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VISIBLE SPECTROPHOTOMETRIC METHODS FOR THE ESTIMATION OF LOSARTAN POTASSIUM AND OMEPRAZOLE IN SINGLE COMPONENT PHARMACEUTICAL FORMULATIONS

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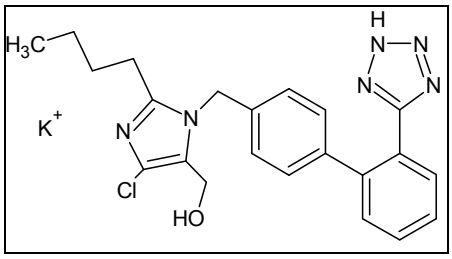
ABSTRACT: Three simple new visible spectrophotometric methods has been developed for determination of Losartan potassium and Omeprazole, in single component pharmaceutical dosage forms. The methods were based on the formation of ion-pair complexes of the drug with dye Bromocresol purple(BCP) and Bromophenol blue(BPB), in acidic buffer solutions followed by their extraction in chloroform. Experiments were carried out to optimize the reaction conditions for complete colour formation. It was found that 5 ml BCP & BPB reagents and 5 ml of buffer solutions were optimum for the achievement of maximum colour intensity. BCP with Acid phthalate buffer of pH3 gave more absorbance at 430 nm this process was optimized(with BPB 400nm)The optical charactersic such as beer's law, correlation coefficient, slope, Y intercept, and Molar absorptivity were calculated for all the methods and the analysis results of marketed formulations were in good agreement with their labeled claim. The recovery ranged from between 98 to 100 % for BCP& BPB which comply with official limits. The proposed methods were simple, sensitive, accurate and precise and can be successfully applied for the estimation of Losartan potassium and Omeprazole. Most of the Formulations contain excepients, which are added along with the active drug constituents. These substances may cause some interference during estimation of the active drug constituents, so the recovery study was employed. This was satisfactory & indicates the non-interferance of excipients. Results of the method were validated statistically and by recovery studies, this method was demonstrated to be adequate for routine analysis.
Keywords: - Losartan potassium, Omeprazole visible spectrophotometric.

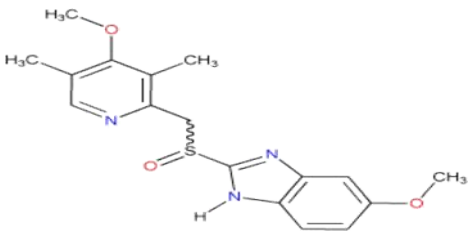
INTRODUCTION

Losartan, chemically [2-butyl-5-chloro-3-[[4-[2-(2H-tetrazol-5-yl)phenyl]phenyl]methyl] imidazol-4-yl]methanol, is a anti-hypertensive agent called angiotensin-II (AGII) receptor antagonist. Losartan is official in I.P. literature survey reveals that a few spectrophotometric[1-2], HPLC[3], methods were reported for it's analytical monitoring in formulation.

Omeprazole is a proton pump inhibitor which reduces gastric acid secretion through inhibition of H+/K+-ATPase in gastric parietal cells. The inhibition of this enzyme the drug prevents formation of gastric acid. Only few spectrophotometric methods were reported for the estimation of Omeprazole in pharmaceutical dosage forms.[4-7]



Losartan



Omeprazole

EXPERIMENTAL

Shimadzu U.V Spectronic spectrophotometer (model 1700) with 1 cm matched quartz cells. All reagents used were of analytical grade. Following reagents and solutions were used.

1. **Preparation of buffer[8]:** pH 3 buffer solution was prepared as per IP [8] by mixing appropriate quantities of 0.2 M potassium hydrogen phthalate.

2. **Bromocresol purple solution:** 0.05% solution was prepared by dissolving 50mg bromocresol purple in 0.92 ml of 0.1 M NaOH and 20 ml of alcohol (95%) and made up to 100ml with water.

3. Chloroform Spectrophotometric grade.

Standard drug solutions

A. A stock solution of drug is prepared by dissolving accurately weighed 50 mg of pure losartan in 50 ml of distilled water. So as to give the stock solution A of concentration 1 mg/ml.

B. 5 ml of stock solution-A was pipetted in to a 50 ml volumetric flask. And was diluted to 50 ml with distilled water to give stock solution–B. of concentration 100 mcg/ml.

C. Sample solution (tablets): Twenty tablets were taken and average weight was calculated. The tablets were powdered gently in a glass motor, tablet powder equivalent to 100 mg of drug was weighed accurately and transferred to 100 ml volumetric flask. chloroform was added to the flask and the contents were shaken well for 10 minute and the volume was made up with chloroform. This was filtered; rejecting the first few ml of filtrate, 5 ml of the filtrate was pipetted into 50 ml flask and was diluted to the mark. From this 5 ml was pipette into 25 ml flask, 5 ml of the reagent, 5 ml of buffer was added and the volume made up with chloroform.

PROCEDURE

For Losartan potassium

Method(using bromocresol purple):

From solution–B 15, 20, 25, 30, 35, 40 ml was pipetted in to 6 separate separating funnel, and 5 ml of chloroform, 5 ml of buffer and 5 ml of BCP (bromo cresol purple) were added. The contents were shaken for two minutes and the two phases were allowed to separate. The lower chloroform layer was collected in separate 50 ml volumetric flasks. The aqueous phase was further extracted five times with 5 ml portions of chloroform. The chloroform layer was combined and the volume was made up with chloroform so the concentration of the drug would be 30, 40, 50, 60, 70, 80, mcg/ml. the absorbance was measured at **430** nm against blank solution obtained in the same way omitting the drug. The amount of Losartan present in the sample was computed from the calibration curve results are reported in tables I and II.

For Omeprazole

Method 1 (using bromocresol purple):

5 ml of stock solution-I was pipettes in to a 50 ml volumetric flask and was diluted to 50 ml with distilled water to give stock solution –II. From solution –II 15, 20, 25, 30, 35, 40 ml was pipetted in to 6 separate separating funnel, and 5 ml of chloroform, 5 ml of buffer and 5 ml of BCP (bromo cresol purple) were added . The contents were shaken for two minutes and the two phases were allowed to separate. The lower chloroform layer was collected in separate 50 ml volumetric flasks. The aqueous phase was further extracted five times with 5 ml portions of chloroform. The chloroform layer was combined and the volume was made up with chloroform so the concentration of the drug would be 10, 20, 30, 40, 50, 60, 70, 80, mcg/ml. The absorbance was measured at **400** nm against blank solution obtained in the same way omitting the drug. The amount of Omeprazole present in the capsule dosage form was computed from the calibration curve. The results are shown in tables I & III.

Method II (using bromophenol Blue)

Same procedure was followed by using BPB instead of BCP. The amount of Omeprazole present in the capsule dosage form was computed from the calibration curve.The results are shown in tables I & III.

RESULTS AND DISCUSSION

The proposed methods are colorimetric methods for determination of Losartan potassium and Omeprazole from bulk powder and formulations. These methods are very simple, accurate, sensitive and give reproducible results. Proposed methods can be used for determination of Losartan potassium and Omeprazole in bulk powder and formulations in a routine manner

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TABLE-I: OPTICAL CHARACTERISTICS AND OTHER PARAMETERS

	Losartan (with BCP)	Omeprazole (with BCP)	Omeprazole (with BPB)
λmax (nm)	430	400	400
Beer's Law limits(mcg/mL)	30-80	10-80 mcg/ml	10-80 mcg/ml
Molar absorptivity	2.604×10^3	$6393.7 mol^{-1}cm^{-1}$	$4929.87 mol^{-1}cm^{-}$
Standard deviation	1.0086	1.0057	0.906
Coefficient variation (%	1.566	1.21	1.287

TABLE-II: RESULTS OF THE ESTIMATION OF LOSARTAN IN TABLETS

Formulation*	Claim (mg/tab)	Amount of pure Drug added (mg)	Content determined in Assay (mg)	% recovery#
REVAS	50	10	59.70	99.51
LOSAR	50	10	59.68	99.45
LOSACAR	50	10	59.72	99.53

***Tablets from different manufacturers.**
#Average of five determinations.

TABLE-III: RESULTS OF THE ESTIMATION OF OMEPRAZOLE IN CAPSULES

			Bromocresol Purple		Bromophenol Blue	
Formulation	Claim (mg/tab	Amount of Pure Drug added (mg)	Content determined in Assay (mg)	% recovery	Content determined in Assay (mg)	% recovery
OMWIN	20	10	29.54	98.46	29.65	98.83
TOM 20	20	10	29.68	98.93	29.71	99.03
OMEZ	20	10	29.82	99.40	29.75	99.16

***Capsules from different manufacturers.**
#Average of five determinations.

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