Spectrophotometric Method for Estimation of Amlodipine Besylate and Benidipine Hydrochloride from Tablets

I. SINGHVI* AND S.C. CHATURVEDI†
Dept. of Pharmacy, College of Science,
M. L Sukhadia University, Udaipur (Raj.) 313 001
†Dept. of Pharmacy, SGSITS, Indore (M.P.) 452 001

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A simple spectrophotometric method in visible region is described for estimation of amlodipine besylate and benidipine hydrochloride from their respective tablet formulations.The developed method is based on formation of coloured chloroform extractable complex of drug with rhodizonic acid. Extracted complex of amlodipine besylate showed absorbance maxima at 450 nm while complex of benidipine hydrochloride showed absorbance maxima at 497.5 nm. Beer's law is obeyed in the concentration range of (0.1-1.5 mg/ml) for both the drugs. Results of analysis were validated statistically and by recovery studies.

Amlodipine besylate and benidipine hydrochloride are relatively new calcium channel blocking agent with antihypertensive activity. A number of analytical methods for estimation of amlodipine besylate[1-7] and benidipine hydrochloride[8-10] from body fluids and tablet formulation are reported. An attempt has been made in the present study to develop a simple spectrophotometric method for the analysis of these drugs from tablet formulation.

A Jasco UV/visible recording spectrophotometer (model 7800) with 1 cm matched quartz cells was used. Rhodizonic acid solution (2%) in distilled water and standard drug solution of amlodipine besylate (3 mg/ml) and benidipine hydrochloride (3 mg/ml) in chloroform were prepared. To a series of 10 ml volumetric flasks aliquots of standard drug solution were added and diluted with chloroform so as to give several dilutions in the concentration range of 0.1 to 1.5 mg/ml of respective drug. Each dilution was taken in a separating funnel, 5 ml of rhodizonic acid solution was added, shaken for 5 min and allowed to stand so as to separate aqueous and organic layer. Coloured chloroform layer was separated and the absorbance was measured at 450 nm for amlodipine besylate and 497.5 nm for benidipine hydrochloride against a reagent blank. Calibration curve for each drug was prepared.

*For Correspondence

Twenty tablets were accurately weighed and average weight per tablet determined. The tablets were powdered and powder equivalent to 25 mg amlodipine besylate (or benidipine hydrochloride) was accurately weighed and transferred to a 100 ml volumetric flask. Chloroform (75 ml) was added and shaken for 5 min. The solution was filtered through Whatman filter paper no.41 into another 100 ml volumetric flask. The filter paper was washed with chloroform and the washings were added to the filtrate, the final volume was made up to 100 ml. Ten millilitres of this solution was treated as per method used for calibration curve and the amount of drug present in sample was computed from the respective calibration curve. Process was repeated three times with two different batches of tablet formulations for both the drugs. Recovery studies were carried out by adding known standard drug solution to pre-analysed sample solution at three different levels. Results of analysis and recovery studies are presented in Table-1.

The proposed visible spectrophotometric method for determination of amlodipine besylate and benidipine hydrochloride from tablet formulations are based on formation of chloroform extractable complex of drug with rhodizonic acid. The developed method was found to be simple, accurate, rapid and sensitive. These developed methods may be used for analysis of drugs, from tablet formulation.

Table I - Results of Assay and Recovery Experiments

Drug	Pharmaceutical formulation	Labelled amount (mg)	Amount (%) found		% Recovery by proposed method
			Proposed	Reported	
Amlodipine	Tablet A	5	99.12	99.03	100.32
	Tablet B	10	98.87	99.80	99.72
Benidipine	Tablet A	4	98.68	98.34	99.68
Hydrochloride	Tablet B	8	98.96	99.08	100.50

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