International Journal of Pharmacy and Analytical Research (IJPAR)

IJPAR |Vol.13 | Issue 3 | Jul - Sept -2024

www.ijpar.com

DOI : https://doi.org/10.61096/ijpar.v13.iss3.2024.421-425

ISSN: 2320-2831

Review

A review on analytical method development and validation of Nimodipine using UV Spectroscopy

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Published on: 24 Sept 2024

Published by:
DrSriram Publications

Abstract

A simple, specific, precise and efficient UV Spectrophotometric method has been developed and validated for the quantification of Nimodipine in pharmaceutical products. The absorption peak for Nimodipine was found at 239.0 nm, exhibiting a strong linear relationship with a correlation coefficient of 0.9996. The validation process encompassed studies on precision and accuracy, and optimal analytical conditions were established. The maximum wavelength (λ max) for Nimodipine was identified as 238.5 nm. The method complied with Beer's law over a concentration range of 5-30 mcg/mL, represented by the linear equation y = 0.033x + 0.020 and a correlation coefficient of 0.9981. Furthermore, parameters such as slope, intercept, correlation coefficient, detection limits, and quantification limits were determined. The analytical results were statistically validated and corroborated through a recovery study. This method is deemed appropriate for the routine analysis of Nimodipine in tablet formulations.

Keywords: Nimodipine, UV Spectrophotometer, Accuracy, Precision, ICH.

INTRODUCTION

Nimodipine, a cardiac specific calcium channel blocker and anti-hypertensive medication, is used to treat cerebrospinal hemorrhage. Nimodipine has been shown to significantly affect cerebral blood vessels and may have cytoprotective benefits by lowering calcium input into the nervous system. IUPAC name: 3, 5-Pyridinedicarboxylic acid, 1, 4-dihydro-2, 6-dimethyl-4-(3-nitrophenyl)-, 2-Methoxyethyl 1-Methylether ester. Nimodipine has a chemical formula $C_{21}H_{26}N_2O_7$ has a molecular weight of 418.44 g/mole. The European/British pharmacopoeia and the United States pharmacopoeia both use the Potentiometric titration assay method. A literature review found just a few available analytical procedures, such as titration, UV spectroscopy, and HPLC. This study introduces a simple, accurate, and sensitive approach for measuring Nimodipine levels in pure pharmacological substances. There is no straightforward method for estimating Nimodipine formulation drugs.

The documented procedures for assay content analysis are either time-consuming or use mobile phases with pH modification of buffer solutions for sample preparation, which can be tedious and abnormal. This is particularly relevant for routine testing of quality control samples. Therefore, it was deemed necessary to construct up.[1]

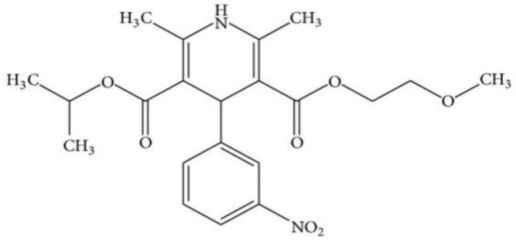

Fig 1: Chemical structure of Nimodipine

Table 1: Analytical methods for Nimodipine

S.No	Author name	Journal name	Title name	Analytical conditions
1	Lubna B Shaikh et al, 2015[2]	Scholars Research Library	Development and Validation of RP-HPLC Method For Estimation of Process Related Impurity in Nimodipine Bulk and Formulation	Solvent: Methanol , Acetonitrile, Water (35v:40v:25v) λ max: 234 nm Linearity: 2-12µg/ml. Correlation coefficient: 0.980. LOD:0.2177µg/ml LOQ:0.6597µg/ml
2	Gurumurthy T et al, 2022[3]	International Journal ofPharmacy and Pharmaceutical Science	Analytical Method Development and Validation For The Estimation of Nimodipine in Pure and Marketed Formulation by UV Spectrophotometric Method	Solvent:Methanol,Water (60:40 v/v) λmax: 239 nm. Beer's Law:5-25 µg/mL r2=0.9995 LOD:1.2µg/ml LOQ:3.6µg/ml
3	Sonali G. Lahamage et al,2020[4]	World Journal Of Pharmaceutical Research	RP-HPLC Forced Degradation Studies of Nimodipine in Pharmaceutical Dosage Form	Solvent:Methanol :Acetonitrile:Water(35v: 38v:27v) λmax:236nm Linearity: 1-6µg/ml Correlation coeffient:0.999 LOD:0.4462 LOQ:0.1352
4	B.Rajani et al,2014[5]	International Journal of Research in Pharmacy and Chemistry	Optimized and Validated RP-HPLC Method for the Estimated of Nimodipine in Tablet Dosage	Solvent:Buffer:Acetonitrile(30:70) λmax:236nm Linearity:37.225 µg/ml Correlation coefficient:0.999 LOD:0.68 µg/ml LOQ:2.07 µg/ml

			Form	
5	Sahana R et al,2023[6]	World Journal of Pharmaceutical and Medical Research	Validated Spectrophotometric Method for the Estimation of Nimodipine in Bulk and Tablet Dosage Form	Solvent:Acetonitrile Linearity :2-12µg/ml Correlation coeffient:0.9998Detection Wavelengths:230/240 nm
6	CH.Raghunath et al, 2023[7]	International Journal of Enhanced Research in Medicines and Dental Care	Method Development and Validation of UV-Spectrophotometric Method for Quantitative Estimation of Nimodipine in Pharmaceutical Dosage Form	Solvent:Methanol,Acetonitrile,Water Beer's law:15 µg/ml Maximum Absorbance :238.50nm
7	ManoelaK.Riekes et al,2012[8]	Journal of Chromatographic Science	Determination of Nimodipine in the Presence of its Degradation Products and Overall Kinetics Through a Stability – Indicating LC Method	Solvent: Acetonitrile: Methanol : water (55:11:34 v/v/v/)
8	R.Swetha Sri et al , 2020[9]	Asian Journal of Chemical and Pharmaceutical Research	A Novel HPLC Method for Quantitative Estimation of Nimodipine in Bulk and Pharmaceutical Dosage Forms	Solvent: Methanol : Water 60:40 Linearity:2 to 12 µg/ml Correlation coeffient: 0.9998 LOD: 0.13 µg/ml LOQ: 0.40 µg/ml
9	SandeepLahoti et al, 2012[10]	Asian Journal of Biomedical and Pharmaceutical Science	Development and Validation of UV Spectrophotometric Method of Nimodipine in Bulk and Tablet Formulation	Linearity: 5-30 µg/ml Correlation coeffient: 0.9981 Absorption Maxima:238,5nm LOD: 0.7469 µg/ml LOQ; 2.26 µg/ml
10	Banothu Bhadru et al, 2023[11]	International Journal of Research in Pharmacy and Pharmaceutical Sciences	Method development and validation of Amlodipine Besylate in API and pharmaceutical	Solvent: methanol : Acetonitrile : Water (35:40:25 v/v/v/) Linearity: 2-12 µg/ml Correlation coeffient: 0.980 LOD: 0.2177 µg/ml LOQ: 0.6597 µg/ml

			dosage form by UV Spectroscopy	
11	Meshwa M. Patel et al 2017[12]	Pharma Science Monitor an international Journal of Pharmaceutical Science	Development and Validation of UV Methods for Estimation of Nimodipine in Soft Gelatin Capsule	Beer's law:4-20 µg/ml Correlation coeffient: r = 0.9984 in Method A r = 0.9960 in Method B r = 0.9989 in Method C
12	Razi Khan Sameera et al, 2023[13]	Iran J.Chem. chem.Eng	Determination of Nimodipine Stability by UV-Spectroscopy Along With Quantum Mechanics to Establish Method, Validation, and Force Degradation Study	Solvent: methanol : Acetonitrile : Water (35:40:25 v/v/v/) Linearity: 2-12 µg/ml Correlation coeffient: 0.980 LOD: 0.2177 µg/ml LOQ: 0.6597 µg/ml
13	Y.S.R Krishnaiah et al, 2003[14]	Asian Journal of Chemistry	Development and Validation of a Reversed-Phase HPLC Method for The Analysis of Nimodipine in Pharmaceutical Dosage Forms	Solvent: Acetonitrile: Water (58:42 V/V) Flow Rate 1 ml/min Linearity: 0.1-40 µg/ml
14	Kasture V.S et al, 2014[15]	International Journal of Pharmacy	Development and Validation of RP-HPLC Method for the Estimation of Process Related Impurities From Nimodipine Bulk and Formulation	Solvent: Methanol: Acetonitrile : Water (35:38:27) Linearity:1-6 µg/ml λ max: 236 nm LOD= 3.3×SD/SLOPE LOQ= 10×SD/SLOPE

CONCLUSION

The Development and Validation of the UV Spectrometric Method for The Estimation of Nimodipine Content Have Been Successfully Accomplished. The Method Was Optimized and Validated According to ICH Guidelines, Demonstrating its Reliability, Accuracy, Precision, and Linearity Across the Specified Concentration Range. The Method is both simple and Cost-effective, Making it Suitable for Routine Analysis of Nimodipine in Bulk and Dosage forms. Moreover, The Method's Robustness and reproducibility ensure that it can be effectively utilized in Quality control Laboratory for the Consistent and Accurate Determination of Nimodipine Content.

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