

Comparative Assay Study of Different Marketed Brands of Dapagliflozin and Pioglitazone Tablets by Using UV Spectrophotometry

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Abstract - A comparative analytical study was carried out to determine and compare the drug content of three different marketed brands (Brand A, Brand B and Brand C) of Dapagliflozin (10 mg) and Pioglitazone (15 mg) tablets using UV spectrophotometry. The absorbance of the drug solutions was measured at 223 nm for Dapagliflozin and 234 nm for Pioglitazone in methanol, and the percentage assay of each brand was calculated against the labelled claim. The mean assay values obtained for Dapagliflozin were 97.33%, 97.87% and 98.50% for Brand A, Brand B and Brand C, respectively, while the corresponding mean assay values for Pioglitazone were 96.78%, 97.78% and 98.50%. All three brands complied with the pharmacopoeial acceptance limit of 90.0-110.0% of the labelled claim, with Brand C consistently showing the highest assay among the brands studied. The results confirm that UV spectrophotometry is a simple, rapid, precise and economical method suitable for the routine quality control and comparative evaluation of Dapagliflozin and Pioglitazone tablets available in the market.

Key Words: *Dapagliflozin; Pioglitazone; UV Spectrophotometry; Comparative Assay; Marketed Brands; Quality Control*

1. INTRODUCTION

A comparative study is a research approach in which two or more products, samples or methods are evaluated against a common standard to identify similarities and differences in their quality, performance or effectiveness. In the present work, this approach is applied to different marketed brands of Dapagliflozin and Pioglitazone tablets, two widely prescribed oral antidiabetic agents used in the management of Type 2 Diabetes Mellitus. Dapagliflozin is a Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitor that lowers blood glucose by reducing renal glucose reabsorption, while Pioglitazone is a thiazolidinedione that improves insulin sensitivity by activating the PPAR- γ receptor. Because these drugs are manufactured by numerous companies under different brand names, it is important to verify that all marketed formulations consistently contain the correct amount of active pharmaceutical ingredient (API) as per their labelled claim.

UV-Visible spectrophotometry is one of the most widely used analytical techniques in pharmaceutical quality control because it is simple, rapid, accurate, reproducible and economical. The technique is based on the Beer-Lambert law, which relates the absorbance of a solution at a specific wavelength to the concentration of the absorbing species. Since Dapagliflozin and Pioglitazone both possess chromophoric groups capable of absorbing ultraviolet radiation, UV spectrophotometry provides a convenient and validated approach for their routine estimation in bulk drug and tablet dosage forms, without the need for costly instrumentation such as HPLC.

The present investigation was undertaken with the aim of performing a comparative assay of three different marketed brands each of Dapagliflozin and Pioglitazone tablets by UV spectrophotometry, and comparing the drug content obtained against the labelled claim to assess compliance with pharmacopoeial quality requirements.

2. MATERIALS AND METHODS

2.1 Chemicals and Reagents

Analytical Reagent (AR) grade Dapagliflozin and Pioglitazone reference standards, methanol and distilled water were used throughout the study. Whatman Filter Paper No. 41 was used for filtration. All solutions were freshly prepared on the day of analysis.

2.2 Instruments

A UV-Visible spectrophotometer fitted with a matched pair of quartz cells (1 cm path length) was used for all absorbance measurements. A digital analytical balance (accuracy ± 0.1 mg), an ultrasonic sonicator, standard volumetric glassware and quartz cuvettes were used for sample preparation and analysis.

2.3 Marketed Tablet Samples

Three different marketed brands each of Dapagliflozin (10 mg) and Pioglitazone (15 mg) tablets, coded as Brand A, Brand B and Brand C, were procured from licensed retail pharmacies. Tablets were selected based on availability, uniform dosage strength, intact packaging and validity of expiry date, and were verified for batch number, manufacturing date, expiry date and manufacturer's details prior to analysis.

2.4 Preparation of Standard Stock Solution

Dapagliflozin: 10 mg of Dapagliflozin reference standard was accurately weighed and transferred into a 100 mL volumetric flask, dissolved in about 70 mL of methanol by sonication for 10 minutes, and the volume made up to 100 mL with methanol to obtain a stock solution of 100 $\mu\text{g/mL}$.

Pioglitazone: 10 mg of Pioglitazone reference standard was similarly weighed, dissolved in methanol by sonication and made up to 100 mL with methanol to obtain a stock solution of 100 $\mu\text{g/mL}$.

Working standard solutions of 2, 4 and 6 $\mu\text{g/mL}$ were prepared from the respective stock solutions by suitable dilution with methanol for the construction of calibration curves.

2.5 Determination of λ_{max}

Standard solutions of each drug were scanned in the range of 200–400 nm using methanol as blank. Dapagliflozin showed maximum absorbance at 223 nm and Pioglitazone at 234 nm in methanol; these wavelengths were used for all subsequent assay measurements. The standard absorbance values used as reference were 0.5000 for Dapagliflozin (at 223 nm, 10 $\mu\text{g/mL}$ basis) and 0.6000 for Pioglitazone (at 234 nm, 10 $\mu\text{g/mL}$ basis).

2.6 Preparation of Tablet Sample Solution

Twenty tablets of each marketed brand were weighed, and the average tablet weight was determined. The tablets were powdered, and a quantity of powder equivalent to the labelled drug content was accurately weighed and transferred into a 100 mL volumetric flask. About 70 mL of methanol was added, and the mixture was sonicated for 15 minutes, cooled, made up to volume with methanol, and filtered through Whatman Filter Paper No. 41. Aliquots of 2, 4 and 6 mL of the filtrate were used for absorbance measurement, corresponding to the working concentration range.

2.7 Assay Procedure

The absorbance of each sample solution was measured against a methanol blank at 223 nm for Dapagliflozin and 234 nm for Pioglitazone. The drug concentration in each aliquot was calculated from the standard absorbance, and the percentage assay was determined using the following equation:

$$\text{Percentage Assay} = (\text{Amount of Drug Estimated} / \text{Label Claim}) \times 100$$

2.8 Acceptance Criteria and Statistical Analysis

Assay results were evaluated against the pharmacopoeial acceptance limit of 90.0-110.0% of the labelled claim. Each sample was analysed in triplicate (2, 4 and 6 mL aliquots), and results are expressed as individual and mean percentage assay values for comparison among brands.

3. RESULTS AND DISCUSSION

The absorbance of three marketed brands (Brand A, Brand B and Brand C) of Dapagliflozin and Pioglitazone tablets was measured at 223 nm and 234 nm respectively, for three aliquot volumes (2, 4 and 6 mL) of the sample solution. The percentage assay was calculated for each aliquot and the mean assay was determined for every brand. The results are summarised in Tables 1 to 3.

Table 1: Absorbance and Percentage Assay of Dapagliflozin Tablets (223 nm)

Brand	Sample Volume	Absorbance	Concentration (µg/mL)	% Assay
Brand A	2 mL	0.4820	9.64	96.40
Brand A	4 mL	0.9760	9.76	97.60
Brand A	6 mL	1.4700	9.80	98.00
Brand A	Mean	-	-	97.33
Brand B	2 mL	0.4860	9.72	97.20
Brand B	4 mL	0.9800	9.80	98.00
Brand B	6 mL	1.4760	9.84	98.40
Brand B	Mean	-	-	97.87
Brand C	2 mL	0.4900	9.80	98.00
Brand C	4 mL	0.9850	9.85	98.50
Brand C	6 mL	1.4850	9.90	99.00
Brand C	Mean	-	-	98.50

Table 2: Absorbance and Percentage Assay of Pioglitazone Tablets (234 nm)

Brand	Sample Volume	Absorbance	Concentration (µg/mL)	% Assay
Brand A	2 mL	0.5760	9.60	96.00
Brand A	4 mL	1.1640	9.70	97.00
Brand A	6 mL	1.7520	9.73	97.33
Brand A	Mean	-	-	96.78
Brand B	2 mL	0.5820	9.70	97.00
Brand B	4 mL	1.1760	9.80	98.00
Brand B	6 mL	1.7700	9.83	98.33

Brand	Sample Volume	Absorbance	Concentration (µg/mL)	% Assay
Brand B	Mean	-	-	97.78
Brand C	2 mL	0.5880	9.80	98.00
Brand C	4 mL	1.1820	9.85	98.50
Brand C	6 mL	1.7820	9.90	99.00
Brand C	Mean	-	-	98.50

Table 3: Comparative Mean Percentage Assay of Marketed Brands

Drug	Brand A	Brand B	Brand C
Dapagliflozin	97.33%	97.87%	98.50%
Pioglitazone	96.78%	97.78%	98.50%

Discussion

The absorbance of all three brands, for both Dapagliflozin and Pioglitazone, increased progressively and proportionately with increasing sample volume from 2 mL to 4 mL to 6 mL, indicating a linear and reproducible response consistent with the Beer-Lambert law. The mean assay of Dapagliflozin ranged from 97.33% (Brand A) to 98.50% (Brand C), while the mean assay of Pioglitazone ranged from 96.78% (Brand A) to 98.50% (Brand C). All the individual and mean assay values obtained for both drugs, across all three brands, fell within the acceptable pharmacopoeial limit of 90.0-110.0% of the labelled claim, confirming that the marketed formulations tested comply with the required quality standards.

Among the three brands evaluated, Brand C consistently showed the highest mean assay for both Dapagliflozin and Pioglitazone, followed by Brand B and then Brand A. The relatively narrow spread of assay values among the three brands (within about 1.2-1.7 percentage points) indicates comparable drug-content performance and suggests satisfactory manufacturing and quality control practices across the brands studied. These findings also demonstrate that UV spectrophotometry, being simple, sensitive and reproducible, is well suited for the routine comparative quality assessment of Dapagliflozin and Pioglitazone tablets in a quality-control laboratory setting.

4. CONCLUSION

The present study successfully compared three marketed brands each of Dapagliflozin (10 mg) and Pioglitazone (15 mg) tablets by UV spectrophotometry at 223 nm and 234 nm, respectively. The mean assay values obtained were 97.33%, 97.87% and 98.50% for Dapagliflozin, and 96.78%, 97.78% and 98.50% for Pioglitazone, in Brand A, Brand B and Brand C respectively, all of which complied with the pharmacopoeial acceptance limit of 90.0-110.0% of the labelled claim. Brand C consistently exhibited the highest drug content among the three brands studied. The results confirm that UV spectrophotometry is a simple, accurate, precise and economical analytical technique suitable for the routine quality control and comparative brand-to-brand evaluation of Dapagliflozin and Pioglitazone tablets. Further studies employing fully validated methods (linearity, accuracy, precision, LOD, LOQ as per ICH Q2(R1) guidelines) across a larger number of brands are recommended to strengthen these findings.

ACKNOWLEDGEMENT

The authors express their sincere gratitude to Ms. Ramya. R, Assistant Professor, Department of Pharmaceutical Analysis, Sri Vijay Vidyalaya College of Pharmacy, Nallampalli, Dharmapuri, for her valuable guidance, constant support and encouragement throughout the course of this project work. The authors also thank the management and

faculty of Sri Vijay Vidyalaya College of Pharmacy for providing the necessary laboratory facilities to carry out this study.

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