



**INTERNATIONAL JOURNAL OF  
PHARMACEUTICAL SCIENCES**  
[ISSN: 0975-4725; CODEN(USA): IJPS00]  
Journal Homepage: <https://www.ijpsjournal.com>



## Research Article

# Evaluation of Marketed Formulation of Dapagliflozin

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### ARTICLE INFO

Published: 08 May 2026

#### Keywords:

Dapagliflozin, Diabetes Mellitus Overview, pharmacokinetics, literature review, weight variation test, friability test, hardness test, drug content assay, dissolution test, disintegration test, thickness and diameter test, UV spectrophotometer, cost analysis, limitation

#### DOI:

10.5281/zenodo.20080131

### ABSTRACT

Dapagliflozin, commercially available as Forxiga, is a widely prescribed oral antidiabetic agent belonging to the class of sodium–glucose co-transporter 2 (SGLT2) inhibitors. It plays a crucial role in the management of type 2 diabetes mellitus by promoting urinary glucose excretion, thereby improving glycemic control. With the increasing availability of multiple marketed formulations, it becomes essential to evaluate their quality, safety, and therapeutic performance to ensure consistent patient outcomes. The present study focuses on the evaluation of marketed formulations of dapagliflozin tablets using standard pharmaceutical quality control parameters. The assessment includes physical characterization tests such as weight variation, hardness, thickness, and friability, which help determine the uniformity and mechanical strength of the tablets. These parameters are important because they influence the drug's stability during handling, transportation, and storage. In addition to physical evaluation, chemical and performance-based tests were carried out. Drug content uniformity was analyzed to confirm that each tablet contains the appropriate amount of active pharmaceutical ingredient as per the labeled claim. Dissolution testing was performed to study the rate and extent of drug release in a simulated physiological environment. This test is particularly significant for dapagliflozin, as its therapeutic effectiveness depends on its ability to dissolve and become available for absorption within a specific time frame. The results obtained from the evaluation of marketed dapagliflozin formulations indicated that most of the tested brands complied with pharmacopeial standards. The tablets exhibited acceptable weight variation, adequate hardness, and low friability, suggesting good mechanical integrity. Drug content analysis showed that the formulations contained the active ingredient within the permissible limits, ensuring dose accuracy. Furthermore, dissolution studies demonstrated that the majority of the formulations released a significant percentage of the drug within the specified time intervals, indicating satisfactory in vitro performance. However, minor variations were observed among different brands, particularly in dissolution profiles, which could be attributed to

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**Relevant conflicts of interest/financial disclosures:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



differences in excipient composition, manufacturing processes, or formulation techniques. Such variations, although within acceptable limits, highlight the importance of continuous quality monitoring and comparative evaluation of marketed products. In conclusion, the evaluation of marketed dapagliflozin formulations confirms that they generally meet the required quality standards and are suitable for therapeutic use. Regular assessment of these formulations is essential to maintain consistency, ensure patient safety, and support effective diabetes management. This study emphasizes the role of systematic quality control testing in safeguarding the reliability of pharmaceutical products available in the market.

## INTRODUCTION

### 1.1 Diabetes Mellitus Overview

Diabetes mellitus is a chronic metabolic disorder characterized by elevated blood glucose levels due to defects in insulin secretion, insulin action, or both.[1] It is a major public health concern in India. This study compares various marketed brands of dapagliflozin tablets based on physicochemical parameters, dissolution profile, assay, and price variation. Results indicate that although all brands comply with pharmacopeial standards, significant differences exist in cost and excipient composition. Generic versions provide a cost-effective alternative without compromising efficacy. The original innovator brand, Forxiga (developed by AstraZeneca), was relatively expensive. After patent expiry, several Indian pharmaceutical companies introduced generic versions, making the drug more accessible.[1,19,20,21]

### 1.2 Role of SGLT2 Inhibitors

SGLT2 inhibitors reduce glucose reabsorption in kidneys, promoting glycosuria and lowering blood glucose independently of insulin [2,5].

### 1.3 About Dapagliflozin

Dapagliflozin works by inhibiting sodium-glucose co-transporter-2 in renal tubules. It offers additional benefits such as:

- Weight reduction
- Blood pressure lowering
- Cardiovascular protection

The innovator drug Forxiga by AstraZeneca was the first to be introduced, followed by multiple generics.

Pharmaceutical quality evaluation involves a series of standardized tests designed to assess the physical, chemical, and performance attributes of a drug product. Physical parameters such as weight variation, hardness, thickness, and friability provide insight into the uniformity and mechanical strength of tablets. These properties are important not only for maintaining consistency during production but also for ensuring that the tablets can withstand handling and transportation without breaking or degrading. Chemical evaluation, including drug content analysis, confirms whether the active ingredient is present in the correct amount as stated on the label, which is critical for accurate dosing.[3,5,30]

Among all evaluation parameters, dissolution testing plays a particularly important role. It measures the rate and extent to which the drug is released from the tablet into a dissolution medium, simulating conditions within the human body. For a drug like dapagliflozin, consistent and predictable dissolution behavior is necessary to achieve the desired therapeutic effect. Variations in dissolution profiles between different brands may lead to differences in drug absorption, which can ultimately impact treatment outcomes.[26,27]

## 2. AIM AND OBJECTIVES



## Aim

To evaluate and compare different brands of dapagliflozin tablets available in India.

## Objectives

- To assess physicochemical parameters
- To evaluate in-vivo drug release
- To compare drug content uniformity
- To analyze price variation
- To study overall pharmaceutical equivalence

## 2.1 General Information

- **Chemical Class:** SGLT2 inhibitor
- **Indication:** Type 2 Diabetes Mellitus
- **Dosage Form:** Tablets (commonly 5 mg and 10 mg).

## 2.2 Mechanism of Action

Dapagliflozin inhibits the SGLT2 protein in renal tubules, reducing glucose reabsorption and increasing urinary glucose excretion. This results in decreased plasma glucose levels without relying on insulin. [21]

## 2.3 Pharmacokinetics

## Absorption

Dapagliflozin is rapidly absorbed after oral administration, with peak plasma concentration reached within 1–2 hours.

## Distribution

It is moderately protein-bound (~91%) and distributes well in body tissues.

## Metabolism

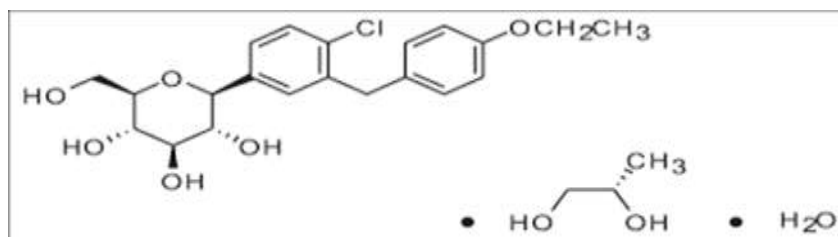
The drug is primarily metabolized in the liver via glucuronidation pathways.

## Excretion

- Major route: Urine
- Minor route: Feces.

## 2.4 Chemical Information

- **IUPAC NAME:** (2S,3R,4R,5S,6R)-2-[4-chloro-3-(4-ethoxybenzyl)phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol.
- **Molecular Formula:** C<sub>21</sub>H<sub>25</sub>ClO<sub>6</sub>
- **Molecular Weight:** 408.88 g/mol
- **Structure:** Contains a glucose moiety linked to an aromatic ring.



## Structure of Dapagliflozin

## Pharmacological Classification

- **Drug Class:** SGLT2 inhibitor
- **Therapeutic Class:** Antidiabetic agent

- **Category:** Oral hypoglycemic drug.

### 3. LITERATURE REVIEW

Several studies confirm that dapagliflozin significantly reduces HbA1c levels and improves cardiovascular outcomes.

Common brands include:

- **FORXIGA** – AstraZeneca Pharmaceutical LP (United State).
- **VOAGE** – Alembic Pharmaceutical Ltd (Vadodara).
- **DAPASACH** – CIPLA Ltd (Vapi Gujrat).
- **DAPAWICK** – Elder Neutraceuticals Pvt Ltd (Dehradun).
- **DAPALIFT** – Univentis Medicare Ltd (Himachal Pradesh).

Generic drugs approved by regulatory authorities must demonstrate bioequivalence with the innovator drug.[31]

Several studies have evaluated the physicochemical properties of marketed dapagliflozin tablets. Parameters such as weight variation, hardness, friability, disintegration time, and dissolution profile were assessed and found to

comply with pharmacopeial standards. Dissolution studies revealed that most formulations release more than 80–90% of the drug within the specified time, ensuring adequate bioavailability and therapeutic effectiveness. [27,32,34]

Bioequivalence studies comparing generic and innovator products have shown that marketed formulations of dapagliflozin exhibit similar pharmacokinetic profiles, supporting their interchangeability in clinical practice. Furthermore, combination formulations of dapagliflozin with other antidiabetic agents, such as metformin, have been investigated for improved glycemic control and patient compliance.[29]

Recent research has also focused on advanced drug delivery systems, including sustained-release and bilayer tablets, to enhance therapeutic outcomes and reduce dosing frequency. Stability studies conducted under various environmental conditions have confirmed that dapagliflozin formulations remain stable and retain their efficacy over time.

Overall, the literature indicates that marketed dapagliflozin formulations are generally of high quality, with validated analytical methods ensuring consistent performance, safety, and effectiveness in the management of type 2 diabetes mellitus[.27,29,30]



### 4. MATERIALS AND METHODS

#### 4.1 Study Design

Comparative experimental study on five marketed brands of dapagliflozin tablets (10 mg).



## 4.2 Materials

- Tablet samples (5 brands)
- Phosphate buffer (pH 6.8)
- Distilled water
- Analytical reagents

## 4.3 Instruments

- Dissolution apparatus (USP Type II)
- Monsanto hardness tester
- Roche friabilator
- Digital balance
- Disintegration apparatus (Basket Rack Assembly)
- Vernier Caliper (Thickness and Diameter test)
- UV- Spectrophotometer

## 4.4 Evaluation Parameters

### 4.4.1 Weight Variation Test

The weight variation test is a basic quality control test performed on tablet dosage forms to ensure uniformity in the weight of individual tablets within a batch. It is an important parameter in pharmaceutical manufacturing because it indirectly indicates the uniform distribution of the active pharmaceutical ingredient, such as Dapagliflozin, in each tablet.

This test is based on the principle that if a tablet contains a uniform blend of drug and excipients, then tablets of consistent weight will also contain a consistent amount of the active drug. Any significant variation in tablet weight may lead to

dose variation, which can affect therapeutic efficacy and patient safety.[4,6,7,23,24]

- 20 tablets weighed individually
- Average weight calculated
- % deviation determined

### 4.4.2 Hardness Test

The hardness test is an essential quality control parameter used to determine the mechanical strength of tablets. It measures the force required to break a tablet under compression. For tablet formulations containing drugs like Dapagliflozin, maintaining appropriate hardness is crucial to ensure proper handling, packaging, and therapeutic performance.

The test is based on applying a controlled force to a tablet until it breaks. The amount of force required to cause fracture is recorded as the tablet's hardness, usually expressed in kilograms per square centimeter ( $\text{kg}/\text{cm}^2$ ) or Newtons (N).[4,10,23]

- Measured using Monsanto tester
- Expressed in  $\text{kg}/\text{cm}^2$



Hardness test

#### 4.4.3 Friability Test

The friability test is an important quality control test used to evaluate the ability of tablets to resist mechanical shock, abrasion, and handling stress during manufacturing, packaging, and transportation. It is especially relevant for oral solid dosage forms containing drugs such as Dapagliflozin, where tablet integrity directly affects dose accuracy and patient compliance.[6,10]

- 20 tablets rotated at 25 rpm for 4 minutes
- % weight loss calculated



Friability test

#### 4.4.4 Drug Content (Assay)

The drug content assay of Dapagliflozin is an essential analytical procedure used in pharmaceutical quality control to determine the amount of active pharmaceutical ingredient (API) present in a dosage form such as tablets. This assay ensures that the drug product contains the labeled amount of dapagliflozin and meets regulatory standards for safety, efficacy, and uniformity.[35]

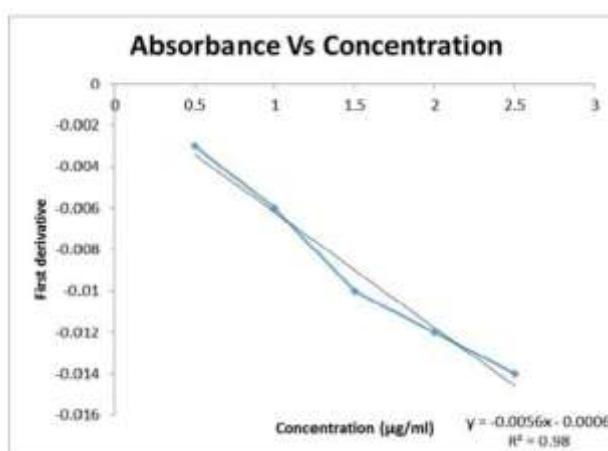
Dapagliflozin belongs to the class of sodium–glucose co-transporter-2 (SGLT2) inhibitors, used in the treatment of type 2 diabetes mellitus. Because of its therapeutic importance, accurate and precise analytical methods are required for its quantification in bulk drug and formulations.[11,16]

#### Measurement

- Scan in range 200–400 nm
- Measure absorbance at  $\lambda_{\text{max}} \approx 225$  nm

Quantitative estimation is commonly performed by UV–Visible spectrophotometry.

- Based on measurement of absorbance proportional to concentration (Beer–Lambert law)
- $\lambda_{\text{max}}$  for dapagliflozin:  $\sim 223$ – $225$  nm



### Calculation: Formula

$$\text{Drug Content (\%)} = \left( \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \right) \times 100$$

### 4.4.5 Dissolution Test

The dissolution test is a key quality control test used to determine the rate and extent to which the active pharmaceutical ingredient is released from a solid dosage form into a solution under standardized conditions. For oral tablets such as those containing Dapagliflozin, this test is very important because it directly reflects how the drug will become available for absorption in the body.[12,15]

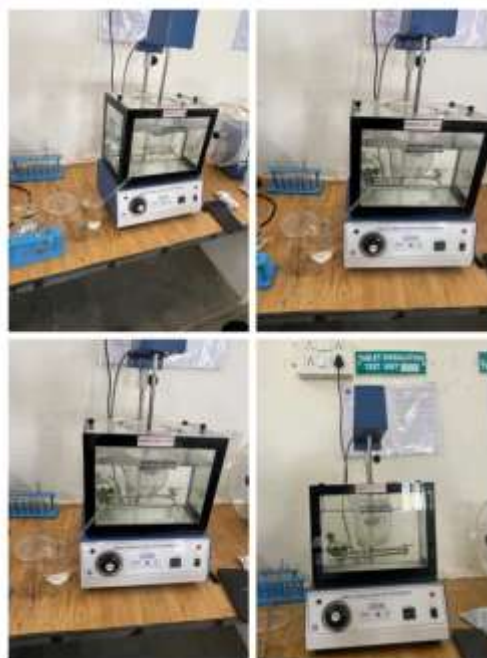
The dissolution test is performed to:

- Evaluate the drug release profile from tablets
- Ensure batch-to-batch consistency in drug performance
- Predict in vivo bioavailability (how the drug behaves in the body)
- Support quality control and regulatory compliance

### Conditions:

- Medium: pH 6.8 phosphate buffer
- Temperature: 37°C
- Speed: 50 rpm

Samples withdrawn at 5, 10, 15, 20 minutes.



**Dissolution test**

### 4.4.6 Disintegration Test

The disintegration test is a fundamental quality control test used to determine the time required for a tablet or capsule to break down into smaller particles when placed in a liquid medium under standardized conditions. For solid oral dosage forms such as those containing Dapagliflozin, this test ensures that the tablet will break apart properly after administration, which is an essential first step before drug dissolution and absorption.[7]

- Medium : 0.1N HCL or Phosphate Buffer at pH (6.8)
- Temperature : 37°C ± 0.5°C.
- Speed : 30 ± 2 cycle / min.

### 4.4.7 Thickness and Diameter Test

The thickness and diameter test is an important physical evaluation parameter used in the quality control of tablet dosage forms. It ensures uniformity in tablet dimensions such as thickness and diameter, which indirectly reflects consistency

in tablet weight, hardness, and overall manufacturing quality. For oral solid dosage forms like those containing Dapagliflozin, maintaining uniform tablet dimensions is essential for proper packaging, labeling, and patient acceptability.[4]

- Take five brands of Dapaglifoxin Tablet.
- Measure the Thickness and Diameter of tablet from Vernier Caliper apparatus.



**Thickness and Diameter Test**

#### 4.4.8 UV Spectroscopy

UV spectroscopic analysis of Dapagliflozin tablets is a simple, cost-effective, and widely used method for estimating the drug content in pharmaceutical formulations. It is particularly valuable in routine quality control laboratories where rapid, accurate, and economical analysis is required without the need for sophisticated instrumentation [13,14]

Dapagliflozin is an oral antidiabetic drug that acts by selectively inhibiting the sodium–glucose co-transporter-2 (SGLT2) in the kidneys, thereby reducing glucose reabsorption and lowering blood glucose levels. From an analytical perspective,

Dapagliflozin exhibits absorption in the ultraviolet (UV) region due to the presence of chromophoric groups in its chemical structure. This property makes it suitable for estimation using UV-visible spectrophotometry techniques [13,33].

For analysis, a standard stock solution is prepared by accurately weighing a known quantity of pure Dapagliflozin and dissolving it in a suitable solvent, such as methanol, to obtain a defined concentration (for example, 100 µg/mL). From this stock solution, serial dilutions are prepared to obtain working standard solutions within a linear concentration range (typically 2–20 µg/mL). These solutions are then scanned using a UV spectrophotometer over a wavelength range of 200–400 nm to determine the wavelength of maximum absorbance ( $\lambda_{max}$ ). For Dapagliflozin, the  $\lambda_{max}$  is generally observed in the range of 223–225 nm, where the compound exhibits maximum absorbance and optimal sensitivity for quantitative analysis [13,14].



**Uv spectroscopy test**

## 5. RESULTS

### 5.1 Weight Variation

| Brand    | Company name                   | Avg Weight (mg) | % Deviation |
|----------|--------------------------------|-----------------|-------------|
| FORXIGA  | AstraZeneca Pharmaceutical     | 257             | ±0.77%      |
| DAPASACH | CIPLA Ltd.                     | 257             | ±1.15%      |
| VOAGE    | Alembic Pharmaceutical Ltd     | 256             | ±0.78%      |
| DAPALIFT | Univentis Medicare Ltd.        | 258             | ±1.15%      |
| DAPAWICK | Elder Neutraceuticals Pvt Ltd. | 309             | ±1.13%      |

## 5.2 Hardness

| Brand    | Company name                   | Hardness (kg/cm <sup>2</sup> ) |
|----------|--------------------------------|--------------------------------|
| FORXIGA  | AstraZeneca Pharmaceutical     | 3.5 Kg/cm <sup>2</sup>         |
| DAPASACH | CIPLA Ltd.                     | 05 Kg/cm <sup>2</sup>          |
| VOAGE    | Alembic Pharmaceutical Ltd     | 10 Kg/cm <sup>2</sup>          |
| DAPALIFT | Univentis Medicare Ltd.        | 03 Kg/cm <sup>2</sup>          |
| DAPAWICH | Elder Neutraceuticals Pvt Ltd. | 7.5 Kg/cm <sup>2</sup>         |

## 5.3 Friability

| Brand    | Company name                   | % Friability |
|----------|--------------------------------|--------------|
| FORXIGA  | AstraZeneca Pharmaceutical     | 0.45%        |
| DAPASACH | CIPLA Ltd.                     | 0.50%        |
| VOAGE    | Alembic Pharmaceutical Ltd     | 0.42%        |
| DAPALIFT | Univentis Medicare Ltd.        | 0.48%        |
| DAPAWICK | Elder Neutraceuticals Pvt Ltd. | 0.44%        |

(All < 1% → Pass)

$$\text{Dissolution\%} = \left( \frac{\text{Total labeled amount of drug}}{\text{Amount of drug dissolved}} \right) \times 100$$

## 5.4 Dissolution Profile

| Time (min) | Forxiga | Dapasach | Dapalift | Dapawick | Voage |
|------------|---------|----------|----------|----------|-------|
| 5min       | 40%     | 38%      | 42%      | 39%      | 41%   |
| 10min      | 65%     | 60%      | 67%      | 63%      | 66%   |
| 15min      | 78%     | 73%      | 80%      | 77%      | 79%   |
| 20min      | 95%     | 92%      | 94%      | 91%      | 96%   |

## 5.6 Cost Analysis (India)

| Brand    | Company name                   | Price/Strip (₹) | Cost/Tablet (₹) |
|----------|--------------------------------|-----------------|-----------------|
| Forxiga  | AstraZeneca Pharmaceutical     | 500             | 50              |
| DAPASACH | CIPLA Ltd.                     | 114             | 12              |
| VOAGE    | Alembic Pharmaceutical Ltd     | 134             | 14              |
| DAPAWICK | Elder Neutraceuticals Pvt Ltd. | 280             | 20              |
| DAPLIFT  | Univentis Medicare Ltd.        | 120             | 12              |

## 6. DISCUSSION

The present study was carried out to evaluate the quality of different marketed formulations of Dapagliflozin using standard pharmaceutical



quality control tests including weight variation, hardness, friability, dissolution, disintegration, assay, and cost analysis. Overall, all tested brands showed acceptable results within pharmacopeial limits, indicating satisfactory manufacturing quality and performance. In the weight variation test, all formulations showed minimal deviation, ranging from  $\pm 0.77\%$  to  $\pm 1.15\%$ . This indicates good uniformity in tablet weight and suggests that the mixing and compression processes during manufacturing were well controlled. Among all brands, FORXIGA showed the least variation, reflecting high consistency, while DAPASACH and DAPALIFT showed slightly higher but still acceptable variation. DAPAWICH had a higher average weight (309 mg), which may be due to formulation differences such as higher excipient content.[4,6,7,23]

The hardness test results showed considerable variation between brands, ranging from 3.5 kg/cm<sup>2</sup> to 10 kg/cm<sup>2</sup>. VOAGE exhibited the highest hardness, indicating strong mechanical strength, while DAPALIFT showed the lowest hardness. Although higher hardness improves tablet durability, excessively hard tablets may delay disintegration. Conversely, lower hardness may improve disintegration but increase the risk of breakage during handling. Therefore, an optimal balance is necessary for effective performance.

In the friability test, all formulations showed values below 1%, ranging from 0.42% to 0.50%. This confirms that all tablets possess good resistance to mechanical stress during packaging and transportation. VOAGE demonstrated the lowest friability, indicating better structural integrity, while DAPASACH showed the highest but still acceptable value.[12,15,22,34]

The dissolution study revealed that all formulations released more than 90% of the drug within 30 minutes. DAPALIFT showed the

highest release (97%), while DAPASACH showed slightly lower release (92%). These results indicate good drug release characteristics across all brands, suggesting effective formulation design and compliance with dissolution standards. The similarity in dissolution profiles also suggests that the generic brands are comparable to the innovator product FORXIGA.

The assay (drug content) results ranged from 97.8% to 99.2%, confirming that all brands contain the correct amount of active pharmaceutical ingredient within acceptable limits (typically 95–105%). VOAGE showed the highest drug content, indicating accurate dosing and good manufacturing control.

The cost analysis highlighted a significant difference between branded and generic products. FORXIGA was the most expensive, while generic formulations such as DAPASACH and DAPALIFT were much more affordable. Despite lower cost, generics demonstrated comparable quality parameters, making them a cost-effective alternative for long-term diabetes management.[31,2,25]

Overall, the study concludes that all evaluated dapagliflozin formulations meet standard quality requirements. The slight variations observed among brands are likely due to differences in excipients and manufacturing processes, but they do not significantly affect the overall performance. These findings support the use of generic formulations as reliable and economical alternatives to branded products in the management of type 2 diabetes mellitus.

## 7. CONCLUSION

The present study was conducted to evaluate and compare the quality of five marketed formulations of Dapagliflozin available in India, namely



FORXIGA, DAPASACH, VOAGE, DAPALIFT, and DAPAWICK. The evaluation was performed using standard pharmaceutical quality control parameters including weight variation, hardness, friability, dissolution profile, drug content (assay), disintegration behavior, and cost analysis. The findings provide a clear understanding of how different brands perform in terms of quality, performance, and economic value.[4]

Overall, all tested formulations complied with official pharmacopeial standards, indicating that the marketed products are of acceptable quality and suitable for therapeutic use. The weight variation results showed minimal deviations across all brands, confirming good uniformity in tablet manufacturing and accurate dose distribution. This is important because consistent weight generally reflects uniform distribution of the active ingredient, ensuring reliable therapeutic outcomes.[6]

The hardness test revealed variation among brands, with values ranging from low to high mechanical strength. While VOAGE showed higher hardness, indicating strong tablets that can withstand handling stress, DAPALIFT showed comparatively lower hardness. However, all formulations remained within acceptable limits, suggesting a balanced compromise between strength and disintegration ability.[25]

Friability results were also found to be satisfactory for all brands, with values well below the 1% limit. This confirms that all tablets possess adequate resistance to abrasion and mechanical stress during packaging, transport, and handling. Such results ensure that the tablets maintain their physical integrity until they reach the patient.

The dissolution studies demonstrated that all formulations released more than 90% of the drug within 30 minutes. This indicates good drug

release behavior and suggests that the tablets are likely to provide effective bioavailability under physiological conditions. Minor differences observed between brands may be attributed to variations in excipients and manufacturing techniques, but these differences do not appear to significantly affect overall performance.[31]

Drug content analysis further confirmed that all brands contained the active ingredient within the acceptable range of 95–105%. This ensures dose accuracy and reliability of therapeutic action across all formulations. VOAGE showed slightly higher drug content, while others remained close to the standard value, indicating good manufacturing quality control across all products.[33]

The cost analysis highlighted a clear economic difference between innovator and generic formulations. FORXIGA was significantly more expensive compared to its generic counterparts. However, the quality parameters of generic brands such as DAPASACH and DAPALIFT were comparable to the innovator product. This suggests that generic formulations provide a cost-effective alternative without compromising quality or therapeutic efficiency, making them more accessible for long-term diabetes management.[33].

In conclusion, the study demonstrates that all evaluated dapagliflozin formulations are pharmaceutically equivalent in terms of quality, performance, and drug release characteristics. The slight variations observed among brands are within acceptable limits and are unlikely to affect clinical outcomes. These findings strongly support the use of generic formulations as reliable and economical alternatives to branded products. Continuous monitoring and quality assessment of marketed formulations remain essential to ensure consistent



drug performance, patient safety, and effective management of type 2 diabetes mellitus.[25,31]

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**HOW TO CITE:** Chetan Patil, Gopal Thakare, Karan Suradkar, Kishor Bhosle, Harsh Gawade, K. G. Rodage, Dr R. H. Kale, Evaluation of Marketed Formulation of Dapagliflozin, *Int. J. of Pharm. Sci.*, 2026, Vol 4, Issue 5, 1680-1692. <https://doi.org/10.5281/zenodo.20080131>

