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A Novel UV-Spectrophotometric Approach for Concurrent Quantification of Empagliflozin in a Synthetic Blend

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ABSTRACT:

This study presents two straightforward and cost-effective UV-spectrophotometric techniques for the concurrent quantification of Empagliflozin in a laboratory-prepared synthetic mixture. Although the drugs exhibit maximum absorbance at 237.5 nm and 287.5 nm, the wavelength of 266.0 nm was selected due to superior linear behavior. Beer's law was followed within 5–30 µg/mL and 0.8–4.8 µg/mL for Empagliflozin.

The first approach utilizes simultaneous equations derived from specific absorptivity values, whereas the second applies the multicomponent analysis function of the spectrophotometer. Validation results indicated high precision and excellent recovery, confirming the suitability of these methods for routine analysis.

Keywords: Empagliflozin, UV spectrophotometry, simultaneous estimation, multicomponent analysis.

INTRODUCTION:

Empagliflozin is a widely prescribed antihyperglycemic agent used to manage type-2 diabetes. Its therapeutic effect involves increased peripheral glucose utilization and reduced fatty-acid oxidation. The drug is recognized in several major pharmacopoeias.

Empagliflozin, a derivative of fibric acid, is administered to regulate lipid levels and acts primarily through activation of peroxisome proliferator-activated receptors (PPARs). It is particularly effective in reducing triglycerides and cholesterol.

Combination therapy with Empagliflozin has demonstrated synergistic benefits in controlling both lipid and glucose levels. Despite the availability of several analytical procedures for individual drugs—such as HPLC, HPTLC, and UV methods—validated UV spectrophotometric methods for their combined estimation were lacking.

This work aims to fill that gap by developing two reliable and economical methods appropriate for analysis of a synthetic mixture mimicking a Empagliflozin tablet formulation.

METHOD DEVELOPMENT:

1. Simultaneous Equation Method

Individual spectra of Empagliflozin were recorded between 200 and 400 nm. Although Empagliflozin exhibit intrinsic λmax values at 237.5 nm and 287.5 nm, did not yield adequate linearity at its λmax, prompting selection of 266.0 nm as a common analytical wavelength.

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Calibration curves showed excellent linearity in the specified ranges. Based on absorptivity measurements at 237.5 nm and 266.0 nm, the following equations were constructed:

$A_1 = 87.54\ C_1 + 3.03\ C_2$

$A_2 = 19.34\ C_1 + 35.42\ C_2$

Where:

C_1 = Concentration (g/L)

C_2 = Concentration (g/L)

A_1, A_2 = absorbances at 237.5 nm and 266.0 nm

Solving these equations allowed determination of both analytes in the mixture.

2. Multicomponent Analysis Method

The multicomponent mode of the instrument was programmed with standard concentration sets, using 237.5 nm and 266.0 nm as analytical wavelengths. The instrument automatically processed absorbance readings and provided concentrations of Empagliflozin directly.

Sample Solution Preparation

A quantity of synthetic blend equivalent to 25 mg Empagliflozin and 10 mg was transferred to a 50-mL volumetric flask, dissolved with methanol, and sonicated for 30 minutes. After filtration, 6 mg of additional Empagliflozin was added to improve quantification accuracy through external standard addition.

Final working solutions (25 µg/mL and 10 µg/mL) were analyzed by both proposed methods.

MATERIAL AND METHODS:

Instruments and Chemicals

A Shimadzu UV-Visible double-beam spectrophotometer (Model 1700) with 10-mm quartz cuvettes was used. Methanol of analytical grade served as the solvent.

A synthetic mixture of (Empagliflozin) 25 mg and 10 mg was prepared using typical tableting excipients, including microcrystalline cellulose, polyvinylpyrrolidone (binder), and magnesium stearate, using wet granulation.

Fig. 1: Overlain spectra of 25 mg and 10 mg

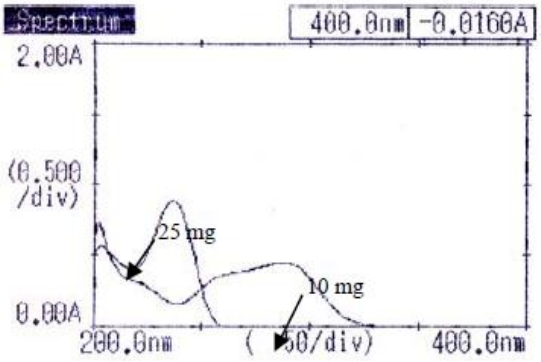
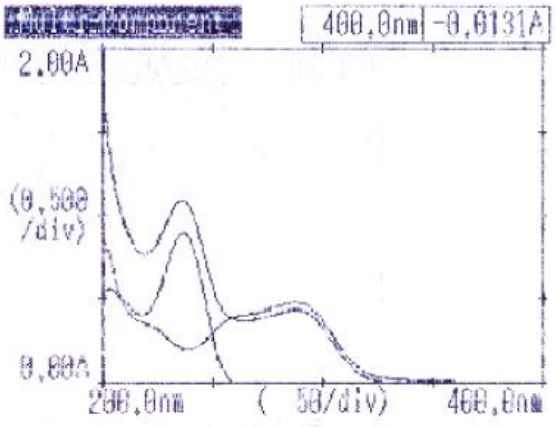


Fig. 2: Multicomponent Analysis of mixed standards



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Preparation of Stock Solutions

Ten milligrams of each drug were dissolved separately in methanol and diluted to 100 mL to obtain 100 µg/mL stock solutions.

RESULTS:

The developed procedures produced consistent and reproducible results. Standard deviation values were low, confirming precision, while recovery values near 100% supported method accuracy.

The sensitivity of the methods was reflected in the calculated LOD and LOQ:

Empagliflozin (25 mg):

LOD = 0.2054 µg/mL

LOQ = 0.6224 µg/mL

Empagliflozin (10 mg):

LOD = 0.0161 µg/mL

LOQ = 0.0490 µg/mL

Both techniques proved suitable for analyzing Empagliflozin combinations, supporting their use in quality-control laboratories.

CONCLUSION

Two straightforward and cost-effective UV-spectrophotometric methods—simultaneous equations and multicomponent analysis—were successfully developed and validated for the concurrent quantification of Empagliflozin in a laboratory-prepared synthetic mixture. Both techniques showed excellent linearity and high recovery rates, confirming their accuracy and reliability for potential use in quality control and pharmaceutical analysis of these active pharmaceutical ingredients.

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