Development and Validation of a UV-Spectroscopic Method of Nitrendipine

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ABSTRACT

A new, simple, accurate, precise, linear, and sensitive UV-Spectroscopic method has been developed and validated for the simultaneous estimation of Nitrendipine in pharmaceutical tablet dosage form. The developed method was then validated for linearity, accuracy, and precision in accordance with ICH Guidelines. From all these results it can be concluded that the current research was new, accurate, efficient, precise, rapid, reproducible, simple, and sensitive. The proposed method for this research can be successfully used to estimate the Nitrendipine in marketed formulations.

Keywords: Nitrendipine, UV-Spectroscopy, Estimation and Validation

1. INTRODUCTION:

Nitrendipine acts as antihypertensive, a dihydropyridine calcium channel blocker. Nitrendipine is used in the treatment of primary hypertension to decrease blood pressure and can reduce the cardiotoxicity of cocaine[1]. Pharmacologically a calcium ion influx inhibitor (slow-channel blocker or calcium ion antagonist) which selectively inhibits the transmembrane influx of calcium ions into cardiac muscle and vascular smooth muscle. The contractile processes of the muscles depend on the movement of extracellular calcium ions into these cells through specific ion channels[2-4]. Nitrendipine is used in the treatment of high blood pressure.

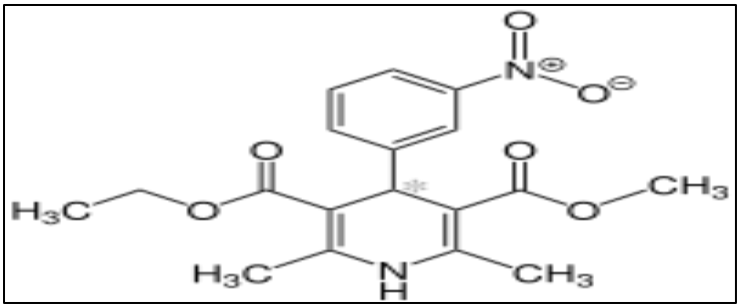

Fig. 1: Chemical structure of nitrendipine

2. MATERIALS AND METHOLOGY:

2.1 Method Development:

2.1.1. UV spectrum of Nitrendipine

The solvent utilised was methanol, which was easily soluble for both drugs. As a result, the suggested procedure's solvent was decided to be methanol.

2.1.2 Preparation of Standard Stock Solution:

The standard stock solutions of nitrendipine was prepared by dissolving drug into a 100ml volumetric flask containing methanol. An accurately measured amount of 10mg of drug was transferred into the 100 ml volumetric flasks separately. To acquire the necessary concentration of each drug, 100µg/ml, methanol was added to the flask and it was manually shaken to complete the dissolution of drug. The flask needs to be marked, and it should be stored at room temperature[4-7].

2.1.3 Preparation of working standard:

An accurately measured volume of a 100µg/ml stock solution of nitrendipine was diluted with methanol to obtain appropriate dilutions of 1–10µg/ml and 1–12µg/ml, respectively, and was then analysed spectrophotometrically at 236 nm.

2.1.4 Method of Validation [8-12]:

The method of validation in UV-Spectroscopy was validated by following ICH-guidelines.

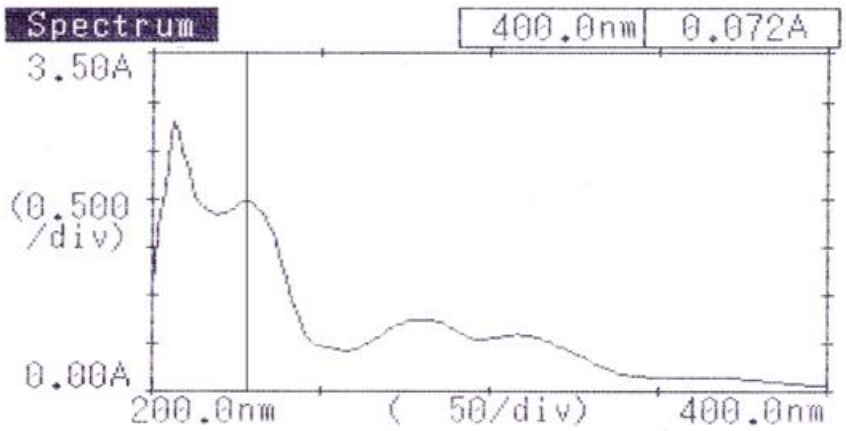

Figure1 : UV spectra of nitrendipine in standard solution

Table1: Analysis of Tablet formulation

Replicate No.	**Label claim (mg/Tab)**	**Conc. Found (mg/Tab)**	**Percentage found**
	NIT	**NIT**	**NIT**
Replicate-1	100	98.091	100.21
Replicate-2	100	99.210	100.00
Replicate-3	100	100.123	100.11
Replicate-4	100	100.148	100.02
Replicate-5	100	100.211	100.10

2.1.5 Linearity:

Reliable quantification requires the selection of an appropriate calibration model. As a result, it is necessary to look at how the concentration of an analyte in the sample and the corresponding response relate to one another. The isoabsorptive point, which is an isosbestic point present in zero order absorption spectra, can be analysed using the absorption subtraction method, which is based on the absorption factor approach and uses equal absorptivity values for the components showing this point. As a result, the linearity curve was drawn at the individual wavelengths of nitrendipine (236 nm).[13-15]

2.1.6 Repeatability:

Repeated scanning and measurements of the absorbance of solutions comprising (n = 6) of nitrendipine (5µg/ml) at the same time was used to test the instrument's accuracy without altering the parameters of the suggested approach.

2.1.7 Precision:

Precision is defined as the degree of agreement between quantity values acquired by repeated measurements of a quantity under predetermined conditions by the ISO International Vocabulary of Basic and General Terms in Metrology (ISO-VIM) and ICH. When evaluating precision, it is necessary to use the standard deviation, variance, or coefficient of variation to numerically quantify the random error or level of dispersion of a collection of individual measurements.

2.1.8 Limit of Detection:

The lowest amount of analyte in a sample that can be detected but not always quantitated as an accurate number is the Detection Limit of a specific analytical method. The expression for the detection limit (LOD) is: According to ICH recommendations, the limit of detection can be computed using the following calculation.

$LOD = 3.3 \times N/S$

Where, N is the standard deviation of the intercepts of the drug and S is the slope of the corresponding calibration curve.

2.1.9 Limit of Quantification [16-21]:

The lowest amount of analyte in a sample that can be quantitatively measured with enough precision and accuracy was the quantitation limit of an analytical method. According to ICH recommendations, the limit of quantification can be computed using the following calculation.

LOQ = 10 × N/S

Where, N is the standard deviation of the intercepts of the drug and S is the slope of the corresponding calibration curve.

2.2.0 Robustness[21]:

The impact of small, purposeful modifications to the isoabsorptive wavelength (±2 nm) on the outcomes was investigated.

2.2.1 Ruggedness[21]:

The degree of consistency of findings produced by the successful application of the assay over different analysts is characterised as the ruggedness test of the analytical assay method. Two analysts carried out the suggested methodologies in this investigation for the determination of nitrendipine and hydrochlorothiazide.

2.2.2 Forced degradation studies[21]:

Different ICH-recommended stress conditions (acidic, basic, oxidative, thermal, and photolytic) were used in this investigation.

It is concluded that the proposed method is new, simple, cost effective, accurate, safe, and can be successfully employed in the routine analysis of nitrendipine in pharmaceutical dosage forms.

Source of Support: Nil

Conflict of interest: Nil

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