International Journal of Pharmacy and Pharmaceutical Sciences
Vol 2, Issue 2, 2010

Research Article

VISIBLE SPECTRO PHOTOMETRIC DETERMINATION OF AMLODIPINE IN PHARMACEUTICAL FORMULATION AND BULK DRUG BY USING BROMOPHENOL BLUE

ASGAR ALI*[1], KHAJA PASHA[1], S.A.RAJU2, AEJAZ AHMED[1]

[1]Luqman College of Pharmacy, Gulbarga -585102, [2]H.K.E.S College of Pharmacy, Gulbarga – 585105.

E mail: asgarpharm23@rediffmail.com

Received: 15 Dec 2009, Revised and Accepted: 13 Jan 2010

ABSTRACT

A simple & sensitive visible spectro photometric method has been developed for the quantitative estimation of Amlodipine in bulk drug and pharmaceutical dosage forms (tablets). Amlodipine exhibited absorption maximum at 413 nm in bromo phenol blue 0.05%. 2.4 buffer solution and as obeyed beers law in concentration range 4-20 mcg/ml. The result of analysis in this method has been validated statistically & by recovery studies. This method as extended for the analysis of drug & in pharmaceutical formulation.

Key words: Amlodipine, Validation, Visible Spectro photometry.

INTRODUCTION

Amlodipine is chemically 2-[(2-Amino ethoxy) 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 : $C_{20}H_{25}ClN_2O_5$

No reports were found in the literature for its quantitative estimation by HPLC, HPTLC and spectro photometry, in the present work, a simple and sensitive visible spectro photometric method has been developed for the quantitative estimation of Amlodipine in the bulk drug and pharmaceutical dosage form. In this method Amlodipine exhibits absorption maximum at 413 nm in Bromo phenol blue 0.05% 2.4 buffer and obeyed beers law in concentration range of 4-20 mcg/ml. The result of analysis in this method has been validated statistically and by recovery studies. The method is extended for the analysis of drug in pharmaceutical formulations.

EXPERIMENTALS

All spectral measurements were done on UV-visible spectro photometer model Systronic 119.

Reagents

Analytical grade reagents were used. Commercially available sample were purified.

- Bromo phenol blue 0.05% in 0.1M NaOH & 20ml of ethanol
- 2.4 Acid phthalate buffer solution
- Chloroform
- Distilled water

Working standard of drug solution

About 100mg of Amlodipine was actually weighed and dissolved in Chloroform in 100ml volumetric flask and make up the volume up to mark with chloroform 1mg/ml. The final concentration of Amlodipine was brought to 100.00µcg/ml with Chloroform.

Sample preparation

One branded of commercial tablets from two tablets were analyzed by the proposed method 20 tablets of formulation each centering 10mg of Amlodipine were accurately washed & powdered weight of tablet equivalent to 100mg of drug was taken in 40ml of Chloroform and shake for 15 min filter into 100ml of volumetric flask high cotton wool and the remaining amount of Chloroform is added. Final concentration was brought upto 100.0mg/100.0ml with Chloroform.

Assay

Aliquots of Amlodipine ranging from 1 to 5 ml (1.0ml = 100µg) 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% Bromo phenol blue shake two minute and organic layer transferred to 25.0 ml volumetric flask and volume was made upto the mark with Chloroform. The absorbance of this solution was measured 410nm against reagent blank. The amount of Amlodipine present in the sample was computed from the calibration curve.

RESULTS AND DISCUSSION

The optical characteristic such as absorption maxima Beers Law limits molar absorptivity & Sandells sensitivity are present at in Table.1. The regression analysis using the method of least squares was made for the slope (b) intercepts (a) & correlation (r) from different concentration and results are summarized in Table.1. The percent relative standard deviation and percent range of error (0.05 & 0.01 level of confidence limit) calculate from eight measurement $3/4^{th}$ of the upper Beers law limits of Amlodipine are given in Table.1. The result showed that this method has reasonable precision.

Table 1: OPTICAL CHARARCTERISTIC & PRECISION

λMax	413nm
Beers law limits	4-20µg/ml
Molar absorptivity (Lit.mol^{-1}cm^{-1})	1.90129 x 10^6
Sandells sensitivity (µg/cm^2 0.001 Absorption limit)	0.021
Regression equation y*	
Slope (b)	4.51 x 10^{-3}
Intercept (a)	8.0 x 10^{-3}
Co-relation co-efficient	.9986
% RSD	0.8346
Range of error**	
Confidence limit with 0.05 level	± 0.8822
Confidence limit with 0.01 level	± 1.3051

The proposed method was found to be simple, sensitive, selective, economical, and accurate and it 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 in mg	Amount obtain (mg)	Percentage recovery**
T1	10	9.90	99.94
T2	10	9.90	99.66

T1 & T2 are tablet (Amlodac Cadila Pharmaceutical Ahmedabad) from different batches.

** Average of eight determination ± SD 10mg of drug was added and recovered.

ACKNOWLEDGEMENTS

The Authors are thankful to M/s Reddy laboratories, Hyderabad for the gift sample of drug for research. The Authors are also thankful to the principal of Luqman College of Pharmacy, Gulbarga for providing laboratory facilities.

References

1. The Merck Index 12th Ed. Merck Research Laboratories White House Station New Jersey 517 (1996).
2. Martindale the Extra Pharmacopoeia 31st Ed.819, 1996
3. Sethi P.D. Quantitative analysis of drug in pharmaceutical formulation Third Ed.CBS publisher New Delhi.
4. Baur.E L A statistical manual for chemist Academic press New York 1960.
5. CIMS – 69 printed and published by Mrs.Lakshmi Krishna for BIO-GARD private limited 640,10-A cross WEST of cord road 2nd stage Bangalore drug profile.vol.23 Jan 2000-p-101.
6. Indian pharmacopoeias Ministry of Health and family welfare Government of India New Delhi 1996.Vol-II-p-202, A.202, A.144.