

DETERMINATION OF λ -MAX AND LINEARITY FOR NIMODIPINE AND ASSAY METHOD FOR AMLODIPINE TABLETS I.P. USING UV-VIS SPECTROSCOPY

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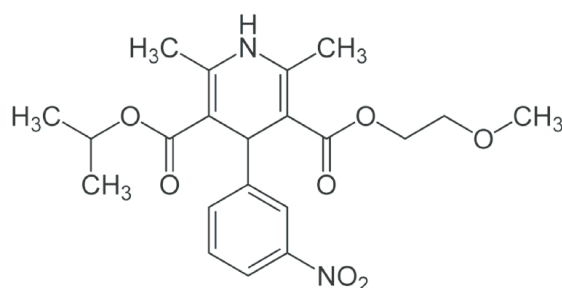
ABSTRACT

A simple, specific, and precise UV spectrophotometric method has been developed and validated for the determination of Nimodipine in pharmaceutical formulations. Nimodipine exhibited an absorption maximum at 239.0 nm, with a linear response over a concentration range of 5–25 $\mu\text{g/mL}$ and a correlation coefficient of 0.9995. This method adheres to Beer's law, with the linear equation $y = 0.0332x + 0.0216$, confirming high accuracy and reproducibility within the specified range. Additionally, an efficient and straightforward UV spectrophotometric method has been employed for the assay of Amlodipine, a long-acting calcium channel blocker. The analysis was conducted at a wavelength of 238 nm using water as the solvent, yielding a solution with a percentage purity of 98.3% w/v. This rapid method is effective for routine quality control of Amlodipine tablets. Both methods were validated based on parameters such as specificity, precision, linearity, range, ruggedness, accuracy, and recovery. The results affirm that the proposed spectrophotometric methods are reliable for the quantitative analysis of Nimodipine and Amlodipine, making them suitable for pharmaceutical quality control.

KEYWORDS: Nimodipine, Amlodipine, UV Spectrophotometry, Pharmaceutical Analysis, Validation, Absorption Maximum.

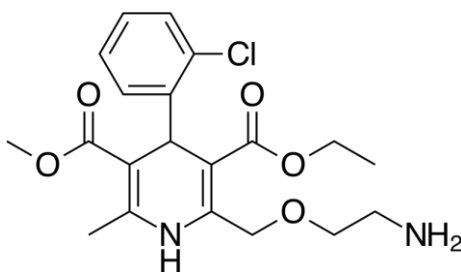
INTRODUCTION

Nimodipine is a cardioselective calcium channel blocker and antihypertensive agent primarily used to treat cerebrospinal hemorrhage. Renowned for its strong effect on cerebral blood vessels, Nimodipine also exhibits cytoprotective properties by reducing calcium influx into nerve cells. Its chemical designation is 3,5-Pyridinedicarboxylic acid, 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-, 2-Methoxyethyl 1-Methylether ester, with the molecular formula $C_{21}H_{26}N_2O_7$ and a molecular weight of 418.44 g/mol.^[1] This review focuses on the development and validation of a UV spectrophotometric method for estimating Nimodipine content, adhering to the International Conference on Harmonization (ICH) guidelines. The proposed method is characterized by its simplicity, specificity, stability, rapidity, and accuracy, offering a cost-effective and efficient approach to the quantitative analysis of Nimodipine in pharmaceutical preparations.^[2]



Chemical structure of nimodipine

Amlodipine is a calcium channel blocker widely used to manage hypertension and angina. Known for its antihypertensive effects, Amlodipine also exhibits antioxidant properties and promotes the release of nitric oxide (NO), a vasodilator that contributes to blood pressure reduction. Its suitability for once-daily dosing enhances its therapeutic appeal. The IUPAC name for Amlodipine is 3-ethyl 5-methyl 2-[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate, with a molecular weight of 408.87 g/mol and a chemical formula of $C_{20}H_{25}ClN_2O_5$.^[3] This study aimed to quantify the percent assay of Amlodipine using a UV spectrophotometric method. This approach provides a straightforward, accurate, and cost-effective method for analyzing Amlodipine in its dosage form, making it suitable for routine pharmaceutical quality control.



Chemical structure of amlodipine

MATERIALS AND METHODS

1. Determination of λ -max and verification of linearity of nimodipine

Determination of λ -max of nimodipine solution Selection of solvent

- Based on the solubility study performed, 60:40 methanol-water mixture was chosen as the solvent (diluent) for dissolving Nimodipine.

Preparation of standard stock solution of Nimodipine

- To make a standard drug solution of Nimodipine, dissolve 10mg in 10ml of methanol:water (60:40v/v) in a volumetric flask, yielding a stock solution of 1000 µg/ml. 1ml of The stock solution was removed and diluted with 10ml of methanol:water(60:40)v/v in a volumetric flask to create a 100 µg/ml concentration.^[4]

Preparation of sample solution

- Accurately weighed of 10 tablets, Average weight is taken and powdered amount equivalent to 10 µg/ml weighed and transferred into 10ml of volumetric flask and made upto mark to make mobile phase. This solution was filtered through Whatsmann filter paper number 40. From the above solution 1ml is taken and future diluted in 10 ml volumetric flask with mobile phase to accurate acceleration of 100 µg/ml of Nimodipine.

Determination of λ Max of Nimodipine

- To determine the maximum wave length, a standard solution with a concentration of 10 µg/ml was scanned at 200-400nm using a diluent and blank. Nimodipine's wavelength maxima were observed at 239 nm (λ max) in the spectra shown in fig 1.

Wavelength Vs Absorbance

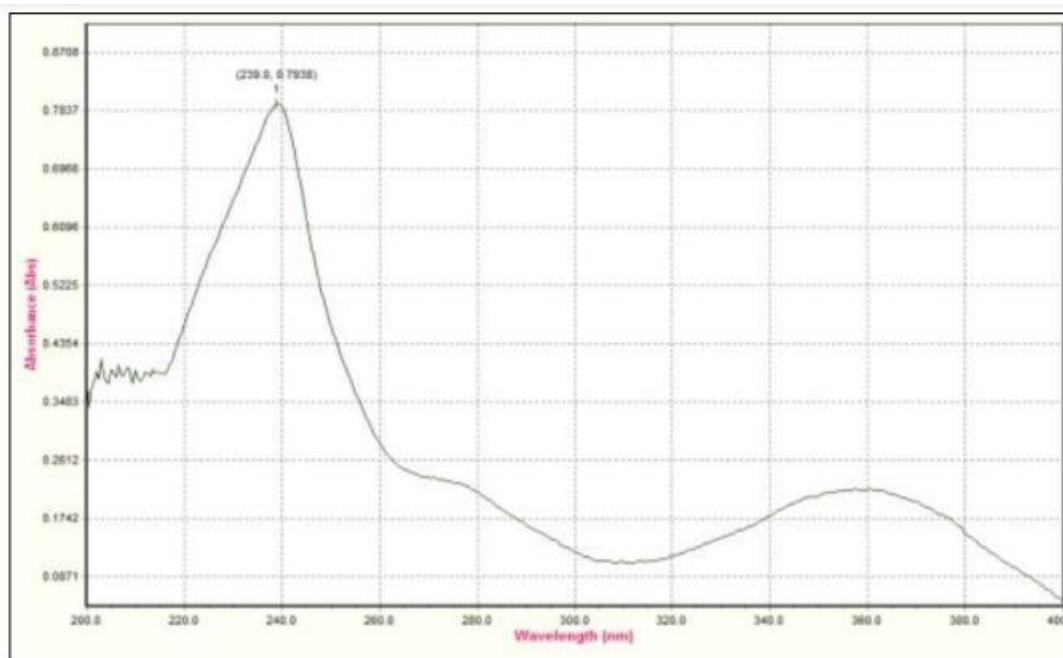


Figure No.1: Wavelength Vs Absorbance curve.

Determination of linearity

- Five levels of five different concentrations, lique of standard solutions of suitable concentration of Nimodipine were transferred into a series of 10ml standard volumetric flask and volumes are made upto the mark with methanol: water(60:40v/v). Five dilution concentrations (5-25 µg/ml) were made and absorbance was measured at 239nm with diluent as a blank. The obtained values are plotted against the concentration of Nimodipine to get the calibration curve.

Table 1.

Concentration($\mu\text{g/ml}$)	Absorbance at 239 nm
5	0.199
10	0.401
15	0.624
18	0.065
22	0.835
25	0.996

Linearity of Nimodipine

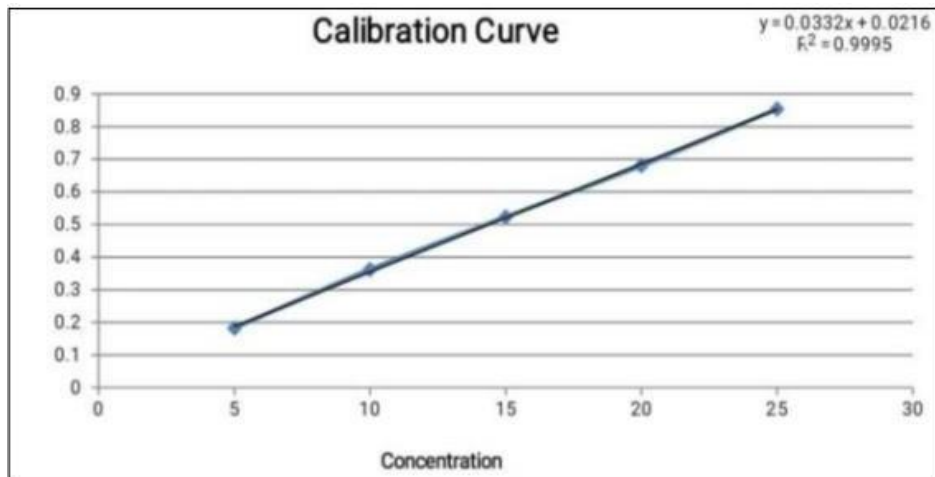


Figure No.2: Nimodipine Calibration Curve.

2. Assay of Amlodipine tablets I.P.

Procedure

- Weigh 20 tablets correctly and calculate their average weight.
- To calculate weight to be taken of sample by using average weight, label claim and required weight.

Solution A

- Weigh accurately 0.15g and transfer to 250ml standard flask and add 50ml of 0.1M sodium hydroxide.
- Dilute with 100ml of water to produce 250ml filter it.

Solution B

- Dilute 10ml of filtrate to 100ml of 0.1M sodium hydroxide dilute to 100ml with water
- Measure the absorbance of solution B at 238nm calculate the content of Amlodipine taking as the value & $E_{1\%}^{1\text{cm}} = 238\text{nm}$.

Calculation

Weight of 20 tablets	= 0.2772 gm
Average weight	= 0.01386 gm
Label claim	= 0.01 gm
Required weight	= 0.004 gm

Weight to be taken = Average weight / Label claim × Required weight

$$= (0.01386 / 0.01) \times 0.004$$

$$= 0.005544.$$

Amount present

Amount present = (absorbance of sample / absorbance of standard) × (standard wt / sample wt) dilution factor × average weight

$$= (0.60/0.65) \times (0.01/0.013) \times (100/100) \times (100/10) \times (10/100) \times 0.01386$$

$$= 0.00983\text{gm.}$$

Percentage purity of sample

Percentage purity = Amount present / Label claim × 100

$$= (0.00983/0.01) \times 100$$

$$= 0.983 \times 100$$

$$= 98.3\% \text{ w/v.}$$

RESULTS AND DISCUSSION

The UV spectrophotometric method developed in this study offers a straightforward, stable, rapid, and precise approach for the analysis of Nimodipine. With an absorption maximum (λ -max) identified at 239.0 nm, the method demonstrated excellent linearity across a concentration range of 5–25 $\mu\text{g/mL}$, with a correlation coefficient of 0.9995. These findings indicate the method's reliability, cost-effectiveness, and suitability for routine analysis of Nimodipine in pharmaceutical formulations. Additionally, a simple and efficient UV spectrophotometric method for the quantification of Amlodipine in various dosage forms was successfully established. The method's low limit of quantification, minimal sample volume requirement, and brief analysis time make it particularly well-suited for routine assays. Results adhered to ICH guidelines, ensuring compliance and reliability in quality control settings. For the Amlodipine assay, the percentage purity of Amlodipine tablets was determined to be 98.3% w/v, indicating that the method is effective for routine quality control and pharmaceutical analysis.

CONCLUSION

This study successfully developed and validated two UV spectrophotometric methods for the analysis of Nimodipine and Amlodipine in pharmaceutical formulations. The method for Nimodipine, with its absorption maximum at 239.0 nm, exhibited excellent linearity and proved to be simple, accurate, and cost-effective for quantitative analysis. Similarly, the Amlodipine assay demonstrated a high level of precision, with a percentage purity of 98.3% w/v, confirming its suitability for routine quality control. Both methods comply with ICH guidelines and are advantageous due to their rapid execution, minimal sample requirements, and reliability, making them well-suited for routine pharmaceutical applications. These findings affirm that UV spectrophotometry provides a viable and efficient approach for the quality control of these cardiovascular drugs, supporting its continued use in pharmaceutical analysis.

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