked to obesity, decreased physical activity. The term maturity-onset diabetes mellitus (MOM) relates to non-insulin-dependent diabetes mellitus (NIDDM). Typical symptoms linked to elevated blood sugar include polyuria (frequent urination), polydipsia (intense thirst), and polyphagia (increased appetite).

Anti-diabetic medications are utilized to manage diabetes mellitus by reducing glucose levels in the blood. Some of these medications are taken orally, known as oral hypoglycemic or oral anti-hyperglycemic agents; In T2DM, the body's response to insulin is reduced, characterizing it as insulin resistance.

It is the most prevalent form of diabetes and can be treated with

- Agents that enhance insulin secretion from the pancreas,
- Agents that improve the sensitivity of target tissues to insulin, and
- Agents that reduce the absorption rate of glucose from the gastrointestinal tract.

Hypoglycaemic medications are employed in the management of diabetes mellitus to decrease blood sugar levels. With the exception of insulin, exenatide, liraglutide, and pramlintide, all other hypoglycaemia medications are taken orally and are therefore referred to as oral hypoglycaemia agents or oral anti-hyperglycaemic agents.

Evaluation of tablet contents involves a series of quality control tests that are performed to confirm that the tablets meet the standards specified in pharmacopeia such as IP. These tests help in assessing physical characteristics, mechanical strength, drug content, and release profile of the tablets. Proper evaluation ensures uniformity of dosage units, consistency in drug release, and stability during storage and transportation. It also helps in identifying defects during manufacturing and maintaining batch-to-batch uniformity.

Oral Tablets are solid pharmaceutical dosage forms containing one or more active pharmaceutical ingredients along with suitable excipients. They are usually prepared by compression or moulding methods. Tablets are the most widely used dosage form because they are convenient, stable, easy to administer, and allow accurate dosing.

Tablets may contain diluents, binders, disintegrants, lubricants, and glidants to ensure proper formulation and performance. After manufacturing, tablets must undergo various quality control tests to ensure uniformity, strength, and therapeutic effectiveness.

These are evaluated several tests for evaluation of tablets in two kind tests namely that.
A) Non -official test involving general appearance, size, shape, thickness test, hardness test, friability test.
B) Official test involving weight variation, disintegration test, dissolution test, content uniformity test, identification test.

2. DRUG PROFILE

Glimepiride appears to lower blood glucose levels by stimulating insulin release from the pancreas. Glimepiride is a new hypoglycemic sulfonylurea, with the advantage of being completely bioavailable, being effective at low doses in patients with non-insulin-dependent diabetes mellitus (NIDDM), and showing linear pharmacokinetics.

Recognized as the most recent second-generation SU, glimepiride is sometimes considered a third-generation SU due to its larger modifications compared to other second- generation SUs. Glimepiride was initially introduced in clinical settings in Sweden, and in 1995, the FDA approved it for the treatment of type 2 diabetes mellitus (T2DM), both as a standalone therapy and in conjunction with metformin or insulin.

The primary physical, chemical, and biological clearance constraints governing the model drug entity are detailed below:

Table 1: Technical Drug Profile of Pure Glimepiride API.

PARAMETERS	FICATION DETAILS
Official IUPAC Identity	3-Ethyl-4-methyl-*N*-[2-(4-{[(*trans*-4-methylcyclohexyl) carbamoyl] sulfamoyl} phenyl) ethyl]-2-oxo-2,5-dihydro-1*H*- pyrrole-1-carboxamide
Empirical Formula	$C_{24}H_{34}N_4O_5S$
Molecular Weight Balance	490.62 g/mol
Melting Point Range	207 °C (405 °F).
GI absorption	Low
BBB permeant	No
bioavailability	100%
Protein binding	>99.5%
Metabolism	Complete liver (1 st stage through CYP2C9)
Onset of action	2-3 hours
Elimination half life	5-8 hours
Duration of action	24 hours
Excretion	Urine (~60%), feces (~40%)

Pregnancy Category for glimepiride AU:C - Risk cannot be ruled out.

Lactation category for glimepiride: L3- moderately safe.

3. AIM AND OBJECTIVES

The aim of this work is to evaluate and comparative the glimepiride tablet by using uncoated tablet.

1. To Evaluate the glimepiride tablets.
2. To Compare the overall quality among the four marketed brands of Glimepiride 1 mg tablets.
3. To evaluate the physical parameters such as weight variation, hardness, thickness, diameter and friability of the selected tablet brands according to Indian Pharmacopoeia.

4. MATERIALS AND METHODS

MATERIAL

Glimepiride 1 mg tablets (4 different marketed brands – Brand A, Brand B, Brand C, Brand D), Distilled water, Thermometer.

Four different brand names are A, B, C, D respectively. These are evaluated several tests for evaluation of tablets

1. General appearance Evaluation of tablet color, size, shape, odor and surface defects.
2. Thickness test Measured using vernier calipers to ensure uniform size.
3. Hardness test Measures tablet strength using Monsanto/Pfizer hardness tester.
4. Friability test Determines resistance to abrasion using Roche friabilator.
5. Weight variation Ensures uniform drug content by checking tablet weight.
6. Disintegration test Time taken for tablet to break into particles.

Instruments

- Digital weighing balance
- Vernier caliper
- Monsanto / Pfizer hardness tester
- Roche friabilator
- Disintegration test apparatus

TABLET LABEL CLAIM

Each uncoated tablet contains:
Glimepiride IP 1 mg
Excipients q. s.
Storage: Store protected from moisture, at a temperature not exceeding 30• c. Protect from light.
Dosage: As directed by the physician
Keep out of reach of children.
Schedule H prescription drug –
Caution: Not be sold by retail without the prescription of a Registered Medical Practitioner

GENERAL APPEARANCE

Table 2: GENERAL APPEARANCE OF TABLET.

TABLET	COLOUR	SHAPE	SIZE
A	White colour	Flat circular	3.18 inch's
B	Yellow lake colour	Flat circular	2.79 inch's
C	White colour	Oval / Oblong	4.17 inch's
D	Brown red colour	Oval /Oblong	4.01inch's

5. Thickness and Hardness Test

Table 3: Thickness and Hardness of Tablet.

Tablet	Thickness test(mm)	Hardness test(kg/cm2)
A	2.8	8
B	2.66	7.5
C	3.44	4
D	2.65	6.5

- Thickness test: All four tablets demonstrate excellent dimensional consistency across trials. Tablet A shows the least variation, making it the most uniform. Tablets A and B are circular, while Tablets C and D are oval-shaped. Consistent dimensions ensure proper packaging, coating, and accurate dosage delivery in pharmaceutical manufacturing.
- Hardness test: Tablet A is the hardest and most consistent, making it the best performer in hardness testing. Tablet C records the lowest hardness, which may affect its durability and handling. Tablets B and D fall within acceptable ranges. Higher hardness with low variation indicates better tablet quality in manufacturing

Tablet-wise Performance

- Tablet A maintains consistent values between 7.5 to 8.5 kg/cm² with an average of 8 kg/cm², showing excellent hardness and uniformity.
- Tablet B ranges from 7 to 8 kg/cm² with an average of 7.5 kg/cm², reflecting good and stable hardness.
- Tablet C records the lowest hardness with all values between 4 to 4.5 kg/cm² and an average of 4 kg/cm², indicating softer tablets compared to others.
- Tablet D ranges from 5.5 to 7 kg/cm² with an average of 6.5 kg/cm², showing moderate hardness with slight variation across trials

6. FRIABILITY TEST

Table 4: PERCENTAGE FRIABILITY OF TABLET.

	Tablet A	Tablet B	Tablet C	Tablet D
Friability %	0.25%	0.35%	0.55%	0.41%

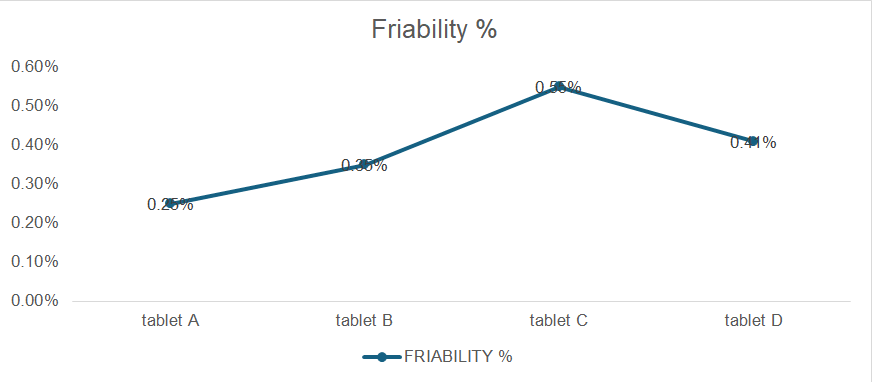

Figure No. 1 Graphical view of friability percentage.

7. WEIGHT VARIATION

The formula of Weight Variation = $\frac{Iw - Aw}{Aw} \times 100\%$

Table 5: WEIGHT VARIATION OF TABLE.

S. No.	Tablet A	Tablet B	Tablet C	Tablet D
Average weight	**0.19 gm**	**0.13 gm**	**0.17gm**	**0.12gm**
Upper limit	**204.25 mg**	**139.75 mg**	**182.75mg**	**129 mg**
Lower limit	**175.75 mg**	**120.25 mg**	**157.25 mg**	**111mg**
Maximum Weight variation ranges	**±5.26**	**± 6.153846**	**±5.88**	**±6.666667**

The table presents the weight variation analysis of four tablet formulations (Tablet A, Tablet B, Tablet C, and Tablet D) as part of a quality control study.

Average Weight: Among the four tablets, Tablet A has the highest average weight of 0.19 gm, followed by Tablet C (0.17 gm), Tablet B (0.13 gm), and Tablet D with the lowest at 0.12 gm.

Upper and Lower Limits: The upper and lower limits define the acceptable weight range for each tablet. Tablet A has the range (204.25 mg to 175.75 mg), while Tablet D has the narrowest range (129 mg to 111 mg), indicating tighter control over its weight consistency.

Weight Variation Range (±%): The weight variation percentage reflects how much the tablet weight is allowed to deviate from its average. Tablet D shows the highest variation of ±6.666667%, followed by Tablet B at ±6.153846%, Tablet C at ±5.88%, and Tablet A with the lowest variation of ±5.26%, suggesting Tablet A has the most consistent weight among the four.

Overall Interpretation: Tablets with lower variation percentages (like Tablet A) indicate better uniformity in manufacturing, which is a positive sign in quality control. Tablets with higher variation (like Tablet D) may require further process optimization to ensure dosage accuracy and patient safety.

8. DISINTEGRATION TEST

Disintegration trials were conducted in an IP-standard basket-rack assembly filled with simulated gastric fluid (0.1 N HCl, pH 1.2) maintained at 37 ± 0.5°C.

Table 6: Disintegration Profiles (Minutes).

Tablet no.	Tablet A	Tablet B	Tablet C	Tablet D
1	4.56	3.48	2.20	6.47
2	5.33	3.51	2.21	6.47
3	5.34	3.52	2.21	6.48
4	5.54	3.58	2.21	6.57
5	5.55	4.06	2.24	7.01
6	6.01	4.11	2.29	7.13
Range (mins)	**4.56 to 6.01**	**3.48 to 4.11**	**2.2 to 2.29**	**6.47 to 7.13**

9. CONCULSION AND SUMMARY

The evaluation results show that all tablets meet acceptable limits for hardness, friability, weight variation, and disintegration. Tablet A shows the highest hardness and lowest friability indicating good mechanical strength, while Tablet C shows the fastest disintegration time but lower hardness. Tablet B and Tablet D exhibit intermediate properties with acceptable tablet quality. Overall, all formulations show satisfactory tablet characteristics.

The present study was carried out to evaluate and compare the quality of four different marketed brands of Glimepiride 1 mg tablets available in India. Various quality control parameters such as physical evaluation and other standard tests were performed to assess the pharmaceutical equivalence of the selected brands.

This comparative study for the evaluation of four different brands of oral anti diabetic drug “glimepiride 1 mg” was studied and evaluated. As per Indian pharmacopoeia (IP) all the tablets were under normal ranges so, they passed out the evaluation tests. We found tablet C was with faster disintegration time than other tablets so it was found to be with better bioavailability.

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