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COMPREHENSIVE INSIGHTS INTO FINERENONE: RECENT HPLC ADVANCEMENTS AND CLINICAL PROSPECTS

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Abstract:
This review article provides a comprehensive overview of recent developments in analytical methods for the analysis of Finerenone, a pharmaceutical compound with significant therapeutic potential. The review covers a spectrum of analytical techniques, including high-performance liquid chromatography (HPLC) and spectrophotometry, employed for the quantification of Finerenone in pharmaceutical formulations and biological samples. The article details the instrumentation, chromatographic conditions, and method development strategies utilized in various studies, aiming to offer a profound understanding of the analytical techniques prevalent in the pharmaceutical industry. Furthermore, this review delves into the importance of the FINE-REAL prospective study, a significant international clinical investigation. The study aims to assess the clinical impact of Finerenone, a novel mineralocorticoid receptor antagonist, in the context of chronic kidney disease (CKD) and type 2 diabetes (T2D). The review outlines the study's objectives, design, and anticipated outcomes, emphasizing its relevance in evaluating Finerenone's therapeutic efficacy and safety in real-world clinical settings.

Keywords: Finerenone, Analytial method, HPLC, Type 2 diabetes (T2D), FINE REAL studies, clinical studies.

INTRODUCTION

Finerenone is a promising medicine that has grabbed a lot of attention because it might be really helpful for treating certain health problems. To make sure it's of high quality and does its job correctly, we need to have precise and trustworthy methods to analyze it in medications. In this review, we're going to talk about special ways of using machines (called HPLC) to measure Finerenone accurately. Finerenone is not a steroid, and it can act against some specific hormones in our body. It could be a helpful treatment for people with kidney problems and type 2 diabetes. This review article wants to give you a clear and complete picture of how we test Finerenone and about an important study called FINE-REAL. This study is all about figuring out if Finerenone works well and is safe for people with certain health conditions.

INSTRUMENTATION AND OPTIMIZED CONDITIONS

Several HPLC systems have been employed for the analysis of Finerenone. One such system is the fully automated Waters HPLC system, which consists of a quaternary pump, autosampler, column oven, and a PDA detector. Empower2 software is commonly used for data acquisition and processing. The chromatographic separation is achieved using an X-bridge C18 Column (150 mm x 4.6 mm, 3.5 µm) with a mobile phase

consisting of Acetonitrile and Ortho-Phosphoric acid (70:30% v/v). The flow rate is set at 1 mL/min, and detection is performed at a wavelength of 225 nm.
Chromatographic Conditions
The chromatographic conditions for Finerenone analysis are as follows:
- Column: X-bridge C18 column, 150 mm x 4.6 mm, 3.5 µm
- Wavelength: 225 nm
- Injection Volume: 10 µL
- Column Temperature: Ambient (25°C)
- Flow Rate: 1.0 mL/min
- Sample Temperature: Ambient
- Run time: Ambient

METHOD DEVELOPMENT
The preparation of standard and sample solutions is a crucial step in HPLC method development. For standard solution preparation, 10 mg of Finerenone working standard is accurately weighed and transferred into a 10 mL volumetric flask. Approximately 7 mL of methanol is added, and the solution is sonicated to ensure complete dissolution. The volume is adjusted to the mark with methanol. A 0.3 mL aliquot of this solution is further diluted to 10 mL with methanol to create the working standard.
For sample solution preparation, an equivalent weight of Finerenone sample (10 mg) is weighed into a 10 mL volumetric flask. About 7 mL of diluent is added, and sonication is employed for complete dissolution. The volume is then adjusted to the mark with the same solvent. Similarly, 0.3 mL of this solution is pipetted into a 10 mL volumetric flask and diluted to the mark with methanol.

MOBILE PHASE OPTIMIZATION
Initial trials with different mobile phase compositions (methanol: water and ACN: water) led to the optimization of ACN: Methanol (80:20% v/v) as the ideal mobile phase. This choice provided optimal peak shape and resolution at a flow rate of 1 mL/min.

DILUENT PREPARATION
The mobile phase itself is used as the diluent, ensuring consistency throughout the analysis.

CHROMATOGRAPHY INSTRUMENT
The quantitative HPLC analysis is performed using a liquid chromatograph equipped with a variable wavelength PDA detector. An Inertsil ODS-3V C18 column (250 mm x 4.6 mm, 5 µm) is employed, with the analysis conducted at ambient temperature. The mobile phase consists of 0.03M Potassium Dihydrogen Orthophosphate in water at pH 3.2, along with Orthophosphoric acid and Acetonitrile (30:70 v/v). A 10 µL injection volume is used, and UV detection is performed at 309 nm.

ANALYTICAL METHODS FOR FINERENONE ESTIMATION
This section delves into various analytical methods employed for estimating Finerenone:

- **Validated Stability-Indicating RP-HPLC**

The first method discussed involves a validated RP-HPLC method utilizing a mobile phase of Trifluoroacetic acid and Acetonitrile (70:30). The analysis is carried out using a Hemochrom C18 column on an HPLC system with quaternary gradient pump and prominent autosampler. The method demonstrates linear calibration within the concentration range of 5-45 µg/ml.

- **Forced Degradation Studies by RP-HPLC**

The second method involves forced degradation studies conducted using an HPLC system with an X-bridge C18 column. The mobile phase consists of Acetonitrile and Ortho-Phosphoric acid (70:30 v/v). UV detection is employed at 225 nm. This method showcases a linear calibration range of 1 µg/ml to 50 µg/ml.

- **Spectrophotometric Estimation**

A spectrophotometric method is discussed, employing ethanol as the solvent and UV-visible double beam spectrophotometry. This method offers a concentration range of 2-14 µg/ml with LOD and LOQ values of 1.220 µg/ml and 5.220 µg/ml, respectively.

- **Analytical RP-HPLC Method**

Another RP-HPLC method is presented, using a mobile phase of Acetonitrile and Methanol (80:20% v/v) and achieving a linear response in the drug concentration range of 10-50 mcg/ml.

- **Liquid Chromatography Method**

This method development involves a mobile phase of 0.03M potassium dihydrogen orthophosphate in water pH 3.2, with orthophosphoric acid and acetonitrile (30:70) at a flow rate of 1 ml/min. UV detection is performed at 309 nm, using an Inertsil ODS-3V C18 column.

FINE-REAL Prospective Study

The FINE-REAL study is described as an international, multicenter, single-arm prospective study, enrolling approximately 5500 adults with CKD and T2D across 22 countries. This ongoing study, expected to continue until 2207, aims to assess the clinical impact of Finerenone in real-world scenarios. Key objectives, design, and anticipated outcomes of the study are detailed in this section.

CONCLUSION:

In conclusion, this review article offers valuable insights into the utilization of HPLC methods for the analysis of Finerenone in the realm of pharmaceutical research and development. The detailed coverage of instrumentation, chromatographic conditions, and method development strategies presented herein constitutes a valuable resource for researchers and analysts within the field. These insights are instrumental in ensuring the precise and dependable analysis of this promising pharmaceutical compound.

Furthermore, the review underscores the remarkable diversity of analytical methods employed for the quantification of Finerenone, with a particular focus on their application in pharmaceutical tablet formulations and the assessment of human plasma samples. Additionally, the article highlights the pivotal significance of the ongoing FINE-REAL prospective study. This international clinical investigation holds the potential to provide invaluable insights into the clinical effectiveness and safety profile of Finerenone in the management of chronic kidney disease (CKD) and type 2 diabetes (T2D). Together, these contributions advance our understanding of Finerenone, both in the laboratory and in real-world clinical practice.

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