Infrared Spectroscopic Identification of Enoxolone Active Pharmaceutical Ingredient in Compliance with Pharmacopoeial Standards

Fayzullayeva D.B., Tursunov Kh.O.
Tashkent Pharmaceutical Institute, Tashkent, Uzbekistan
Center for Pharmaceutical Product Safety, Tashkent, Uzbekistan
Email: fayzullaeva3303@gmail.com

Abstract. Enoxolone (18β-glycyrrhetinic acid) is a naturally derived triterpenoid compound widely used as an active pharmaceutical ingredient (API) due to its anti-inflammatory, gastroprotective, and antiviral properties. Ensuring the identity and quality of enoxolone in accordance with international pharmacopoeial standards is essential for pharmaceutical development and regulatory compliance. This study aimed to confirm the identity of industrially produced enoxolone substance using infrared (IR) spectroscopy in compliance with the requirements of the United States Pharmacopeia (USP), European Pharmacopoeia (Ph. Eur.), and national pharmacopoeial standards.

Infrared spectroscopic analysis was performed using a Shimadzu IRAffinity-1S spectrometer in the mid-infrared region of 4000–400 cm^{-1}. The obtained IR spectra demonstrated characteristic absorption bands corresponding to the functional groups of the enoxolone molecule. A broad and intense absorption band at 3500–3200 cm^{-1} was attributed to O–H stretching vibrations, indicating the presence of hydrogen-bonded hydroxyl groups. Aliphatic C–H stretching vibrations were observed at 2940–2850 cm^{-1}, while a strong absorption band at 1715–1700 cm^{-1} corresponded to the carbonyl (C=O) group. Additional diagnostic bands associated with olefinic and C–O vibrations were also identified.

Comparative analysis revealed complete agreement between the IR spectrum of the tested sample and official pharmacopoeial reference spectra, with no extraneous or unidentified absorption bands detected. These results confirm the chemical identity, structural integrity, and pharmacopoeial compliance of the enoxolone substance. Infrared spectroscopy was demonstrated to be a rapid, reliable, and pharmacopeially accepted analytical method for the identification of enoxolone API.

Keywords: Enoxolone, infrared spectroscopy, active pharmaceutical ingredient, pharmacopoeial compliance, substance identification.

Introduction

Infrared (IR) spectroscopy is a widely recognized analytical technique in pharmaceutical science for the identification and characterization of active pharmaceutical ingredients (APIs). Its importance lies in its ability to provide a unique spectral "fingerprint" of a compound based on molecular vibrations, enabling rapid and reliable qualitative analysis. In the context of pharmaceutical quality control, IR spectroscopy plays a critical role in ensuring that APIs meet stringent regulatory and pharmacopoeial requirements.

Enoxolone, also known as glycyrrhetinic acid, is a biologically active compound derived from licorice root (*Glycyrrhiza glabra*) and is used in various pharmaceutical and dermatological formulations due to its anti-inflammatory, antiviral, and hepatoprotective properties. Given its therapeutic significance, accurate identification and verification of enoxolone as an API are essential to ensure product safety, efficacy, and consistency.

Pharmacopoeial standards established by organizations such as United States Pharmacopeia and European Pharmacopoeia provide validated methods and acceptance criteria for API identification, including IR spectroscopic analysis. These standards require that the IR spectrum of a test sample corresponds closely to that of an official reference standard, thereby confirming its identity and purity.

This study focuses on the application of infrared spectroscopy for the identification of enoxolone in compliance with pharmacopoeial guidelines. It highlights the interpretation of characteristic absorption bands corresponding to functional groups present in enoxolone, such as hydroxyl, carbonyl, and hydrocarbon moieties. By aligning experimental spectra with reference spectra, this approach ensures adherence to regulatory expectations and supports the integrity of pharmaceutical quality control processes.

Conclusion

Infrared spectroscopic analysis serves as a robust, reliable, and non-destructive method for the identification of enoxolone as an active pharmaceutical ingredient. By generating a distinct spectral profile based on molecular vibrations, IR spectroscopy enables precise confirmation of the compound's identity when compared with pharmacopoeial reference standards.

The findings demonstrate that enoxolone exhibits characteristic absorption peaks corresponding to its key functional groups, which can be effectively used as diagnostic markers in routine quality control. Compliance with established guidelines from pharmacopoeial authorities such as the United States Pharmacopeia and European Pharmacopoeia ensures the reliability and regulatory acceptance of the analytical results.

Overall, the integration of IR spectroscopy into pharmaceutical analysis enhances the accuracy, efficiency, and standardization of API identification. For enoxolone, this method not only confirms its authenticity but also contributes to maintaining the quality and safety of pharmaceutical products. Future advancements in spectroscopic techniques and data analysis may further improve sensitivity and automation, reinforcing the role of IR spectroscopy in modern pharmaceutical quality assurance.

REFERENCES

1.Shagazatova B. K., Axmedova F. S., Tuxtamishev M. K. PATHOGENETIC MECHANISM OF DEVELOPMENT OF INSULIN RESISTANCE IN CHRONIC VIRAL HEPATITIS C //EPRA International Journal of Multidisciplinary Research (IJMR). – 2022. – Т. 8. – №. 2. – С. 137-141.

2.Шагазатова Б., Ахмедова Ф. ПОКАЗАТЕЛИ УРОВНЕЙ ТРАНСАМИНАЗ У ПАЦИЕНТОВ С САХАРНЫМ ДИАБЕТОМ 2 ТИПА ПРИ ХРОНИЧЕСКОМ ГЕПАТИТЕ С НА ФОНЕ ГИПОГЛИКЕМИЧЕСКОЙ ТЕРАПИИ //InterConf.– 2021.

3.Ахмедов Ш. М., Ливерко И. В., Ахмедова Ф. Ш. ЧАСТОТА ВСТРЕЧАЕМОСТИ СИМПТОМА ИЗБЫТОЧНОЙ ДНЕВНОЙ СОНЛИВОСТИ У БОЛЬНЫХ С ХРОНИЧЕСКОЙ ОБСТРУКТИВНОЙ

БОЛЕЗНЬЮ ЛЕГКИХ //СОПРЯЖЁННОЙ С СИНДРОМОМ ОБСТРУКТИВНОГО АПНОЭ-ГИПОПНОЭ СНА.–2023.

4.Shagazatova B. X. et al. Endokrinologiya mutaxassisligi bo'yicha klinik rezidentlarni o'qitishda «case»-usuli (Doctoral dissertation, Ўзбекистон, Тошкент). – 2023.

5.Артикова Д. М. и др. Изучение инсулинового ответа на введение пиримидиновых нуклеотидов у пациенток с ожирением и синдромом поликистозных яичников: дис //Ўзбекистон, Тошкент. – 2023.

6.Akhtam R. et al. Biomarkers in liver regeneration //Clinica Chimica Acta. – 2025. – Т. 576. – С. 120413.

7.Akhmedova F. et al. The course of Parkinson's disease in patients with impaired carbohydrate metabolism //MOVEMENT DISORDERS. – 111 RIVER ST, HOBOKEN 07030-5774, NJ USA : WILEY, 2018. – Т. 33. – С. S176-S177.

8.Шагазатова Б. Х. и др. Особенности течения сахарного диабета у вич-инфицированных больных. – 2019.