



VISIBLE SPECTROPHOTOMETRIC DETERMINATION OF AMLODIPINE IN PHARMACEUTICAL FORMULATION AND BULK DRUG BY USING BROMOCRESOL PURPLE

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ABSTRACT

A simple and sensitive visible spectrophotometric method has been developed for the quantitative estimation of amlodipine in bulk drug and pharmaceutical dosage forms (tablets). Amlodipine exhibited absorption maximum at 410 nm in bromocresol purple 0.05% 2.4 buffer solution and obeyed Beer's law in concentration range 4-20 µg/mL. The result of analysis in this method has been validated statistically and by recovery studies. This method is extended for the analysis of drug and in pharmaceutical formulation.

Key words: Amlodipine, Validation, Visible spectrophotometric.

INTRODUCTION

Amlodipine is chemically 2-[(2-aminoethoxy) methyl]-4-[2-chlorophenyl]-1, 4-dihydro-6-methyl/-3, 5-pyridine dicarboxylic acid-3-ethyl-5-methyl ester, which is used in the treatment of angina pectoris and in hypertension.

Amlodipine inhibits the movement of calcium ions (Ca^{2+}) across the cell membrane into vascular smooth muscles and myocytes.

Molecular formula: $\text{C}_{20}\text{H}_{25}\text{ClN}_2\text{O}_5$

No reports are found in the literature for its quantitative estimation by HPLC, HPTLC and spectrophotometry. In the present work, a simple and sensitive visible spectrophotometric method has been developed for the quantitative estimation of amlodipine in the bulk drug and pharmaceutical dosage form. In this method, amlodipine exhibits absorption

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maximum at 410 nm in bromocresol purple 0.05% 2.4 buffer and obeyed Beer's law in concentration range of 4-20 $\mu\text{g/mL}$. The result of analysis has been validated statistically and by recovery studies. The method is extended for the analysis of drug in pharmaceutical formulations.

EXPERIMENTAL

All spectral measurements were done on UV-visible spectrophotometer Model Systronic 119.

Reagents

Analytical grade reagents were used and commercially available sample were purified before use.

- (i) Bromocresol purple 0.05% in 0.1M NaOH and 20 mL of ethanol
- (ii) 2.4 Acid phthalate buffer solution.
- (iii) Chloroform.
- (iv) Distilled water.

Working standard of drug solution

About 100 mg of amlodipine was actually weighed and dissolved in chloroform in 100 mL volumetric flask and the volume was made up to mark with chloroform (1 mg/mL). The final concentration of amlodipine was brought to 100.00 $\mu\text{g/mL}$ with chloroform.

Sample preparation

One branded commercial tablets (from two tablets) were analyzed by the proposed method. 20 Tablets of formulation each containing 10 mg of amlodipine were accurately weighed and powdered. Weight of tablet equivalent to 100 mg of drug was taken in 40 mL of chloroform and shaken for 15 min and filtered into 100 mL of volumetric flask using cotton wool and then remaining amount of chloroform was added. Final concentration was brought upto 100.0 mg/100.0 mL with chloroform.

Assay

Aliquots of amlodipine ranging from 1 to 5 mL (1.0 mL = 100 μg) were transferred into a series of 250.0 mL separating funnel. 5.0 mL of 2.4 buffer solution and 5.0 mL of 0.05% bromocresol purple were shaken for two minutes and organic layer was transferred to

25.0 mL volumetric flask and volume was made upto the mark with chloroform. The absorbance of this solution was measured at 410 nm against reagent blank. The amount of amlodipine present in the sample was computed from the calibration curve.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's Law limits, molar absorptivity and Sandell's sensitivity are presented in Table 1. The regression analysis using the method of least squares was made for the slope (b), intercept (a) and correlation coefficient (r) from different concentrations and the results are summarized in Table 1. The percent relative standard deviation and percent range of error (0.05 & 0.01 level of confidence limit) were calculated from eight measurements $3/4^{\text{th}}$ of the upper Beer's law limits of amlodipine and these are given in Table 1. The results showed that this method has reasonable precision.

Table 1: Optical characteristics and precision

λ_{max}	410 nm
Beer's law limits	4-20 $\mu\text{g/mL}$
Molar absorptivity (Lit.mol ⁻¹ cm ⁻¹)	1.7275×10^5
Sandell's sensitivity ($\mu\text{g/cm}^2$ 0.001 Absorption limit) Regression equation y*	0.031
Slope (b)	4.61×10^{-2}
Intercept (a)	-4.16×10^{-2}
Correlation coefficient	1.000
% RSD range of error**	0.6628
Confidence limit with 0.05 level	± 0.7015
Confidence limit with 0.01 level	± 1.0387

The proposed method was found to be simple, sensitive, selective, economical, accurate and precision and can be used for determination of amlodipine in bulk drug and its pharmaceutical dosage form in a routine manner.

Table 2: Evaluation of amlodipine in pharmaceutical dosage form

Sample	Labeled Amount (mg)	Amount obtained (mg)	Percentage recovery **
T1	10	9.90	99.94
T2	10	9.90	99.66

T1 and T2 are tablet (Amlodac Cadila Pharmaceuticals, Ahmedabad) from different batches.

** Average of eight determinations \pm SD 10 mg of drug was added and recovered.

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