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COMPARATIVE EVALUATION OF DIFFERENT MARKETED BRANDS OF ANTIDIABETIC TABLETS: A COMPREHENSIVE REVIEW

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ABSTRACT

Diabetes mellitus is a chronic metabolic condition marked by sustained hyperglycemia due to impairments in insulin production, insulin action, or both. It is a significant global health challenge with a swiftly escalating prevalence internationally. The World Health Organization identifies diabetes as a primary contributor to morbidity and death, especially in low- and middle-income nations. Oral antidiabetic agents, particularly Metformin, are commonly employed as first-line treatment in the management of type 2 diabetes mellitus owing to their effectiveness, safety, and cost-efficiency. The existence of several marketed brands of antidiabetic pills prompts significant concerns about pharmaceutical quality, pharmacological equivalence, and interchangeability. This research seeks to assess several marketed brands of antidiabetic pills by examining physicochemical factors, dissolving characteristics, and bioequivalence tests. Evidence from numerous research shows that although most brands conform with pharmacopeial requirements, slight changes in formulation and manufacturing procedures may impact drug release patterns. Nevertheless, these variances often remain within acceptable parameters and do not substantially influence treatment results. The analysis underscores the necessity of ongoing quality control, regulatory oversight, and comparative assessment to guarantee the safety, effectiveness, and uniformity of commercial formulations. It also encourages the use of cost-effective generic pharmaceuticals as viable alternatives to branded treatments in diabetes control.

KEYWORDS: Antidiabetic tablets; Metformin; Dissolution; Bioequivalence; Generic drugs; Pharmaceutical evaluation; Quality control.

1. INTRODUCTION

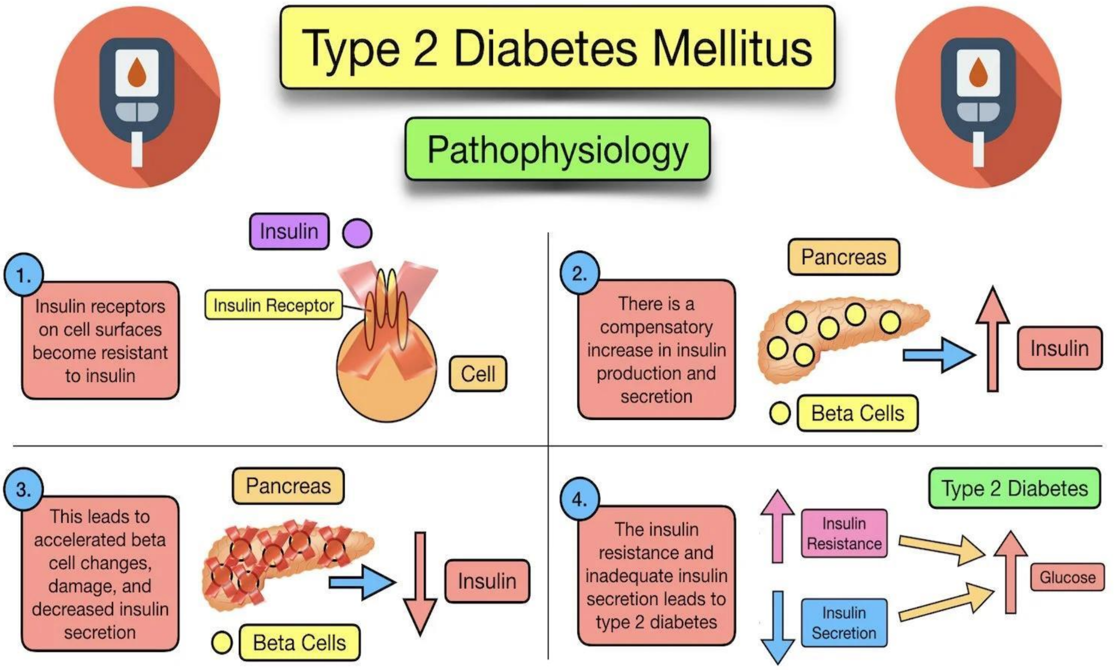

Figure 1: Pathophysiology of diabetes mellitus.

Persistent hyperglycemia brought on by abnormalities in insulin secretion, action, or both is the hallmark of diabetes mellitus, a complicated, long-term metabolic disease. It is seen as one of the 21st century's most significant worldwide public health issues. The International Diabetes Federation estimates that 537 million persons globally had diabetes in 2021, and this figure is expected to increase significantly during the ensuing decades.[1]

Type 1 diabetes mellitus (autoimmune death of pancreatic β-cells), Type 2 diabetes mellitus (insulin resistance with relative insulin insufficiency), and gestational diabetes mellitus are the three main kinds of the disease. Nearly 90–95% of these cases are Type 2 diabetes mellitus, which is closely linked to lifestyle factors such obesity, sedentary activity, and poor eating habits.[2,3]

Chronic hyperglycemia is linked to long-term harm, malfunction, and failure of many organs, including the heart, blood vessels, kidneys, eyes, and nerves, greatly raising morbidity and mortality.[4]

1.2 Oral Antidiabetic Drugs' Function

Pharmacological therapies and lifestyle changes are used in the management of diabetes mellitus. In patients with Type 2 diabetes mellitus in particular, oral antidiabetic medications (OADs) are essential for regulating blood glucose levels. Because of its proven effectiveness, safety record, and affordability, metformin continues to be the first-line medication among them. It mainly works by promoting peripheral glucose absorption, increasing insulin sensitivity, and decreasing hepatic gluconeogenesis.[5,6]

Other classes of oral antidiabetic medications that are frequently used include:

- Sulfonylureas (increase the release of insulin from the pancreas)
- Inhibitors of dipeptidyl peptidase-4 (DPP-4) (increase incretin action)
- Inhibitors of sodium-glucose co-transporter-2 (SGLT2), which increase the excretion of glucose in the urine

Drug selection is patient-specific since each class has a different mechanism of action, effectiveness, safety, and economic considerations.[7]

1.3 Branded vs. Generic Drugs and the Need for Comparative Analysis

Numerous branded and generic antidiabetic medication formulations are on the market due to the pharmaceutical industry's explosive growth. Pharmaceutical products that are therapeutically identical to innovator pharmaceuticals in terms of dose form, potency, mode of administration, quality, and intended purpose are referred to as generic drugs.

The World Health Organization and the U.S. Food and Drug Administration, among other regulatory bodies, require generic medications to exhibit bioequivalency to their branded counterparts, guaranteeing that there is no appreciable variation in the rate and degree of drug absorption.[8,9]

However, important quality characteristics including dissolving rate, drug release profile, stability, and ultimately bioavailability may be impacted by differences in excipients, production methods, and formulation strategies. To guarantee comparable therapeutic effects across many marketed brands, these variances require comprehensive comparative investigation.[10]

1.4 Physicochemical and Dissolution Studies' Significance

A number of crucial physicochemical characteristics, such as weight variation, hardness, friability, disintegration time, drug content homogeneity, and dissolving profile, are evaluated when evaluating commercially available antidiabetic tablets.

As a proxy for in vivo drug efficacy and bioavailability, dissolution testing is regarded as one of the most important quality control methods. Variations in formulation and manufacturing processes can lead to variations in dissolution profiles, which could impact therapeutic efficacy if improperly managed.[11,12]

Comparing the dissolution profiles of various brands is made easier by the use of similarity factors (f2) and other model-independent techniques.

1.5 The Review's Justification

Numerous investigations have shown that while the majority of commercially available antidiabetic pill brands adhere to pharmacopeial requirements, slight differences in physicochemical properties and drug release patterns are often noted. These differences emphasize the significance of ongoing post-marketing surveillance and quality assurance, even though they frequently stay within permissible regulatory bounds.[13,14]

Furthermore, there is a growing demand for solid scientific data to support the safety, effectiveness, and interchangeability of generic medications, especially in developing nations like India.

1.6 Goals and Objectives

The current review seeks to

- Examine various commercial brands of antidiabetic pills critically.
- Examine their physicochemical characteristics.
- Examine drug release behavior and dissolution patterns.

- Evaluate therapeutic and bioequivalency.
- Emphasize the importance of quality control and regulatory standards.

2. Antidiabetic Drug Classification

Based on their mode of action, site of action, and therapeutic function in glycemic control, antidiabetic medications are broadly categorized. These medications lower blood glucose levels through a variety of physiological processes and are mostly used to treat Type 2 diabetes mellitus.[11,14]

Biguanides, sulfonylureas, meglitinides, thiazolidinediones, dipeptidyl peptidase-4 (DPP-4) inhibitors, and sodium-glucose co-transporter-2 (SGLT2) inhibitors are the main families of oral antidiabetic medications; each has a unique efficacy, safety profile, and mode of action.[5,7]

2.1 Biguanides

One of the most commonly administered classes of oral antidiabetic medications is biguanides. The American Diabetes Association and the World Health Organization suggest metformin as the first-line treatment for Type 2 diabetes mellitus, and it is currently the sole medication in this category that is utilized in clinical settings.[4,5]

Action Mechanism

There are several ways that metformin prevents hyperglycemia:

- Hepatic gluconeogenesis reduction (primary action)
- Improvement of peripheral tissues' insulin sensitivity
- Increased skeletal muscle absorption of glucose
- Reduced absorption of glucose in the intestines

Metformin improves glucose metabolism and lowers hepatic glucose production by molecularly activating AMP-activated protein kinase (AMPK), a crucial regulator of cellular energy homeostasis.[6,15]

Benefits

- When administered alone, there is little chance of hypoglycemia
- encourages weight neutrality or mild weight loss
- lowers triglycerides and LDL, improving the lipid profile
- Cost-effective and widely accessible

Restrictions

- unpleasant symptoms related to the digestive system (nausea, diarrhea, discomfort in the abdomen)
- Long-term use increases the risk of vitamin B12 insufficiency.
- Lactic acidosis is an uncommon but dangerous complication, especially in those with renal impairment.

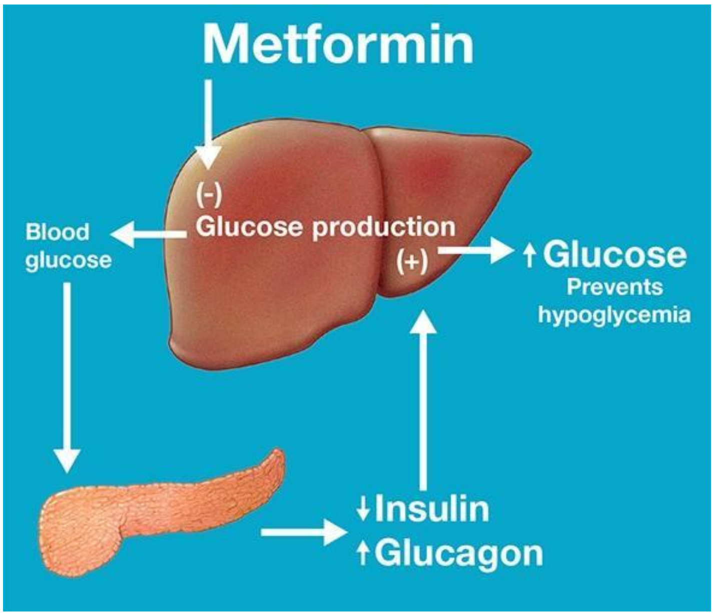

Figure 2: Mechanism of drugs.

2.2 Sulfonylureas

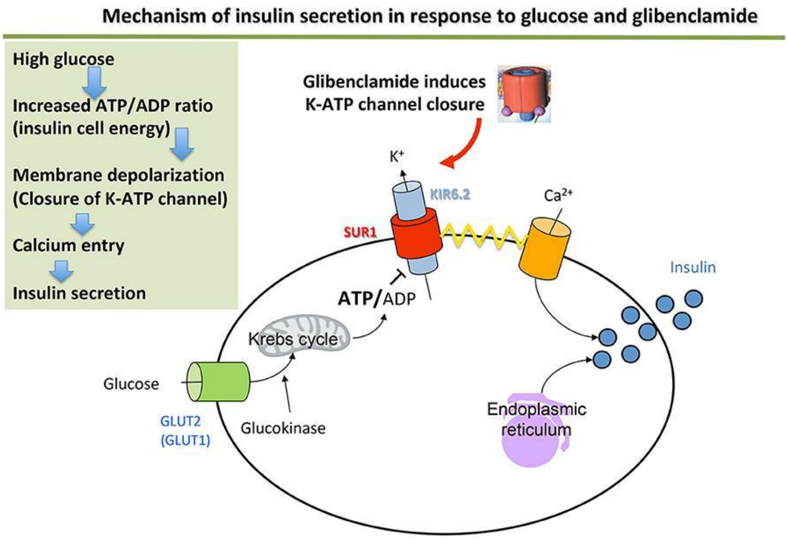

Figure 3: Mechanism of insulin secretion in response to glucose and glibenclamide.

A class of insulin secretagogues known as sulfonylureas increases the release of insulin from healthy pancreatic β-cells.

They are frequently used in conjunction with metformin to help patients with Type 2 diabetes mellitus achieve better glycemic control.[5,14]

Glipizide, glimepiride, and glibenclamide (glyburide) are typical examples.

Action Mechanism

The following mechanism is how sulfonylureas affect pancreatic β-cells to produce their pharmacological effect

- Attachment to β-cell membrane sulfonylurea receptors (SUR1)
- ATP-sensitive potassium (K^+) channel closure
- Depolarization of membranes

- Voltage-gated calcium (Ca2+) channel opening
- elevated intracellular calcium levels
- Increased secretion of insulin

Their increased risk of hypoglycemia is explained by this process, which is independent of glucose.[7,11]

Benefits

- Efficient lowering of blood glucose levels
- Quick onset of action
- Economical and extensively accessible

Restrictions

- Hypoglycemia risk (particularly in older people)
- connected to gaining weight
- decreased efficacy over time as a result of β-cell fatigue

2.3 DPP-4 Inhibitors

Dipeptidyl peptidase-4 (DPP-4) inhibitors boost incretin hormone action.[5]

New oral antidiabetics called DPP-4 inhibitors improve glucose control by increasing incretin hormones like GLP-1.[5,7]

Typical examples are sitagliptin, vildagliptin, saxagliptin, and linagliptin.

Action Mechanism

Prevention of incretin hormone breakdown by inhibiting DPP-4.

Increased GLP-1 and GIP activity

Greater glucose-dependent insulin secretion

Avoiding glucagon release

Hepatic glucose decrease

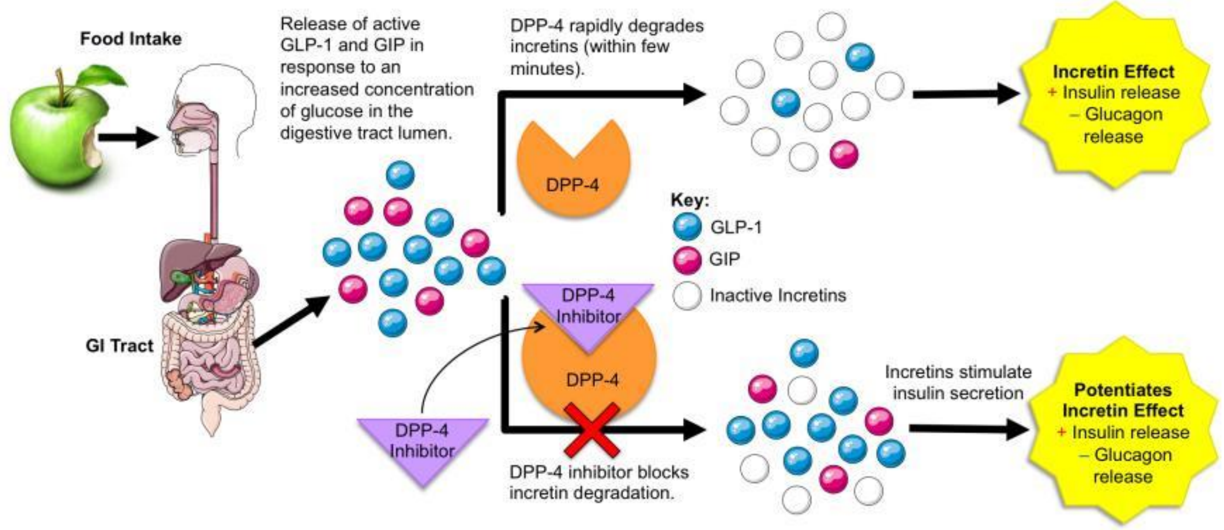

Figure 4: Mechanism of Dipeptidyl peptidase-4 (DPP-4).

Advantages

- Low glucose-dependent hypoglycemia risk
- Weight-neutral effect
- Good tolerability profile

Limitations

- Moderate effectiveness relative to other classes
- Higher cost
- Rare risk of pancreatitis (found in several research)

2.4 SGLT2 Inhibitors 6

Sodium-glucose co-transporter-2 (SGLT2) inhibitors are a unique family of oral antidiabetic medicines that lower blood glucose levels by boosting urine glucose excretion. These medicines work independently of insulin and have gained major importance because to their additional cardiovascular and renal advantages.[5,7]

Common examples include dapagliflozin, canagliflozin, and empagliflozin.

Action Mechanism

- Inhibition of SGLT2 transporters in the renal proximal tubules
- Decreased glucose reabsorption in the kidneys
- Increased urine glucose excretion (glucosuria)
- Reduction in plasma glucose levels

Advantages

- Promotes weight loss
- Provides cardiovascular protection (particularly in heart failure patients)
- Offers renal protective effects
- Low risk of hypoglycemia when administered alone

Limitations

- Risk of urinary tract infections and genital infections
- Dehydration and hypotension (due to osmotic diuresis)
- Higher cost compared to standard therapies

2.5 Other Classes of Antidiabetic Drugs

In addition to the primary classes, several more antidiabetic medications help to glycemic control:

- Thiazolidinediones (TZDs)
- Improve insulin sensitivity in peripheral tissues
- Example: pioglitazone
- Limitation: weight increase, fluid retention
- Alpha-glucosidase inhibitors

Delay carbohydrate breakdown and absorption in the gut

Example: acarbose

Limitation

- gastrointestinal side effects
- Meglitinides
- Short-acting insulin secretagogues

Example: repaglinide, nateglinide

Useful for postprandial glucose control

3. Generic versus Branded Drugs

3.1 Definition of Generic Drugs

Generic pharmaceuticals are pharmaceutical products that are comparable to branded (innovator) drugs in terms of dose form, potency, mode of administration, quality, and intended purpose.[6,7]

According to the World Health Organization, generic medications must demonstrate bioequivalence to the reference product to assure equivalent therapeutic effects.

3.2 Concept of Bioequivalence

Bioequivalence refers to the absence of a substantial difference in the rate and amount of drug absorption between generic and branded formulations under similar settings.[13]

Key Pharmacokinetic Parameters

Cmax → Maximum plasma concentration

Tmax → Time to achieve

Cmax AUC (Area Under Curve) → Total drug exposure

Regulatory organizations such as the U.S. Food and medicine Administration require that generic products fall within the acceptable bioequivalence range of 80–125% compared to the reference medicine.[8,15]

3.3 Differences Between Generic and Branded Drugs

Parameter Generic Drugs Branded Drugs

Cost Low High Manufacturer Multiple businesses Original innovator Marketing Minimal Extensive

4. Evaluation Parameters of Antidiabetic Tablets

The quality, safety, and therapeutic efficacy of oral antidiabetic pills depend on several crucial physicochemical and performance criteria. These characteristics are critical to maintain pharmacological equivalency, constant bioavailability, and similar drug release behavior among different marketed brands.

Evaluation of tablets is carried out according to pharmacopeial standards established by organizations such as the United States Pharmacopeia, Indian Pharmacopoeia Commission, and British Pharmacopoeia Commission.[9,15]

Key Evaluation Parameters

- Weight variation
- Hardness
- Friability
- Disintegration time
- Drug content homogeneity
- Dissolution profile

Among these, dissolution testing is particularly essential as it serves as a prognostic predictor of in vivo drug release and bioavailability. Variations in formulation and manufacturing techniques can dramatically influence dissolving behavior, consequently affecting therapeutic effects.

4.1 Weight Variation Test

Figure 5: Weight variation.

Principle

The weight variation test is performed to guarantee consistent distribution of medication content among individual tablets within a batch. It is based on the idea that a uniform tablet weight equates to uniform drug content, provided the formulation is homogeneous. This test is particularly relevant for tablets having greater concentrations of active medicinal substances.[8,9]

Procedure

1. Select 20 tablets randomly from a batch
2. Weigh each tablet individually using a calibrated analytical balance
3. Calculate the average weight of the pills
4. Determine the percentage departure of each pill from the average weight Acceptance Criteria (USP Guidelines)

According to the United States Pharmacopeia

- Tablets weighing > 250 mg → ±5% deviation permitted
- Tablets weighing 130–324 mg → ±7.5% deviation
- Tablets weighing < 130 mg → ±10% deviation

Not more than two pills should depart from the given limitations, and none shall deviate by more than twice the percentage restriction.

Significance

Uniform pill weight ensures

- Accurate drug dosing
- Consistent therapeutic effect
- Patient safety and compliance
- Batch-to-batch homogeneity

Factors Affecting Weight Variation

Variations may develop owing to

- Improper granulation process
- Poor flow characteristics of granules
- Variation in die fill during compression
- Machine-related inconsistencies

4.2 Hardness Test

Figure 6: Hardness testing machine.

Principle

Tablet hardness, commonly referred to as crushing strength, assesses the mechanical integrity of a tablet and its ability to endure handling, packaging, transit, and storage without breaking or chipping. It reflects the interparticulate bonding inside the tablet matrix.[8]

Method

Hardness is determined using instruments such as the Monsanto hardness tester or Pfizer hardness tester

A tablet is put between two anvils, and force is applied until the tablet breaks

The force necessary to break the tablet is recorded

Unit: kg/cm² (or Newtons in contemporary instruments)

Acceptable Range

Conventional tablets often show hardness in the range of 4–8 kg/cm^2

However, the permissible value may vary based on formulation and planned release characteristics.

Significance

Tablet hardness plays a vital impact in

- Maintaining mechanical strength during handling and transport
- Controlling disintegration time and dissolution rate
- Ensuring constant drug release profile

Balance essential hai

Too hard → delayed breakdown and slower medication release

Too soft → increased friability and likelihood of breakage

Factors Affecting Hardness

- Compression force applied while tableting
- Type and concentration of binder used
- Moisture content of granules
- Particle size and flow characteristics of the formulation

4.3 Friability Test 6 Principle

Figure 7: Friability Testing machine.

Principle

Friability is a measure of the ability of tablets to resist abrasion, surface chipping, and mechanical stress during handling, packaging, and transportation. It reflects the mechanical strength and durability of tablets under stress situations.[8,9]

Procedure

A sample of 10–20 pills is weighed properly (starting weight, W_0)

Tablets are placed in a friabilator (e.g., Roche friabilator)

The device is operated at 25 rpm for 100 revolutions (≈ 4 minutes)

Tablets are removed, dedusted, and reweighed (final weight, W_1)

Percentage friability is calculated as:

%Friability= W 0

W 0−W 1×100 Acceptance Criteria

- According to pharmacopeial standards such as the United States Pharmacopeia:
- Percentage weight loss should be < 1%
- Tablets showing more than 1% loss indicate inadequate mechanical strength.

Significance

Friability testing ensures:

- Adequate mechanical strength of tablets
- Resistance to abrasion during handling and transit
- Stability during packaging and storage
- Maintenance of product quality and patient safety
- Factors Affecting Friability
- Insufficient binder concentration
- Low compression force
- Poor granule cohesion
- Excessive dryness of granules

4.4 Disintegration Test 5 Principle

Figure 8: Disintigration machine.

Principle

Disintegration is the process by which a tablet breaks down into smaller fragments when placed in a defined liquid media under standardized conditions. This process is critical for future drug breakdown and absorption.[9]

Procedure

Tablets are inserted in a disintegration test equipment with a suitable media (typically water or simulated stomach contents).

The temperature is maintained at 37 ± 2°C to replicate physiological circumstances

The apparatus moves up and down at a constant rate

The time required for complete disintegration of each pill is recorded Acceptance Criteria

According to pharmacopeial standards such as the United States Pharmacopeia:

- Uncoated tablets → should dissolve within 15 minutes
- Film-coated pills → within 30 minutes
- Sugar-coated pills → within 60 minutes

No remnant should remain except bits of insoluble coating.

Significance

Disintegration testing is necessary because

- It is the first step toward drug breakdown
- Faster breakdown often leads to faster medication release and start of effect
- Ensures uniform medication availability from diverse tablet batches
- Helps in predicting in vivo drug performance
- Factors Affecting Disintegration
- Type and concentration of disintegrants
- Compression force (hardness of tablet)
- Binder content
- Tablet porosity
- Coating qualities

4.5 Dissolution Test

Principle

Dissolve testing examines the rate and amount of drug release from a solid dosage form into a defined dissolve media under standardized conditions. It acts as a critical quality control metric and a surrogate indicator of in vivo drug efficacy and bioavailability.[9–11]

Apparatus

According to the United States Pharmacopeia, the regularly used devices include:

USP Type I (Basket equipment)

Figure 9: Dissolution Testing Machine.

Type II (paddle) is most often used for conventional immediate-release tablets.

Procedure

- The tablet is placed in a jar containing dissolving media
- Temperature is maintained at 37 ± 0.5°C
- The equipment revolves at a given speed (usually 50–100 rpm)
- Samples are extracted at predefined time intervals
- Drug concentration is measured using UV spectrophotometry or HPLC Significance

Dissolution testing is significant since it

- Predicts in vivo medication release and bioavailability
- Ensures batch-to-batch uniformity
- Detects formulation and manufacturing discrepancies
- Plays a vital part in generic drug evaluation and comparative studies

Comparative studies of marketed brands rely primarily on dissolution data.[10–12]

4.6 Drug Content Uniformity

Principle

Content homogeneity guarantees that each tablet retains the indicated amount of active pharmaceutical ingredient (API), hence maintaining dosage accuracy and therapeutic consistency.[9,12]

Method

Individual tablets are examined using proven analytical techniques such as

- UV spectrophotometry
- High-performance liquid chromatography (HPLC)
- The medication content in each tablet is calculated against a standard calibration curve

Acceptance Criteria

As per pharmacopeial standards

- Drug content should be within 85–115% of the indicated claim Significance
- Ensures therapeutic efficacy
- Prevents underdose or overdose
- Maintains product quality and regulatory compliance

5. Dissolution Profile Comparison & IVIVC

1 Dissolution Profile Comparison

Dissolution profiles of different marketed brands are compared using model-independent mathematical approaches:

Similarity Factor (f2)

f2=50·log{[1+n1∑t=1n(Rt−Tt)2]−0.5×100}

Difference Factor (f1)

$$f1 = [\, \Sigma |Rt - Tt| \,/\, \Sigma Rt \,] \times 100$$

Interpretation

- **f2 = 50–100 → Similar dissolution profiles**
- **f1 ≤ 15 → Acceptable difference**

These statistical tools are widely recommended for comparative evaluation of pharmaceutical products.[10,13]

5.2 In-Vitro In-Vivo Correlation (IVIVC)

IVIVC establishes a predictive association between:

- In vitro dissolution data
- In vivo bioavailability parameters

A good IVIVC model has various advantages:

- Predicts clinical performance from dissolution data
- Reduces the need for lengthy human bioequivalence studies
- Supports formulation optimization and regulatory approval

5. Review of Literature

A considerable number of studies have been conducted to evaluate the quality, safety, and therapeutic equivalency of different marketed brands of antidiabetic pills, particularly metformin. These research generally focus on physicochemical characteristics, dissolving behavior, and bioequivalence to ensure consistent clinical performance across formulations.[22–24]

5.1 Comparative Evaluation Studies

Samar Afifi and Shaimaa Ahmadeen (2012) conducted a comparative review of six brands of metformin hydrochloride tablets available in the Saudi Arabian market. The study includes quality control tests such as weight variation, hardness, friability, disintegration, dissolution, and drug content analysis. All brands conformed with pharmacopeial criteria; nevertheless, modest variations in hardness and dissolution profiles were detected, showing the influence of formulation factors on tablet performance.[22]

Similarly, ***Debanga Das, Jashabir Chakraborty, and Suvakanta Dash (2017)*** performed a comparison research on marketed metformin pills. Their findings indicated that although modest variances existed in physical characteristics, all brands displayed comparable drug release behavior and were judged medically equivalent.[23]

Safila Naveed et al. (2018) assessed several brands of metformin tablets available in Pakistan using standard quality control standards. The results revealed that all brands met pharmacopeial standards, reaffirming their pharmacological equivalence, while also stressing the significance of continuing post-marketing examination.[24]

5.2 Influence of Formulation Variables

Y. Ankamma Chowdary et al. (2014) studied the impact of formulation factors on drug release from metformin tablets. The investigation indicated that excipients and manufacturing procedures greatly alter dissolving behavior and bioavailability, even when the active ingredient stays same.[25]

Diksha Sharma et al. (2019) further confirmed these findings by demonstrating that modifications in excipient makeup can alter medication release rates. Improper formulation may lead to either delayed or fast drug release, consequently altering therapeutic outcomes.[26]

5.3 Dissolution and Bioequivalence Studies

Pratik C. Mate et al. (2020) did a comparative in vitro examination of different marketed brands of metformin tablets. Although all brands fulfilled regulatory specifications, small discrepancies were identified in dissolving profiles, showing heterogeneity in formulation performance under certain conditions.[27]

Ziye Zhou et al. (2021) performed both in vitro and in vivo bioequivalence tests on extended-release metformin formulations. Their results indicated comparable pharmacokinetic parameters across generic and branded medicines, suggesting their interchangeability.[28]

Belachew Umeta et al. (2021) investigated dissolution profiles of numerous brands on the Ethiopian market and found that all formulations satisfied with pharmacopeial standards and had similar release patterns, indicating medicinal equivalence.[29]

5.4 Post-Marketing Surveillance Studies

Mohamed I. Daghman et al. (2024) conducted a post-marketing monitoring research to evaluate the quality of marketed metformin tablets. While most brands conformed with pharmacopeial criteria, slight discrepancies in physicochemical attributes were detected, underlining the need for continual quality monitoring.[30]

M. D. Mohammad Yosuf et al. (2025) compared Jan Aushadhi generic antidiabetic medications with branded formulations in India. The study concluded that generic drugs provide equivalent quality, safety, and therapeutic efficacy, supporting their function as cost-effective alternatives.[31]

5.5 Critical Analysis of Literature

Collectively, the analyzed research suggest that

- Most marketed brands comply with pharmacopeial standards
- Minor differences in physicochemical properties are widespread
- Dissolution profiles may vary due to formulation changes

These differences normally do not significantly alter therapy outcomes

However, the literature also highlights

- The demand for constant quality control and monitoring
- The necessity of post-marketing surveillance
- The crucial function of dissolution testing as a predictive tool

5.6 Research Gap

- Despite substantial research, numerous holes remain:
- Limited long-term stability studies of commercial formulations
- Lack of large-scale comparative clinical trials
- Insufficient data on in vitro–in vivo correlation (IVIVC) for all formulations

These limitations underscore the necessity for future extensive comparative evaluation studies.

6. Comparative Evaluation of Marketed Antidiabetic Tablets

Comparative evaluation studies of different marketed brands of metformin tablets generally focus on physicochemical parameters and dissolving behavior to prove pharmacological and therapeutic equivalency. Although most formulations meet with pharmacopeial requirements, slight deviations are frequently detected due to differences in excipients, manufacturing processes, and formulation techniques.[22–27]

6.1 Comparison of Quality Control Parameters

Parameter	Brand A	Brand B	Brand C	Pharmacopeial Limit
Weight Variation (%)	±2.5	±3.0	±2.8	±5%
Hardness (kg/cm²)	5.2	6.1	5.8	4–8
Friability (%)	0.45	0.60	0.50	<1%
Disintegration (min)	8	10	9	≤15
Drug Content (%)	98.5	101.2	99.3	85–115

Interpretation

- All brands comply with pharmacopeial specifications
- Minor variation in hardness may influence disintegration and dissolution behavior
- Friability values (<1%) indicate good mechanical strength
- Drug content uniformity confirms accurate dosage

Overall, these findings indicate pharmaceutical equivalence among the evaluated brands.[23,24]

6.2 Dissolution Profile Comparison

Time (min)	Brand A	Brand B	Brand C
5	30%	28%	32%
10	55%	52%	58%
20	80%	75%	82%
30	95%	90%	96%

Dissolution testing is regarded the most critical metric in comparative evaluation studies, as it closely correlates with drug release and possible bioavailability.

Several studies have indicated that while most brands display comparable dissolving profiles (f2 value between 50–100), slight variations may exist due to formulation changes such as excipient content and granulation processes.[27–29]

Even when variances exist, they often remain below acceptable ranges and do not significantly impair therapeutic efficacy.

6.3 Bioequivalence Considerations

Bioequivalence studies indicate that generic and branded formulations exhibit comparable pharmacokinetic performance in terms of pace and amount of drug absorption. Regulatory bodies such as the U.S. Food and Drug Administration require that generic formulations fall within acceptable bioequivalence ranges (80–125%) to assure therapeutic equivalence.

Evidence from various research suggests that most marketed metformin brands meet these requirements, supporting their interchangeability in clinical practice.[28,29]

6.4 Impact of Formulation Variables

Differences in excipients, manufacturing techniques, and tablet design can influence:

- Dissolution rate
- Drug release profile
- Stability Bioavailability

Such discrepancies underscore the necessity of formulation optimization and thorough quality control throughout manufacture.[25,26]

6.5 Overall Interpretation

Overall, the comparative examination of marketed antidiabetic medications reveals that:

- Most brands comply with pharmacopeial standards
- Minor physicochemical differences are prevalent
- Dissolution discrepancies exist but are usually below tolerable limits
- Therapeutic equivalence is generally maintained between brands

These findings support the use of generic formulations as safe, effective, and cost-efficient alternatives to branded drugs, providing they meet regulatory standards.

7. CONCLUSION

The present analysis on the comparative examination of different marketed brands of antidiabetic tablets, particularly metformin, indicates that the majority of formulations available in the pharmaceutical market comply with recognized pharmacopeial standards. Key quality control criteria, including weight variation, hardness, friability, disintegration time, dissolving profile, and drug content homogeneity, were found to be within acceptable limits across most investigations.

Although modest variations in physicochemical attributes and dissolving behavior were detected among different brands, these discrepancies are mostly related to variations in excipient composition, formulation procedures, and manufacturing processes. Importantly, such differences often remain below acceptable regulatory limits and do not materially alter therapeutic effects.

Dissolution tests and similarity factor (f2) analysis further indicate that most marketed formulations display comparable drug release characteristics, validating their pharmacological equivalence and bioequivalence. These findings underscore the clinical acceptance of generic formulations as effective alternatives to branded medications.

Regulatory authorities such as the World Health Organization and the U.S. Food and Drug Administration prioritize severe quality control techniques to ensure the safety, efficacy, and uniformity of pharmaceutical goods. Continuous post-marketing surveillance and comparative evaluation studies remain needed to maintain these standards.

Overall, this review strongly supports the use of cost-effective generic antidiabetic medicines in the management of diabetes mellitus, thereby improving accessibility, affordability, and patient compliance without compromising therapeutic efficacy.

8. Recommendations

- Regular post-marketing surveillance should be conducted
- Strict adherence to pharmacopeial standards must be assured
- More in vivo bioequivalence studies are necessary
- Development of robust IVIVC models

Increased awareness regarding the safety and efficacy of generic medicines.

9. Limitations of the Review

- Limited availability of recent large-scale clinical trials
- Heavy dependence on in vitro studies
- Variability in study design and methods
- Lack of long-term stability data

10. Future Perspectives

Future studies should focus on:

- Advanced analytical procedures (HPLC, LC-MS/MS)
- Development of customized medicine techniques
- Large-scale comparative clinical investigations
- Real-world evidence-based investigations

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