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Spectrophotometric estimation of Valsartan and Benazepril hydrochloride in Pure and Pharmaceutical Formulations

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Abstract: A simple spectrophotometric method for the estimation of valsartan and benazepril hydrochloride in both pure and pharmaceutical formulation is described. This method is based on the formation of the ion association complex by the drug with Safranin-O, in buffer of pH 9.8. The ion association complex formed was quantitatively extracted under the experiment conditions into chloroform. The color was found to be stable for one hour. The absorbance of the chloroform layer of each drug was measured at its λmax against the reagent blank. This method has been statistically evaluated and is found to be precise, accurate and economical.
Keywords: Valsartan, Benazepril hydrochloride, Extractive spectrophotometric method, Safranin-O.

INTRODUCTION

Valsartan

It is chemically (S) -3-methyl-2-[*N*-({4-[2-(2*H*-1, 2, 3, 4-tetrazol-5-yl) phenyl] phenyl} methyl) pentanamido] butanoic acid (Fig.1a).It is an angiotensin II receptor antagonist, used in the treatment of high blood pressure, congestive heart failure and post myocardial infraction.

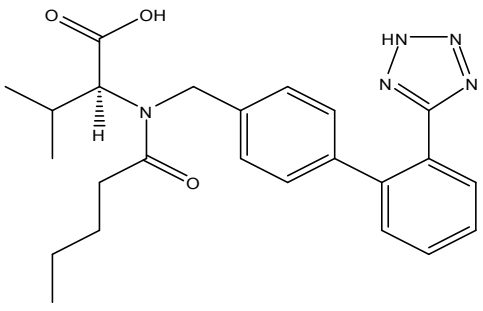

fig.1a valsartan

Benazepril hydrochloride

It is chemically 2-[(3*S*)-3-{[(2*S*)-1-ethoxy-1-oxo-4-phenylbutan-2-yl] amino} - 2-oxo-2, 3, 4, 5-tetrahydro-1*H*-1-benzazepin-1-yl] acetic acid (Fig.1b). It is an ACE inhibitor, used to inhibit blood clots in coronary artery disease, peripheral vascular disease and cerebro vascular disease.

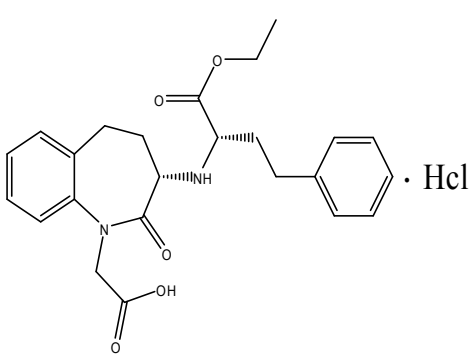

Fig.1 b Benazepril hydrochloride

Literature review describes some analytical methods for estimation of valsartan[1-6] and for benazepril hydrochloride [7-14]. But there is no simple and sensitive spectrophotometric method for the estimation of these drugs. Therefore the aim of the present work is to provide a simple and sensitive spectrophotometric method for the estimation of valsartan and benazepril hydrochloride in dosage forms. The proposed extractive method is based on the formation of ion-pair complexes with drug with dye and the complex formed is quantitatively extracted into chloroform.

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EXPERIMENTAL

Instrument

Shimadzu UV- Visible double beam spectrophotometer (1800) with 1cm matched quartz cells was used for the measurement of absorbance. Mettler electronic balance was used for weighing of the samples.

Chemicals & materials:

Valsartan and benazepril hydrochloride reference materials were obtained from Aurobindo Pharmaceuticals, Ltd., Hyderabad, where as pharmaceutical tablet formulation of valsartan (VALENT FC-TAB-160mg)/benazepril hydrochloride (BENACE FC-TAB-10mg) was obtained from local pharmacy. All the chemicals were used were of analytical grade and distilled water was used for the entire work.

Preparation of reagents:

Safranin –O reagent (0.2%): Safranin-O was prepared by dissolving 0.2 gm of safranin-O in 100 mL distilled water.

Buffer solution (pH 9.8): Ammonia-ammonium chloride buffer solution (pH 9.8) was prepared by mixing 7.0 gm of ammonium chloride with 56.8 mL of ammonia solution and diluted to 100 mL with distilled water.

Standard stock solution: 50 mg of valsartan was taken in to 50 mL volumetric flask and dissolved in 5 mL of methanol and the volume was made up to 50 mL with distilled water (1 mg/mL). For benzapril hydrochloride 50 mg was taken into 50 mL volumetric flask and dissolved in 5 mL of methanol and the volume was made up to 50 mL with distilled water. From that10 mL of solution was pipetted out and the volume was made up to 50 mL with distilled water to get 200 µg/mL solution.

General procedure and calibration curve:

Aliquots of the standard drug 0.5-2.5 mL of 1 mg/mL solution for valsartan and 0.2-1.0 mL of 200 µg/mL solution for benazepril hydrochloride were taken into series of 60 mL separating funnels. To each separating funnel 1.0 mL of pH 9.8 buffer solution for valsartan and 2.0 mL for benazepril hydrochloride was added. Followed by 2.5 mL of safranin-O solution for valsartan and 3.0 mL for benazepril hydrochloride was added. The optimum conditions mentioned in Table-1. The total volume of aqueous layer was adjusted to 10 mL with distilled water. To each separating funnel 10 mL of chloroform was added. Then contents were shaken for thorough mixing of the two layers and were allowed to stand for separation of the chloroform layer. The separated chloroform layer absorbance was measured against the reagent blank at the λ of maximum absorbance (Table-1).The amount of each drug was calculated from their corresponding calibration graphs.

Procedure for pharmaceutical formulations:

Twenty tablets of each drug was taken, weighed accurately and powdered separately. Tablet powder equivalent to 50 mg of valsartan/benazepril hydrochloride was weighed and transferred into two different 50 mL volumetric flasks. Then 5.0 mL of methanol was added to each volumetric flask to dissolve the drug and the solutions were filtered through whatmann filter paper. From the filtrate 1.5 mL of valsartan solution was taken and followed the same procedure. For benazapril hydrochloride, 10 mL of filtrate was taken and diluted to 50 mL with distilled water and from that 0.6 mL of solution was transferred to 60 mL separating funnel and the above procedure was followed for analysis of drug content. The results of analysis are presented in Table- 3.

Table-1: Optimum conditions and results of the proposed method

Reagent	Valsartan	Benazepril Hydrochloride
Drug solution taken (µg/mL)	50-250	20-100
Volume of pH 9.8 buffer (mL)	1.0	2.0
Volume of reagent employed (mL)	2.5	3.0
λmax (nm)	522	560

Table-2: Optical characteristics of the proposed method

Parameters	Valsartan	Benazepril hydrochloride
λmax (nm)	522	560
Beer's law limits (µg/mL)	50-250	20-100
Sandell's sensitivity (mcg/cm^2/0.001 A.U)	0.47619	0.15748
Molar absorptivity (L/mol^{-1} cm^{-1})	914.6022	2695.512
Regression equation (y=b+ax)*	y = 0.1013x - 0.069	y = 0.1269x - 0.1349
Slope (b)	0.1013	0.1269x
Intercept (a)	0.069	0.1349
Correlation coefficient (r^2)	0.9998	0.9984
Range of errors Confidence limit with 0.05level Confidence limit with 0.01level % RSD**	 0.42345 0.626508 0.506433	 0.63141 0.93418 0.75514

(y=b+ax)*, where y is the absorbance, x is concentration in µg/ml
**Average of six determinations

Table 3: Assay and recovery studies of proposed method

Name of the dosage form	Labeled amount (mg)	Content of the drug found mg [a] ± S.D		% Recovery by the proposed method
		Proposed method	Reference method	
Valsartan Tablet	160	160.015±0.0512 F=0.88707 T=0.75584	160.02±0.054	100.009
Benazepril Hydrochloride Tablet	10	10.026±0.054 F=0.88074 T=0.61088	10.03±0.0506	100.26

Average ± standard deviation of eight determinations, the t and F- values referred to comparison of proposed method with reference method. Theoretical values at 95% confidence limits T = 2.365 and F=4.88
Methanol was used as solvent for reference UV methods for both the drugs.

RESULTS AND DISCUSSION

In order to establish the optimum pH range, each drug was allowed to react with dye in buffer solution of pH 9.8 and the complex formed was extracted into chloroform for measurement. The ion-pair complex was stable for one hour. For valsartan 2.5 mL of 0.2 % dye solution and for benazepril hydrochloride 3.0 mL was found to be optimum. The optical characteristics and precision data are presented in Table-2. Interference studies revealed that the common excipients and other additives usually present in the tablet dosage forms did not interfere at their regularly added levels. The values obtained by the proposed and reference methods for formulations were compared statistically by the T test and F test and found not to differ significantly. As an additional demonstration of accuracy, a fixed amount of the drug was added to the pre- analyzed formulations and then recovery experiments were performed. Commercial formulations of these drugs were successfully analysed by the proposed method and the results are summarized in Table-3.

CONCLUSION

The new method developed is simple, sensitive and cost effective and can be used for routine quality control analysis of the above mentioned drugs in pharmaceutical dosage form with reasonable precision and accuracy.

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