EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 10
Issue: 8
70-71
Year: 2023

A COMPREHENSIVE PHARMACEUTICAL ANALYSIS REVIEW ON LEMBOREXANT DRUG

B. Lakshmi Kalyani[1]*, V. Nikhila[2], J. Raga Swetha[3] and B. Sushma Desai[4]

[1,2,3]Department of Pharmaceutical Analysis, Chilkur Balaji College of Pharmacy, Aziz Nagar, Hyderabad.
[4]Department of Pharmaceutics, Chilkur Balaji college of Pharmacy, Aziz Nagar, Hyderabad.

***Corresponding Author: B. Lakshmi Kalyani**
Assistant Professor, Department of Pharmaceutical Analysis, Chilkur Balaji College of Pharmacy, Aziz Nagar, Hyderabad.

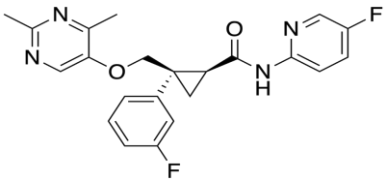
Article Received on 25/5/2023 **Article Revised on 15/6/2023** **Article Accepted on 05/7/2023**

ABSTRACT
This review provides a comprehensive analysis of Lemborexant, a novel pharmaceutical agent used in the treatment of insomnia. The focus is on the pharmaceutical analysis aspects, including the determination of Lemborexant chemical structure, quantitative analysis methods, impurity profiling, and stability assessment. The review highlights the significance of pharmaceutical analysis in ensuring the quality, safety, and efficacy of Lemborexant formulations. This article presents a comprehensive overview of the developed method & process validated for the estimation of drug Lemborexant, which is a dual receptor Orexin antagonist used for sleep onset in the insomnia treatment utilizing instrument High-Pressure Liquid Chromatography (HPLC). The development of an accurate and reliable HPLC method for Lemborexant analysis is crucial for ensuring the quality, safety, and efficacy of pharmaceutical formulations. This article discusses the key steps involved in method development, optimization, and validation, highlighting the importance of each parameter in achieving robust and validated analytical results.

KEYWORDS: Lemborexant, Orexin, Insomnia, Sleep onset, Sleep maintenance.

1. INTRODUCTION

Chemical structure



Chemical Formula: $C_{22}H_{20}F_2N_4O_2$

Lemborexant drug acting on neuropeptides of both Orexin types A & B receptor antagonist has gained attention as a promising therapeutic option for insomnia management (effective binding to the orexin receptors and inhibiting it). Pharmaceutical analysis plays a crucial role in understanding the chemical characteristics, quantitative determination, and stability behavior of Lemborexant, enabling pharmaceutical companies to develop and produce high-quality formulations. Lemborexant, a novel medication for insomnia, requires a reliable analytical method for its quantification in pharmaceutical formulations. High-Pressure Liquid Chromatography (HPLC) is widely used in pharmaceutical analysis due to its versatility, sensitivity, and selectivity. This article focuses on the method development and validation of an HPLC-based assay for the estimation of Lemborexant, providing insights into the parameters and considerations necessary for successful analysis.

2. Determination of lemborexant drug chemical structure

Pharmaceutical analysis techniques, such as mass spectrometry (MS), nuclear magnetic resonance (NMR) & infrared spectroscopy (IR) are employed to determine the chemical structure of drug Lemborexant. These techniques provide insights into the molecular composition, functional groups, and connectivity, which are essential for understanding the drug's pharmacological activity and ensuring consistent manufacturing.

3. Quantitative analysis methods

Accurate quantification of Lemborexant is vital to ensure proper dosing and therapeutic efficacy. Instrumentations High-pressure liquid chromatography (HPLC) & gas chromatography (GC) are the commonly used separation techniques for quantitative analysis. Detection methods, such as UV-Vis spectroscopy or tandem mass spectrometry (LC-MS/MS), offer high sensitivity and selectivity for Lemborexant quantification in pharmaceutical formulations.

4. Method development

Analytical validation is essential to ensure the reliability & accuracy of pharmaceutical analysis methods for Lemborexant drug. The method development process involves selecting appropriate chromatographic conditions to achieve optimal separation and quantification of Lemborexant. Factors such as choice of pH, stationary phase, mobile phase composition, & rate of flow were carefully considered. The aim is to obtain a well-resolved peak with good peak shape, adequate retention time, and minimal interference from excipients or impurities. Validation of the HPLC method is critical to establish its reliability, accuracy, and robustness. Validation parameters include Accuracy, Precision, Specificity, limit of detection (LOD), linearity, limit of quantification (LOQ), and Robustness. These parameters are evaluated using appropriate standards, control samples, and statistical analyses. Method validation ensures that the developed HPLC method is suitable for its intended purpose and provides accurate and precise results.

5. Impurity profiling

Pharmaceutical analysis also focuses on identifying and quantifying impurities that may be present in Lemborexant formulations. Impurity profiling involves the development and validation of methods to detect & quantify impurities, such as degradation products, process-related impurities, and potential genotoxic impurities. These studies ensure the purity and safety of Lemborexant for patient use. As part of method validation, impurity profiling is crucial to assess the purity of Lemborexant formulations. This involves the identification, quantification, and characterization of potential impurities, including degradation products and process-related impurities. Adequate separation and resolution of impurities from the main peak are critical for reliable impurity profiling using HPLC.

6. Stability assessment

Stability studies are critical to determine the shelf life and storage conditions of Lemborexant formulations. Pharmaceutical analysis techniques, including accelerated stability testing and forced degradation studies, evaluate the drug's stability under various conditions, such as temperature, humidity, and light exposure. performing the studies thereby providing valuable information on the various pathways of degradation, potential impurities & appropriate packaging requirements.

7. Optimization

Once the initial method is developed, optimization is performed to enhance the method's performance. Parameters like column temperature, gradient elution program, and detector wavelength are systematically adjusted to improve peak resolution, reduce analysis time, and enhance sensitivity. This iterative process ensures the development of an efficient and reliable HPLC method for Lemborexant.

8. Suitability of system

Suitability of System testing is an essential component of development methodology & validation. It involves evaluating key performance parameters, such as time of retention, theoretical plates, peak asymmetry & resolution, to ensure consistent and reproducible chromatographic results. System suitability tests provide a measure of the method's reliability and suitability for routine analysis.

9. CONCLUSION

Pharmaceutical Analysis playing a pivotal role in the development, production & quality control of drug Lemborexant formulations. Through the determination of chemical structure, quantitative analysis, impurity profiling, and stability assessment, analytical techniques provide critical information to ensure the safety, efficacy, and consistent quality of Lemborexant. The integration of robust analytical methods into pharmaceutical analysis contributes to the advancement and optimization of this innovative insomnia treatment. Development methodology & validation for the estimation of drug Lemborexant using HPLC is an essential process in pharmaceutical analysis. A robust and HPLC validated method ensures the accurate quantification of drug Lemborexant in pharmaceutical formulations, enabling quality control, stability studies, and regulatory compliance. By following a systematic approach to method development, optimization, and validation, analysts can establish a reliable and efficient HPLC method for Lemborexant analysis, contributing to the safe and effective use of this insomnia treatment in clinical practice.

REFERENCES

1. Lemborexant: Uses, Interactions, Mechanism of Action | DrugBank Online
2. lemborexant | CAS#:1369764-02-2 | Chemsrc
3. High Performance Liquid Chromatography (HPLC): Principle, Types, Instrumentation and Applications - Laboratoryinfo.com
4. HPLC Method Development and Validation for Pharmaceutical Analysis (pharmtech.com)
5. WJPR - Abstract File (wjpr.net)
6. Lemborexant Uses, Side Effects & Warnings - Drugs.com
7. Development and validation of novel HPLC method for analytical evaluation of Lemborexant in tablet dosage form | GSC Advanced Research and Reviews (gsconlinepress.com)
8. Handbook of Analytical Validation (routledgehandbooks.com)
9. A practical approach to RP HPLC analytical method development (researchgate.net)
10. Lemborexant - PubMed (nih.gov)
11. Stepsfor HPLC Metho Validation Pharmaguideline.
12. https://go.drugbank.com/drugs/DB11951