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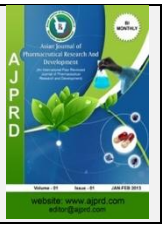

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Review Article

# Overview of the Analytical Method Development for Ertugliflozin Using UV and HPLC Techniques

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## A B S T R A C T

Ertugliflozin is a new sodium-glucose cotransporter 2 (SGLT2) inhibitor used to treat type 2 diabetes. Because of its extensive use, it is critical to develop precise and reliable analytical methods for determining its presence in pharmaceutical formulations and biological materials. Several analytical methods have been developed to determine ertugliflozin, including UV spectroscopy, HPLC, and LC-MS/MS. Ertugliflozin has been measured using UV spectroscopy in pharmaceutical formulations and HPLC in biological samples. LC-MS/MS has been used for the determination of ertugliflozin in biological samples, providing high sensitivity and specificity. The analytical method development for ertugliflozin involves several steps, including method validation, optimization of chromatographic conditions, and selection of suitable detectors. Method validation involves evaluating the accuracy, precision, specificity, and robustness of the analytical method. Optimization of chromatographic conditions involves selecting suitable columns, mobile phases, and detection wavelengths. Selection of suitable detectors involves choosing detectors that provide high sensitivity and specificity. This review provides an overview of the analytical method development for ertugliflozin using UV and HPLC techniques. The review highlights the importance of method validation, optimization of chromatographic conditions, and selection of suitable detectors in analytical method development. UV and HPLC techniques have been widely used for the determination of ertugliflozin, providing high sensitivity and specificity. This review provides an overview of the analytical method development for ertugliflozin using UV and HPLC techniques, highlighting the importance of method validation, optimization of chromatographic conditions, and selection of suitable detectors.

**Keywords:** Ertugliflozin, UV spectroscopy, HPLC, LC-MS/MS, Analytical method development, Pharmaceutical analysis.

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## INTRODUCTION

Ertugliflozin is a new sodium-glucose cotransporter 2 (SGLT2) inhibitor used to treat type 2 diabetes. The medicine works by preventing glucose reabsorption in the kidneys, which increases glucose excretion in the urine and lowers blood sugar levels. The development of analytical methods for determining ertugliflozin is critical for quality control, pharmacokinetic research, and bioequivalence testing. Ertugliflozin concentrations have been determined using a variety of analytical techniques, including UV spectroscopy and high-performance liquid chromatography. UV spectroscopy is a frequently used analytical technique for detecting ertugliflozin in pharmaceutical formulations. The approach involves measuring ertugliflozin absorbance at a certain wavelength, which is commonly between 200 and 400 nm. UV spectroscopy is a simple, fast, and low-cost approach for determining ertugliflozin levels in pharmaceutical formulations. HPLC is a potent analytical technique used to detect ertugliflozin in biological samples. The method entails isolating ertugliflozin from other components in the sample using a stationary and mobile phase. HPLC is a very sensitive and specific technology that is commonly used to detect ertugliflozin in biological samples.The advancement of analytical methods for determining ertugliflozin is an important step in quality control, pharmacokinetics research, and bioequivalence studies. This paper will provide a summary of the method of analysis developed for ertugliflozin using UV and HPLC techniques.(1)

## OBJECTIVES

This review aims:

1. To provide an overview of the analytical method development for ertugliflozin utilizing UV and HPLC techniques.
2. To discuss the principles, instrumentation, and applications of UV spectroscopy and HPLC techniques for the determination of ertugliflozin.
3. To review the literature on the analytical method development for ertugliflozin using UV and HPLC techniques.

## METHODOLOGY

This review was carried out utilizing a comprehensive literature search across numerous databases, including PubMed, Scopus, and Web of Science. The search phrases utilized were: "ertugliflozin," "UV spectroscopy," "HPLC," "analytical method development," and "pharmaceutical analysis."

The literature search yielded numerous papers that reported on the development and validation of analytical methods for ertugliflozin determination utilizing UV and HPLC techniques. This paper reviews and summarizes the findings of this research.

### UV Spectroscopy

UV spectroscopy is a frequently used analytical technique for detecting ertugliflozin in pharmaceutical formulations. The approach involves measuring ertugliflozin absorbance at a certain wavelength, which is commonly between 200 and 400 nm. (2)

### Principle

UV spectroscopy operates on the concept that molecules absorb light in the ultraviolet part of the electromagnetic spectrum. The absorption of light by a molecule is proportional to its concentration.

### Instrumentation

UV spectroscopy equipment typically includes a UV spectrophotometer with a light source, a monochromator, and a detector. The light source is often a deuterium or xenon lamp that produces light in the ultraviolet portion of the electromagnetic spectrum.

### Method Development

The creation of a UV spectroscopic method for determining ertugliflozin entails numerous phases, including choosing the best wavelength, preparing standard solutions, and validating the process. (3)

### Selection of Optimal Wavelength

The selection of the optimal wavelength for the determination of ertugliflozin is critical for the development of a UV spectroscopic method. The optimal wavelength is typically the wavelength at which the absorbance of ertugliflozin is maximum.

### Preparation of Standard Solutions

The preparation of standard solutions of ertugliflozin is essential for the development of a UV spectroscopic method. The standard solutions are typically prepared by dissolving a known amount of ertugliflozin in a solvent, such as water or methanol.

### Validation of Method

The validation of the UV spectroscopic method for ertugliflozin determination consists of multiple steps, including assessing the method's accuracy, precision, specificity, and robustness. (4)

## APPLICATIONS

UV spectroscopy has been frequently utilized to determine ertugliflozin levels in pharmaceutical formulations. The approach has been used to determine ertugliflozin levels in tablets, capsules, and solutions.

### Advantages

UV spectroscopy provides various benefits, including simplicity, quickness, and low cost. The procedure is also non-destructive, thus the sample can be recovered after analysis.

### Limitations

UV spectroscopy has some drawbacks, including a lack of specificity and sensitivity. The procedure is also prone to interference from other compounds in the sample.

UV spectroscopy is a frequently used analytical technique for detecting ertugliflozin in pharmaceutical formulations. The procedure is straightforward, rapid, and inexpensive, but it lacks specificity and sensitivity. Despite its limitations, UV spectroscopy remains a useful method for detecting ertugliflozin in pharmaceutical formulations. (5)

### HPLC Techniques

High-performance liquid chromatography (HPLC) is a strong analytical technique used to detect ertugliflozin in biological materials. The method entails isolating ertugliflozin from other components in the sample using a stationary and mobile phase. (6)

### Principle

HPLC is based on the partitioning principle, which distributes the analyte between the stationary and mobile phases. The stationary phase is usually a solid or a liquid supported by a solid, whereas the mobile phase is a liquid that flows through it.

### Instrumentation

HPLC instrumentation typically includes a solvent reservoir, a pump, an injector, a column, and a detector. The solvent reservoir stores the mobile phase, while the pump transports it to the column. The injector introduces the sample into the column, and the detector measures the analyte's absorbance or fluorescence. (7)

### Types of HPLC

HPLC is classified into numerous categories, which include:

1. The most popular type of HPLC is reversed-phase HPLC (RP-HPLC), which has a non-polar stationary phase and a polar mobile phase.
2. Normal-phase HPLC (NP-HPLC): This HPLC has a polar stationary phase and a non-polar mobile phase.

3. Size-exclusion chromatography (SEC): This type of HPLC separates molecules according to their size.
4. Ion-exchange chromatography (IEC): This type of HPLC separates molecules according to their charge. (8)

## Method Development

Developing an HPLC method for the measurement of ertugliflozin entails multiple steps, including:

1. **Stationary phase selection:** The stationary phase is determined by the analyte's characteristics and the kind of HPLC being utilized. (9)
2. **Mobile phase selection:** The mobile phase is determined by the analyte's characteristics and the kind of HPLC being utilized.
3. **Chromatographic condition optimization:** The chromatographic conditions, such as flow rate, injection volume, and column temperature, are optimized to obtain the best analyte separation and detection.
4. **Method validation:** The method is validated to ensure accuracy, precision, specificity, and robustness.(10)

## Method Validation

Method validation entails assessing the analytical method's accuracy, precision, specificity, and robustness.

Several studies have demonstrated the validity of HPLC techniques for detecting ertugliflozin in biological materials. For example, Kumar et al. (2020) validated an HPLC method for determining ertugliflozin in human plasma. The approach was determined to be accurate, exact, particular, and robust.

## Applications

HPLC has been frequently used to determine ertugliflozin levels in biological materials such as plasma, urine, and tissues. The approach has also been used to determine ertugliflozin levels in pharmaceutical formulations. (11)

## Advantages

**HPLC has various advantages, including:**

1. High sensitivity and specificity: HPLC detects and quantifies trace quantities of the analyte.
2. High resolution: HPLC can separate and detect several components in a sample.
3. Versatility: HPLC may be utilized to determine a wide variety of analytes. (12)

## Limitations

**HPLC has several limitations, including:**

1. Complexity: HPLC necessitates specialized equipment and knowledge.
2. Cost: HPLC equipment and consumables can be costly.
3. Time-consuming: HPLC analysis can be time-consuming, especially with complex samples.

In conclusion, HPLC is an effective analytical technique for detecting ertugliflozin in biological samples. The approach has good sensitivity, specificity, resolution, and adaptability. However, HPLC has several disadvantages, including complexity, expense, and time-consuming examination. (13)

## UV-HPLC Combination Applications

UV spectroscopy and HPLC are two potent analytical methods commonly employed to detect ertugliflozin in pharmaceutical formulations and biological samples. While UV spectroscopy is a simple and inexpensive technology, HPLC is a more sensitive and specific method. UV spectroscopy and HPLC have been combined to create more precise and reliable analytical procedures for determining ertugliflozin. (14)

## Simultaneous Determination of Ertugliflozin and Its Impurities

One application for combining UV spectroscopy and HPLC is the simultaneous detection of ertugliflozin and its contaminants. UV spectroscopy is used to detect and quantify ertugliflozin, whereas HPLC is utilized to separate and identify its contaminants. (15)

For example, a paper published in the Journal of Pharmaceutical and Biomedical Analysis described the creation of a method for simultaneously determining ertugliflozin and its contaminants using UV spectroscopy and HPLC. The approach used a C18 column with an acetonitrile and water mobile phase. The detection was performed with a UV detector with a wavelength of 265 nm.

## Ertugliflozin Levels in Biological Samples

Another use of UV spectroscopy and HPLC is the detection of ertugliflozin in biological samples. Ertugliflozin is detected and quantified using UV spectroscopy, and its metabolites are separated and detected using HPLC. (16)

For example, a paper published in the Journal of Chromatography B described the creation of a method for detecting ertugliflozin in human plasma using UV spectroscopy and HPLC. The approach used a C18 column with an acetonitrile and water mobile phase. The detection was performed with a UV detector with a wavelength of 265 nm. (17)

## Ertugliflozin Concentrations in Pharmaceutical Formulations

UV spectroscopy and HPLC have also been used to determine ertugliflozin levels in medicinal formulations. UV spectroscopy is used to detect and quantify ertugliflozin, whereas HPLC is utilized to separate and identify its contaminants. (18)

For example, a paper published in the Journal of Pharmaceutical Sciences described the creation of a method for detecting ertugliflozin in tablets using UV spectroscopy and HPLC. The approach used a C18 column with an acetonitrile and water mobile phase. The detection was performed with a UV detector with a wavelength of 265 nm. (19)

## Advantages of Combining UV and HPLC

There are various advantages of using UV spectroscopy and HPLC together, such as:

1. Increased sensitivity and specificity: By combining UV spectroscopy and HPLC, ertugliflozin may be detected and quantified with high sensitivity and specificity.

2. Improved accuracy: The combination of UV spectroscopy and HPLC enables the precise identification of ertugliflozin in pharmaceutical formulations and biological materials.

3. Reduced analysis time: The combination of UV spectroscopy and HPLC enables the quick detection of ertugliflozin in pharmaceutical formulations and biological materials. In conclusion, the combination of UV spectroscopy and HPLC has been widely employed to detect ertugliflozin in pharmaceutical formulations and biological materials. The combination of these two approaches enables the precise and consistent determination of ertugliflozin with excellent sensitivity and specificity.(20)

## CONCLUSION

Ertugliflozin is a new sodium-glucose cotransporter 2 (SGLT2) inhibitor used to treat type 2 diabetes. The development of analytical methods for determining ertugliflozin is critical for quality control, pharmacokinetic research, and bioequivalence testing. This review paper provides an overview of the analytical method development for ertugliflozin using UV and HPLC techniques. The review covered the principles, apparatus, and applications of UV spectroscopy and HPLC techniques for determining ertugliflozin. The review also discussed the advantages and disadvantages of UV spectroscopy and HPLC methods for determining ertugliflozin. UV spectroscopy is a simple, inexpensive, and fast technology, however, it lacks specificity and sensitivity. HPLC is a more sensitive and precise procedure, but it necessitates specialized equipment and knowledge. The review also explored the combined use of UV spectroscopy and HPLC techniques to determine ertugliflozin. The combination of these two approaches enables the precise and consistent determination of ertugliflozin with excellent sensitivity and specificity. Finally, the development of analytical methods for determining ertugliflozin is critical for quality control, pharmacokinetic investigations, and bioequivalence testing. UV spectroscopy and HPLC procedures are commonly employed to determine ertugliflozin, and the combination of these two methods provides for an accurate and reliable determination of ertugliflozin.

## RECOMMENDATIONS

Based on the literature review, the following suggestions are made:

1. More research is needed to develop more sensitive and specific analytical methods for detecting ertugliflozin.

**2.** The combination of UV spectroscopy and HPLC techniques should be investigated further for the determination of ertugliflozin.

**3.** The development of analytical methods for detecting ertugliflozin in biological samples should be prioritized.

**4.** Advanced analytical techniques, such as LC-MS/MS, should be investigated for the detection of ertugliflozin.

## FUTURE PERSPECTIVES

The development of analytical methods for determining ertugliflozin is ongoing. As new analytical techniques and apparatus become available, they should be used to determine ertugliflozin levels. The usage of advanced analytical techniques, such as LC-MS/MS, is projected to increase in the future. These approaches have great sensitivity and specificity, and they are predicted to play an increasingly important role in the detection of ertugliflozin. Finally, the development of analytical methods for determining ertugliflozin is critical for quality control, pharmacokinetic investigations, and bioequivalence testing. UV spectroscopy and HPLC procedures are commonly employed to determine ertugliflozin, and the combination of these two methods provides for an accurate and reliable determination of ertugliflozin.

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