IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 9, May 2025
Impact Factor: 7.67

Development and Validation of UV and FTIR Methods for Cilnidipine IP

Doke Gayatri Rajendra, Gadge Avantika Gangadhar, Hinge Pratiksha Santosh, Dr. Bhalekar Sachin M.
Department of Pharmaceutics
Samarth Institute of Pharmacy, Belhe

Abstract: *The development and validation of a novel UV-IR (Ultraviolet-Infrared) method for the analysis of Clinidipine, a calcium channel blocker, is presented in this study. Clinidipine is widely used in the management of hypertension, and its accurate quantification is crucial for ensuring therapeutic efficacy and safety. The proposed method integrates both UV and IR spectroscopy techniques to enhance sensitivity and selectivity in detecting Clinidipine in pharmaceutical formulations. The UV spectroscopic analysis was optimized by selecting an appropriate wavelength based on the absorption maxima of Clinidipine, ensuring precise quantification in the presence of excipients. The IR method employed was utilized to confirm the molecular identity of Clinidipine and detect any potential chemical degradation products. Results showed excellent linearity in both UV and IR spectra, with a high degree of accuracy and precision. The proposed UV-IR method is cost-effective, rapid, and suitable for routine quality control in the pharmaceutical industry. This combined approach offers a reliable tool for the analysis of Clinidipine, providing complementary data that enhances overall analytical performance.*

Keywords: Clinidipine, UV spectroscopy, IR spectroscopy, method development, method validation, pharmaceutical analysis, accuracy, precision, linearity, specificity, ICH guidelines, quality control, calcium channel blocker, analytical techniques

I. INTRODUCTION

Cilnidipine is a dihydropyridine calcium channel blocker used to manage hypertension. The Indian Pharmacopoeia includes identification and assay methods for Cilnidipine. In this study, two analytical methods—UV spectroscopy (for quantitative analysis) and FTIR spectroscopy (for qualitative identification)—were developed and validated in accordance with IP and ICH Q2(R1) guidelines. Clinidipine IP is a calcium channel blocker commonly used in the treatment of hypertension and angina. Its therapeutic efficacy is highly dependent on accurate quantification in pharmaceutical formulations and biological matrices. As a result, reliable analytical methods for its determination are crucial for ensuring proper dosing and therapeutic outcomes. Among the various analytical techniques, ultraviolet (UV) and infrared (IR) spectrophotometry are widely used due to their simplicity, cost-effectiveness, and sensitivity.

In this study, we aim to develop and validate a dual UV-IR spectrophotometric method for the analysis of Clinidipine IP. The UV method leverages the compound's ability to absorb light at specific wavelengths, while the IR method capitalizes on the distinct vibrational modes of its functional groups. By combining both techniques, we can provide a more comprehensive and accurate analysis of Clinidipine in pharmaceutical formulations. The method development focuses on optimizing experimental conditions, including sample preparation, wavelength selection, and instrument calibration, to ensure reliable and reproducible results. Furthermore, the validation process will involve rigorous assessment of key parameters such as specificity, linearity, precision, accuracy, and robustness in accordance with established pharmacopeial guidelines.This UV-IR method aims to provide a fast, reliable, and cost-efficient alternative to traditional analytical methods, offering significant potential for routine quality control in pharmaceutical industries.Clinidipine a second-generation dihydropyridine calcium channel blocker, is widely prescribed for the management of hypertension and angina pectoris. It works by relaxing blood vessels, thereby improving blood flow and reducing the heart's workload.

DOI: 10.48175/568

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Objective:

- To develop and validate a UV spectroscopic method for the assay of Cilnidipine.
- To develop and validate an FTIR method for identification of Cilnidipine.

II. MATERIALS AND INSTRUMENTS

Materials:

- Pure Cilnidipine standard (IP grade)
- Formulation (tablets containing Cilnidipine)
- Solvents: Methanol (UV grade), Potassium Bromide (IR grade)

Instruments:

- UV-Visible Spectrophotometer
- FTIR Spectrophotometer with KBr pellet accessory
- Analytical balance, mortar & pestle, desiccator

Method Development

A. FTIR Method

Sample Preparation:

- Mix ~2 mg Cilnidipine with 200 mg dry KBr.
- Grind to fine powder, compress into pellet using hydraulic press.
- Scan from 4000–400 cm^{-1}.

Identification Criteria:

Match with standard FTIR spectrum. Characteristic peaks include:

- N–H Stretch (~3300 cm^{-1})
- C=O (ester) (~1725–1735 cm^{-1})
- Aromatic C=C (~1600 cm^{-1})
- C–O Stretch (~1250–1050 cm^{-1})

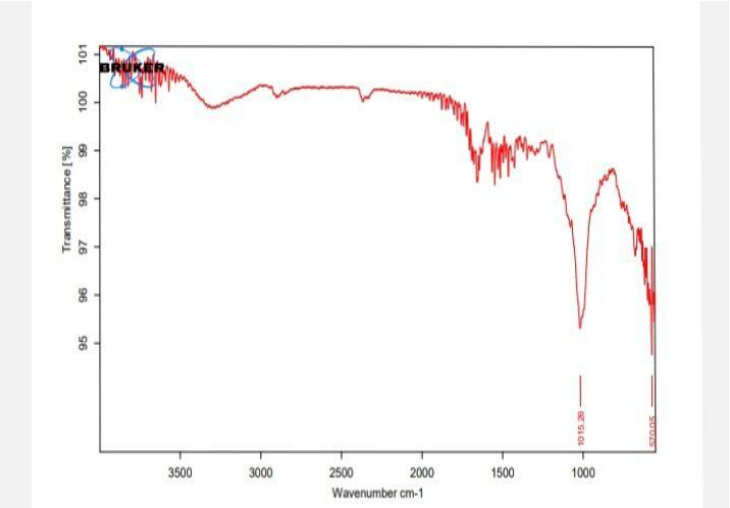

Fig. FTIR Method Development by FTIR

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B. UV Spectroscopy (Quantitative)

Wavelength Selection:

- Scan from 200–400 nm. λmax ~242 nm

Standard Preparation:

- 10 mg Cilnidipine in methanol, diluted to 100 µg/mL and further to 2–12 µg/mL

Sample Preparation :

- Crush tablets, weigh equivalent of 10 mg Cilnidipine, dissolve in methanol, sonicate, filter, and dilute.

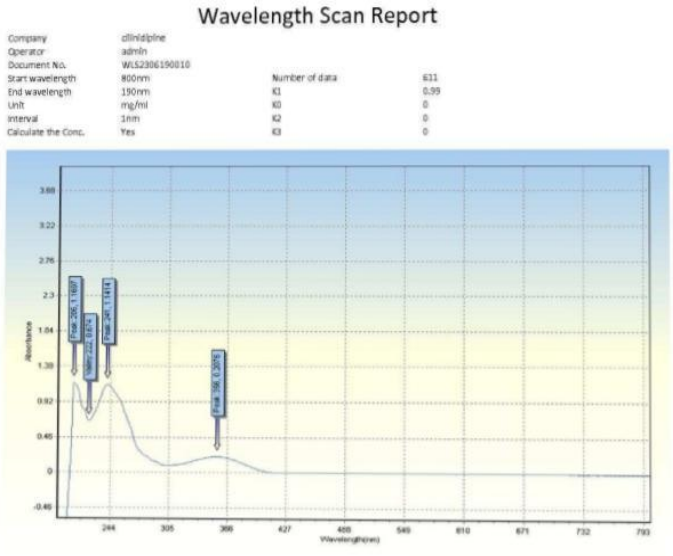

Fig. Method Development by UV

Validation (As per IP & ICH Q2 Guidelines)

Specificity:

- FTIR: No interference in spectrum from excipients.
- UV: Blank methanol shows no absorbance at λmax.

Linearity:

- UV: 2–12 µg/mL, $R^2 \geq 0.999$

Accuracy (Recovery):

- Recoveries within 98–102%.

Precision:

- Repeatability: 6 replicates at 10 µg/mL, %RSD ≤ 2%
- Intermediate precision: different days/analysts

LOD & LOQ (UV only):

- LOD = 3.3 × (σ/S)
- LOQ = 10 × (σ/S)

Robustness:

- Small changes in wavelength, solvent composition; results consistent.

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III. RESULTS AND DISCUSSION

- FTIR spectra confirmed Cilnidipine identity by characteristic peaks.
- UV method showed excellent linearity ($R^2 > 0.999$), accuracy, and precision.
- LOD and LOQ were suitable for routine analysis.
- Both methods were robust and specific.

IV. CONCLUSION

The UV and FTIR methods developed for Cilnidipine were successfully validated as per IP and ICH guidelines.

- UV method: Quantitative estimation.
- FTIR method: Qualitative identification.

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