Visible Spectrophotometric Methods for Estimation of Amlodipine Besylate form Tablets

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Three simple,sensitive and accurate extractive colorimetric methods for estimation of Amlodipine besylate from tablet formulation have been developed. The developed methods involve formation of coloured chloroform extractable ion pair complexes of the drug with bromocresol green (BCG), bromophenol blue (BPB) and methylene blue (MB) in acidic medium. Extracted complexes showed absorbance maxima at 409.0 nm (BCG), 409.0 nm (BPB) and 668.2 nm (MB). Beer's law is obeyed in the concentration range employed (0-80 mcg/ml) for all the three methods. Results of analysis were validated statistically and through recovery studies.

AMLODIPINE besylate is a dihydropyridine calcium channel blocking agent with antihypertensive activity[1]. 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. Quite a few analytical methods[2-7] for the estimation of amlodipine besylate from body fluids and tablet formulation have been reported. An attempt has been made in the present study to develop three simple spectrophotometric methods of analysis of amlodipine besylate from tablets.

A Jasco UV/visible recording spectrophotometer (model 7800) with 1 cm matched quartz cells was used. Acid phthalate buffer pH 2.4, 3.0 and phosphate buffer pH 6.8 were prepared as per IP[8]. Dye (0.1%) solutions were prepared in buffer of pH 2.4 (Solution, A, BCG), pH 3.0 (solution B, BPB) and pH 6.8 (Solution C, MB). Each solution was extracted several times so as to remove chloroform soluble impurities.

Twenty tablets were accurately weighed and average weight per tablet determined. The tablets were powdered and the powder equivalent to 10 mg amlodipine besylate was accurately weighed and transferred to a 100 ml volumetric flask, chloroform (75 ml) was added, shaken well for 5 minutes to dissolve amlodipine besylate and filtered through a Whatman filter paper no. 41 into another 100 ml volumetric flask. The filter paper was washed with chloroform and the washings were added to filtrate, the final volume was made upto 100 ml. Four ml of this solution was diluted to 10 ml with chloroform.

To 10 ml of the final dilution in a separating funnel 5 ml of solution A (B or C) was added and shaken gently for 5 min. The chloroform layer was separated and absorbance measured at respective wavelength maximum using a reagent blank. The amount of drug present in the sample was computed from calibration curve prepared using standard sample solution following same method. Recovery studies were carried out by addition of a known quantity of the standard drug solution to preanalysed sample solution. Recoveries were found to be 100.9 % (method A), 100.5 % (method B) and 98.7 % (method C). Results of analysis are reported in table -1.

The proposed visible spectrophotometric methods for determination of amlodipine besylate from tablet formulations are based on formation of chloroform extractable ion pair complex of drug with various dyes and were found to be simple, accurate, rapid and sensitive. These methods may perhaps be used for routine analysis of drug from tablet formulation.

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Table-1 : Results of Analysis

Drug	Labelled amount (mg/tab)	% of label claim estimated			
		Proposed Method (using)*			Reported[6] Method
		BCG	BPB	MB	
Amlodipine	5	99.03(0.39)	99.0(0.43)	99.0(0.40)	98.0
	10	100.9(0.57)	100.7(0.55)	100.40(0.44)	98.5
	10	99.8(0.54)	99.1(0.30)	99.0(0.48)	97.9

* Average (±standard deviation) of three determinations.

REFERENCES

1. Martindale, The Extra Pharmacopoeia, The Pharmaceutical Press, London, 30th Ed., 1993, 342.
2. Barbalo, F., Coppello, B., Grametto, L. and Morrica, P., **Farmaco,** 1993, 48, 417.
3. Beresford, A. P., Macrae, P V., Stopher. D. A. and Wood, B.A., **J. Chromatogr.,** 1987, 420, 178.
4. Yeung, P. K. F., Mosher, S. T., Pollak, P. and Timothy, **J. Pharm. Biomed. Anal.,** 1991, 9, 565.
5. Narayana Reddy, M., Tulja Rani, G., Prasad Rao, K. V. S., Sankar, D. G. and Sreedhar, K., **Ind. J. of Pharm. Sci.,** 1997, 59, 188.
6. Sridhar, K., Sastry, C. S. P., Narayan Reddy, M., Sankar D. G., and Srinivas, K., **Anal. Lett.,** 1997, 30, 121.
7. Avadhanulu, A. B., Srinivas, J.S. and Anjaneyulu, Y., **Indian Drugs,** 1996, 33, 36.
8. Pharmacopoeia of India, The controller of publication, Delhi, Ed. 111, 1985, A-142.