
Simple and Rapid High Performance Thin Layer Chromatographic Estimation of Amlodipine from Pharmaceutical Dosage Forms

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A new simple method is described for the rapid and quantitative estimation of amlodipine [AML] in drug preparations by high performance thin layer chromatography [HPTLC]. The mobile phase consisted of toluene, acetone, ethanol, ammonia (56.0 : 34.5 : 6.0 : 3.5) using a precoated TLC silica gel F₂₅₄ (10 x 10 cm) and a computer controlled HPTLC scanner with camag cats software for integration.

SEVERAL analytical methods for quantifying AML in biological fluids have been reported, high performance liquid chromatography (HPLC) with amperometric detection¹, HPLC with UV detection²⁻⁵, packed column (or) capillary gas chromatography (GC) with electron capture detection^{6,7}, GC with electron impact mass spectrometry⁸ and reverse phase high performance liquid chromatography⁹.

Since no official has been reported for the quantitative determination of AML in its pharmaceutical dosage forms, in the present communication we describe the results of the quantitative determination of AML from its pharmaceutical dosage forms using HPTLC. Although the GC and HPLC assay procedures possess good sensitivity, they are tedious. TLC on the other hand, is easy but lacks the sensitivity and selectivity necessary in the analysis of pharmaceuticals. HPTLC possesses the advantage of being simple, rapid and easy to operate giving rapid performance with high resolution. The method has widely been accepted for quantitative and qualitative evaluation of drugs belonging to various classes viz vitamins, steroids, and amino acids. The objective of this study was to develop a HPTLC method for determination of AML and to apply the method to the quantitative estimation of AML from pharmaceutical dosage forms.

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Pure sample of AML was obtained from Tamilnadu Dadha pharmaceuticals limited, Madras and solvents of analytical grade were used after filtration through G4 (0.4 μ m) filter. Pure reference standard stock solution was prepared by weighing 5 mg of AML, dissolved in methanol and transferred to 10 ml volumetric flask. The final volume was made upto the mark with methanol and diluted as and when required with methanol. The sample solution of AML was prepared by weighing a powder equivalent to 5 mg of AML and making up the volume with methanol as of with standard solution.

Standard and Sample solutions were injected separately onto a precoated TLC silica gel F₂₅₄ (200 μ m thickness, 10 x 10 cm) using camag linomat IV spotting device. The plate was then developed upto 77.0 mm using the mobile phase in a camag twin through chamber. It was then dried at room temperature and scanned using a computer controlled HPTLC scanner and data stationed with camag cats software programme for integration at 366 nm (optical filter k-400, mercury lamp) with a slit dimension of 5.0 x 0.45 mm. The mode of measurement was fluorescence/reflection.

The calibration curve for AML was linear in the range from 200- 300 ng. The average standard deviation and coefficient of variation for pure drug and formulation was found to be 0.4895 and 0.0058,

Table 1 :Linearity and Assay values of AML by the proposed method

S.No.	PURE DRUG		Densitometry after HPTLC			
	Amount Applied(ng)	SD	CV%	AVG*	FORMULATION SD	CV%
1.	200	0.4898	0.0071	100.02	0.0777	0.07
2.	250	0.4358	0.0050	99.98	0.0217	0.02
3.	300	0.5431	0.0053	100.05	0.0412	0.04

* Average of 5 independent determinations.

0.0468 and 0.0433 respectively. The accuracy of the proposed method was checked by carrying out recovery of the added standards (200 - 300 ng) and was found to be 99.98%. To ensure maximum sensitivity AML was assayed at the absorption maximum of 366 nm and the R_1 value was found to be 0.52.

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