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## Simultaneous estimation of atenolol and amlodipine in formulations by reversed Phase - HPLC

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S. RAVI SANKAR, M.J. NANJAN, M. VASUDEVAN, NAHED SHAAT and B. SURESH

Dept. of Pharmaceutical Analysis  
J.S.S. College of Pharmacy, Ootacamund

A simple, precise and rapid reversed phase HPLC method was developed for the simultaneous determination of atenolol and amlodipine from pharmaceutical formulations. The recovery and statistical validations were also carried out to find its applicability in routine quality control.

**A**TENOLOL is a  $\beta$ -adrenoreceptor blocking agent used widely as an antihypertensive. Chemically it is 4-[2-hydroxy-3-[(methylethyl) amino] propoxy] benzeneacetamide. It is official in Indian Pharmacopoeia<sup>1</sup> and in British Pharmacopoeia<sup>2</sup> which describe a non-aqueous potentiometric titration for the raw material and u.v. spectrophotometric method for its determination from tablet formulations.

Amlodipine is a dihydropyridine calcium channel blocking drug with anti-anginal and antihypertensive activity. Chemically it is 2-[(2-amino ethoxy) methyl]-4-(2-chlorophenyl)-1,4 dihydro-6-methyl-3, 5-pyridine dicarboxylic acid 3-ethyl-5-methyl ester besylate. This drug is not official in any pharmacopoeia. A survey of literature reveals that amlodipine is estimated by a HPLC<sup>3,4</sup> method. A combination of 50 mg of atenolol and 5 mg of amlodipine is available commercially as tablets.

Many methods have been described in the literature for the determination of atenolol and amlodipine individually. There is however, no reported method available for the determination of atenolol and amlodipine in combined dosage forms. The present communication describes a simple, rapid and reproducible method for simultaneous determination

of atenolol and amlodipine from its pharmaceutical formulations.

### Materials and Methods

A Water HPLC system was used for the analysis. The Column used was Spherisorb C<sub>8</sub> (5 $\mu$ ), 250 mm x 3.9 mm id. The mobile Phase, phosphate buffer (pH 5.5) : Acetonitrile (50:50), was used at a flow rate of 1 ml/min with an operating pressure of 3000 psi. A Rheodyne 7125 injector with a 20  $\mu$ l loop was used for the injection of samples. Detection was done at 225 nm, with a sensitivity of 0.005 AUFS. Bondapak C<sub>18</sub>/Corasil was used as guard column. The Data station was computer controlled with a Baseline 810 software. Acetonitrile of HPLC grade, Milli 'Q' water of chromatographic grade and other chemicals of AR grade were used for the preparation of mobile phase. The mobile was filtered through 0.45 $\mu$  membrane and degassed.

Standard stock solution of atenolol (10 mg/ml) and amlodipine (1 mg/ml) were prepared in the mobile phase. The stock solutions were further diluted with mobile phase to get required concentration in the working range.

Table 1

Drug	(Amount/tablet)		% label claim Mean ± S.D.	% Recovery Mean ± S.D.
	Labeled (mg)	Found (mg) Mean ± S.D.		
Atenolol	50	49.23±0.19	98.46±0.09	100.34±0.13
Amlodipine	5	5.02±0.23	100.4±0.13	99.87±0.21

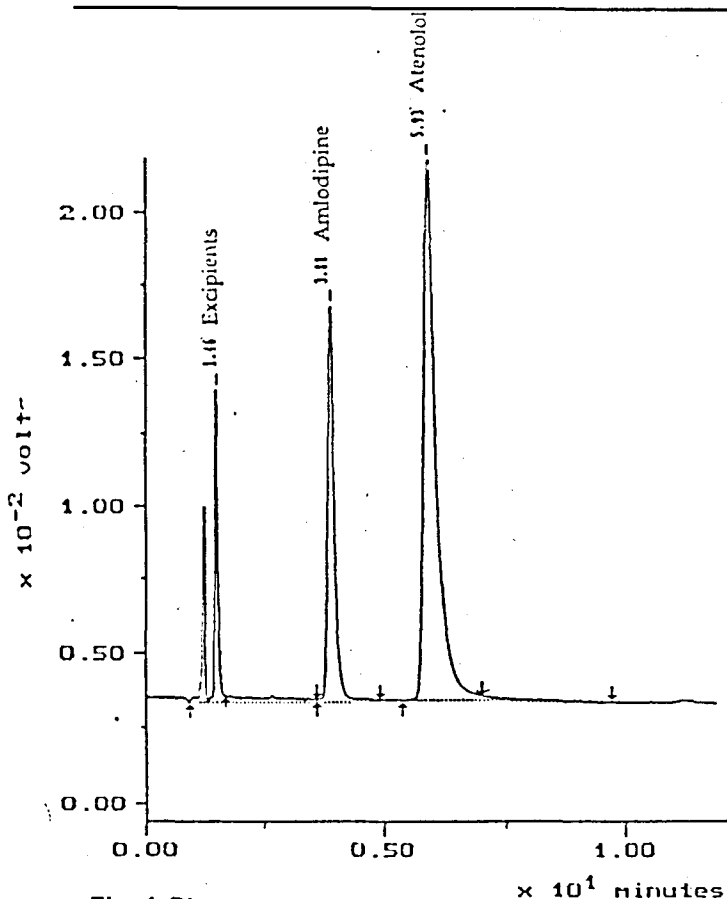


Fig. 1 Chromatogram of Atenolol and Amlodipine in formulation

Sample: SAMPLE Channel: detector 1 File name: TH-SAMPLE  
 Acquired: 30-OCT 95 16:23 Method :\MAX\GR\GR  
 Inj Vol: 20.00  $\mu$ l

Twenty tablets were weighed and finely powdered. A quantity of powder equivalent to 5 mg and 0.5 mg of atenolol and amlodipine respectively was weighed and transferred to 50 ml volumetric flask, dissolved in methanol, made upto the mark with methanol and filtered. 2 ml of this solution was diluted in a 10 ml of volumetric flask with the mobile phase.

Simultaneous estimation by Reversed phase - HPLC method

From the standard stock solution, mixed standards were prepared to contain 10, 20, 30, 40, 50  $\mu$ g/ml of atenolol and 1, 2, 3, 4 and 5  $\mu$ g/ml of amlodipine respectively. Then 20  $\mu$ l of this was injected in triplicate and the chromatogram was recorded. The retention time of atenolol and amlodipine were found to be 3.88 min and 5.93 min respectively. This was followed by injecting the sample solution obtained from the formulation (Fig. 1). Both atenolol and amlodipine showed linearity in the range of 10-50  $\mu$ g/ml and 1-5  $\mu$ g/ml respectively. The calibration curve was plotted using the peak area of the standard chromatogram against the concentration. The peak area of the sample chromatogram was compared and the amount of atenolol and amlodipine were calculated and shown in Table 1.

#### Recovery Studies

To study the accuracy, reproducibility and precision of the above method, recovery experiments were carried out. The recovery of the added standard was studied at three different levels. Each level was repeated six times. To an aliquot of the analysed formulations, a known concentration of standard solution was added. The content of amlodipine and atenolol were once again determined by the proposed method. From the amount of drug present, percentage recovery was calculated using the following formula:

$$\% \text{ Recovery} = \frac{N(\sum xy) - (\sum y)(\sum x)}{(N(\sum x^2))(\sum x)^2}$$

where,  $x$  = Amount of standard drug added  
 $y$  = Amount of drug found by proposed method  
 $N$  = Number of observations

## RESULTS AND DISCUSSION

The reported HPLC method for the simultaneous estimation of amlodipine and atenolol is simple, rapid and accurate. This could be seen from the %label claim and low standard deviation. The reliability and suitability of the method could be seen from the recovery values. Further, there is no interference due to excipients as they have different retention times when compared to that of amlodipine or atenolol. The present HPLC method is suitable for the quality control of raw material, formulations, dissolution studies and for the estimation of amlodipine and atenolol in biological fluids.

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