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Extractive Spectrophotometric Method for the Determination of Tropicamide

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ABSTRACT

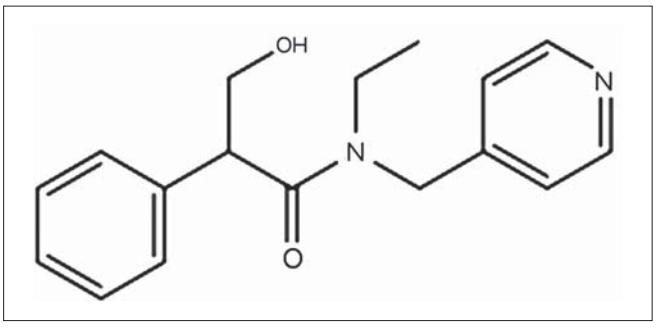
Two simple, rapid, and extractive spectrophotometric methods were developed for the determination of tropicamide (TPC). These methods are based on the formation of ionpair complexes between the basic nitrogen of the drug with bromocresol purple (BCP) and methyl orange (MO) in acidic buffer solution. The formed complexes were extracted with chloroform and measured at 408 and 427 nm using BCP and MO, respectively. Beer's law was obeyed in the range 1.0–16 µg ml^{-1} with correlation coefficient (n=6) ≥0.9991. The molar absorptivity, Sandell sensitivity, detection, and quantification limits were also calculated. The composition of the ion pairs was found 1:1 by Job's method. The proposed methods have been applied successfully for the analysis of TPC in pure and in its eye drops.

Key words: Bromocresol purple, ion pair complex, methyl orange, pharmaceutical formulations, spectrophotometry, tropicamide

INTRODUCTION

Tropicamide (TPC), [Scheme 1] (*R,S*)-*N*-ethyl-3-hydroxy-2-phenyl-*N*-(pyrid-4-ylmethyl) propionamide, is a tropic acid derivative endowed with short duration of antimuscarinic activity and available in 0.5 and 1% ophthalmic solutions. Its maximum effect is achieved in about 20–25 min and lasts about 20 min, with complete recovery being noted in about 6 h. Its action is more rapid in onset and wears off more rapidly than most other mydriatics. Its uses are generally much the same as those described for other mydriatics.[1,2] Since tropicamide use is increasing, it is very much essential to develop simple and suitable analytical method for its quantification in bulks and formulations. Such method should provide proper

Access this article online	
Quick Response Code:	Website: www.jyoungpharm.in
	DOI: 10.4103/0975-1483.93572



Scheme 1: The chemical structure of TPC

sensitivity and selectivity and could be easily adapted for routine quality control analysis, preformulation or similar studies.

There is little information in the literature for quantification of tropicamide in pharmaceutical raw materials and dosage forms.[3,4] The reported analytical methods for determination of TPC are TLC,[5] spectrophotometry,[6–8] and HPLC.[9,10] The United States Pharmacopoeia (USP) and British Pharmacopoeia (BP)[11,12] have described a nonaqueous titration for determination of tropicamide in raw material and an extractive spectrophotometric method for its pharmaceutical preparations. These methods are time consuming and costly for routine analysis. Therefore, having a simple, fast, and accurate method for determination of TPC in raw material and pharmaceutical dosage forms, which can be used in quality control laboratories is a necessity.

Extractive spectrophotometric procedures are popular for their sensitivity in the assay of drugs. The well-established spectrophotometric method employed ion-pair extraction. In this case, an ion-pair is formed between basic pharmaceutical compounds and an anionic dye such as bromocresol purple (BCP) and methyl orange (MO). At a specific pH, the ion-pair is extracted into an organic solvent, which is immiscible with water, and the concentration of the resulting ion pair in the organic phase is determined spectrophotometrically.[13–19]

The present study aims to develop accurate, reproducible, less time consuming, and adequately sensitive validated extractive spectrophotometric methods based on the formation of ion-pair complexes between TPC with bromocresol purple (BCP) and methyl orange (MO). The proposed methods were applied to the determination of TPC in tablets dosage form. No interference was observed in the assay of TPC from common excipients in levels found in dosage form. These methods are validated by the statistical data and can be adopted by the pharmaceutical laboratories for industrial quality control.

MATERIALS AND METHODS

Apparatus

All absorption spectra were made using Optima UV-VIS spectrometer (SP-3000 plus) (Tokyo, Japan), equipped with 10 mm matched quartz cells. Hanna pH-meter instrument (pH 211) (Romania) was used for checking the pH of Buffer solutions.

Materials and reagents

All chemicals and reagents were of analytical grade and water was always bidistilled water.

Materials

Tropicamide (TPC) was kindly supplied by Alexandria pharmaceutical Industries Company (Alex), Alexandria, Egypt.

Pharmaceutical formulations

Mydrapid drops (Alex, Alexandria, Egypt), labeled to contain (0.5% and 1.0%) TPC.

Standard solution

A stock standard solution (100 μg ml^{-1}) and (1.0×10^{-3} M) of TPC were prepared by dissolving appropriate weight 0.01 and 0.0284 g, respectively of pure TPC in 10 ml of methanol and further diluted with double distilled water up to the mark in 100 ml volumetric flask. Working standard solutions were prepared by suitable dilution of stock standard solution with bidistilled water. The solution remained stable for 1 month when kept refrigerated.

Reagents

Bromocresol purple (BCP) and methyl orange (MO) (BDH Chemicals LTD, Poole, England) and used without further purification.

A stock solution (1.0×10^{-3} M) was prepared by dissolving the appropriate weight of bromocresol purple (BCP) and methyl orange (MO) in 10 ml methanol and diluted to 100 ml with bidistilled water.

These solutions are stable for at least 1 week if kept in the refrigerator.

Series of buffer solutions of KCl–HCl (pH 1.5–4.2), NaOAc–HCl (pH 1.99–4.92), NaOAc–AcOH (pH 2.8–6.0) and potassium hydrogen phthalate–HCl (pH 2.0–6.0) were prepared by following the standard methods.[20] Freshly prepared solutions were always employed.

Construction of calibration curves

Aliquots of TPC ranging from 0.1 to 1.6 ml of standard solution (100 μg l^{-1}) were transferred into a series of 100 ml separating funnels. To each separating funnel 2.0 ml of BCP or MO (1.0×10^{-3} M) reagent solutions and 3.0 ml potassium hydrogen phthalate–HCl buffer of pH 3.0, were added and the volume of the aqueous layer was adjusted to