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RESEARCH ARTICLE

Ecofriendly Validated Spectrophotometric Method for the Estimation of Amlodipine Besylate by using Hydrotropic Solubilization Method

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ABSTRACT:
Simple sensitive and accurate spectrophotometric methods were developed for determination of poorly water soluble Amlodipine Besylate in pure and pharmaceutical dosage form using hydrotropic agents ammonium acetate. Hydrotropy is a good choice for replacing organic solvents used for this kind of drugs to reduce the cost and hazards of the analytical method. Amlodipine Besylate shows maximum absorption at 362 nm in 0.5 M of the hydrotropic agents. Beer's law was found to be obeyed in the concentration range of 5 - 25 µg/mL for the hydrotrope. Limit of detection was found to be 1.102µg/mL and limit of quantification was 3.278 µg/mL for ammonium acetate. The results were in a good agreement with those obtained with official USP method.

KEYWORDS:

INTRODUCTION:
Amlodipine is a calcium channel blocker that dilates (widens) blood vessels and improves blood flow. Amlodipine is used to treat chest pain (angina) and other conditions caused by coronary artery disease. Amlodipine is also used to treat high blood pressure (hypertension). Lowering blood pressure may lower your risk of a stroke or heart attack. Amlodipine is for use in adults and children who are at least 6 years old. It is chemically described as 3-ethyl-5-methyl (±)-2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridine dicarboxylate, mono benzene sulphonate. Its empirical formula is $C_{20}H_{25}ClN_2O_5.C_6H_6O_3S$ and its structural formula[1] as in figure No.1.

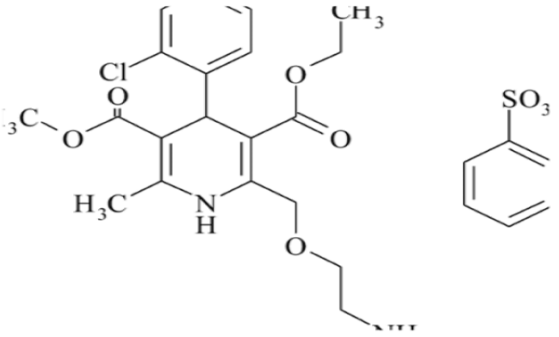

Fig. No. 1 Amlodipine Besylate

Amlodipine besylate inhibits the trans-membrane influx of calcium ions into vascular smooth muscles and cardiac muscle[2]. It is a peripheral arterial vasodilator that acts directly on vascular smooth muscles to cause a reduction in peripheral vascular resistance and reduction in blood pressure. It is effective in both types of angina

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exertional and vasoartic. Several methods were reported for the estimation of amlodipine besylate such as HPLC[3-6], HPTLC[7-9], LCMS/MS[10,11], spectrofluorometry[12] and spectrophotometry[13-18]. Three methods were reported for quantification of amlodipine besylate using hydrotropic agent. These methods include utilization of 1 M sodium acetate, 2 M sodium acetate and 2 M urea[19-21]. These methods suffer from low sensitivity due to high values of limit of detection and limit of quantification and also utilize concentrated solution of hydrotropic agents

MATERIAL AND METHODS:

Materials and chemicals:

Amlodipine besylate with 99.66% purity was obtained from Cipla Pharmaceuticals, Goa as a gift. ARGradesof Ammonium acetate, potassium acetate and nicotineamide were purchased. Amlodipine besylate tablets containing 10 mg AML were obtained from a local pharmacies.

Instruments:

UV spectra of samples were recorded on Bioera double beam spectrophotometer. Contecht electrical analytical balance (0.1 mg – 120 g) is used for weighing the samples.

PREPARATION OF STANDARDS, SAMPLE AND REAGENTS SOLUTIONS:

Preparation of ammonium acetate, potassium acetate and nicotineamide solutions:

0.5 M solution of ammonium acetate, potassium acetate and nicotine amide were prepared by dissolving 3.853, 4.908 and 6.106 g of ammonium acetate, potassium acetate and nicotine amide, respectively in distill water and makeup the volume to 100 mL with distill water.

Preparation of drug solution:

A stock solution of (100 ppm) was prepared by dissolving 10 mg of AML standard in 50 mL of 0.5M hydrotropic agent, sonicated for 20 minutes, then makeup to 100 mL with distill water.

Preparation of Sample Solution:

20 tablets of Amlodipine Besylate (10 mg/tablet) were weighed and finely powdered. A portion of the powder equivalent to 10 mg of drug was dissolved in 50 mL of hydrotropic agent solution, sonicated for 20 minutes, filtered and makeup to 100 mL with distills water to give a solution of 100 ppm.

Procedure for Calibration Curve:

Serial concentrations of 5 to 25 ppm were prepared from the stock solution with distill water. Absorbance of these solutions was recorded at λ max 362 nm against blank solution treated in the same way omitting only the drug.

APPLICATION OF THE PROPOSED METHOD TO ANALYSIS OF AMLODIPINE: BESYLATE DOSAGE FORM:

Amlodipine besylate tablets were subjected to the analysis by the proposed methods and the obtained results were statistically analyzed.

RESULTS AND DISCUSSION:

Absorption spectra:

According to the procedure, the absorption spectrum of AML in ammonium acetate, potassium acetate and nicotineamide was recorded. As the maximum absorption wavelength (λ_{max}) was at 362 nm for the three hydrotropic agents.

Method validation:

The linearity of the methods was investigated and found to be in the range of 5- 25 ppm for the three methods. Regression equation, Beer's law limits, slope, intercept, correlation coefficient, Sandell's sensitivity, molar absorptivity, limit of detection (LOD) and limit of quantification (LOQ) were summarized in Table. 1.

Table 1: Analytical parameters

Parameter	Method 1
λ_{max} (nm)	362
Beer's law limits (μgmL^{-1})	5 - 25
Sandell's sensitivity (μgcm^{-2})	0.0506
Molar absorptivity ($Lmol^{-1}.cm^{-1}$)	0.928×10^4
Std. Dev. of intercept	0.005
LOD (μgmL^{-1})	1.102
LOQ (μgmL^{-1})	3.278
Slope (m)	0.017
Intercept (b)	- 0.0002
Correlation coefficient	0.999

Precision:

To assess the precision, each experiment was repeated the same day (intra-day) and on different days (inter-day). The results shown the methods are precise according to the law values of standard deviation (SD) and percent relative standard deviation (% RSD), as shown in Table. 2.

Table 2: Evaluation of intra and inter day precision.

Method	Taken (μgmL^{-1})	Intra – day			Inter – day		
		Found (μgmL^{-1})	SD	% RSD	Found (μgmL^{-1})	SD	% RSD
Method 1	10	10.009	0.058	0.477	10.101	0.050	0.486
Method 2	10	9.988	0.044	0.445	9.945	0.040	0.402
Method 3	10	9.992	0.0404	0.405	9.960	0.037	0.389

Accuracy and Recovery:

Accuracy is estimated in terms of percent recovery and percent relative standard deviation. Results indicating a high accuracy and precision of the methods as shown in Table. 3.

Table 3: recovery studies

Method	% Recovery	% RSD	Proposed Method Mean ± SD	Reference Method Mean ± SD
Method 1	100.10	0.259	100.04±0.26	99.77±0.30
Method 2	99.85	0.260	99.74 ± 0.26	
Method 3	99.79	0.159	99.83 ± 0.16	

CONCLUSION:

The proposed methods were based on utilization of hydrotropic solubilization technique in developing Ecofriendly, simple and sensitive methods applied for routine analysis in quality control laboratories for the quantification of AML in both pure and pharmaceutical dosage forms.

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