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Research Article

VALIDATION OF SODIUM NITROPRUSSIDE IN VISIBLE SPECTROPHOTOMETRIC DETERMINATION OF TRIPOLIDINE HYDROCHLORIDE

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ABSTRACT

Objective: A simple and sensitive extractive visible spectrophotometric method is developed for the assay of triprolidine hydrochloride using sodium nitroprusside.

Methods: Based on color development with amino groups, presence, which is basic, may be due to the formation of inner complex replacing H_2O by the tertiary amino group present in the drug.

Results: The colored products exhibit absorption λ_{max} at 447 nm. Regression analysis of Beer–Lambert plots showed good correlation in the concentration ranges (40–240) µg/ml and correlation coefficients are 0.994. The Sandell's sensitivities 2.6373×10^{-2} (1 mole cm^{-1}) and molar absorptivity value are 1.1938×10^{4} (µg cm^{-2}). Recovery studies are found to be 99.708–99.786.

Conclusion: The method can be applied successfully for the estimation of the drug in the presence of other ingredients that are usually present in formulations.

Keywords: Tertiary amino group, Inner complex, Regression analysis.

INTRODUCTION

Triprolidine hydrochloride (TPH) is chemically 2-[(1E)-1-(4-methylphenyl)-3-(pyrrolidin-1-yl)prop-1-en-1-yl] pyridine (Fig. 1). This is an anti-allergic, histamine H1 antagonist that blocks the action of endogenous histamine, which subsequently leads to temporary relief of negative symptoms brought on by histamine. It is used for the treatment of seasonal or perennial allergic rhinitis or non-allergic rhinitis, conjunctivitis, and mild urticarial and angioedema [1]. The most common side effects are sedation, dizziness, coordination, gastrointestinal disturbances, nausea, vomiting, and diarrhea. It may also produce blurred vision, dryness of mouth, tight of the chest, and blood disorders, including agranulocytosis and hemolytic anemia [2]. A literature survey revealed that few analytical methods have been reported for the determination of TPH in plasma using thin-layer chromatography [3] simultaneous determination of TPH with other anti-histamines [4-6] other agents [7,8] reported. Few methods have been developed for the determination of triprolidine by high-pressure liquid chromatography (HPLC) [9] and spectrophotometric method [10]. Spectrophotometric and High performance liquid chromatographic method for the determination of TPH and its metabolite in biological samples using liquid chromatography [11], mass spectrometry [12], capillary Zone Electrophoresis Method for Quality Control Analysis of TPH with other drugs [13], degradation studies of TPH and stability-indicating ultra-performance liquid chromatography method [14], new plastic membrane and carbon paste ion selective electrodes for the determination of TPH [15] were reported. TPH is usually administered in combination with dextromethorphan and/or phenylpropanolamine and also with paracetamol [16].

The analytical useful functional groups in TPH have not been fully exploited for designing suitable visible spectrophotometric methods and so still offer a scope to develop more visible spectrophotometric methods with better sensitivity, precision, and accuracy. The author has made some attempts in this direction and succeeded in developing the proposed method. The method is extended to pharmaceutical formulations as well. Reported HPLC methods have lesser output and are occasionally lacking the stress behavior studies. Hence, there is no simple, cost-effective individual method has been reported. Therefore, the author has made an attempt to develop a rapid spectrophotometric method for the estimation of TPH in bulk and tablet dosage form. Validation as per the United States Food and Drug Administration and ICH guidelines [17,18] is done along with stress degradation studies. Methods using various reagents [9,10,19-21] and sodium nitroprusside (SNP) [22-28] were also reported.

METHODS

Instruments used

A Shimadzu ultraviolet-visible spectrophotometer 1801 with 1 cm matched quartz cells was used for all spectral and absorbance measurements. A systronics digital pH meter 361 was used for pH measurements.

Preparation of standard drug solution

The stock solution (1 mg/ml) of TPH was prepared by dissolving 100 mg of it in 100 ml of Milli pore-distilled water. A portion of this stock solution was diluted stepwise with the distilled water to obtain the working standard solution of concentrations 240 µg/ml for the method.

Procedure of assay of TPH in formulations

An accurately weighed amount of formulation (tablet) equivalent to 100 mg of drug was dissolved in 20 ml of distilled water, shaken well, and filtered. The filtrate was further diluted to 100 ml with distilled water to get 1 mg/ml solution of drug in formulations. One milliliter of this solution was furthered diluted to 25 ml to get 40 µg ml^{-1} solution. The absorbance of the solution was determined λ_{max} 223 nm (Fig. 2). The quantity of the drug was computed from Beer's law plot (Fig. 3) of the standard drug in distilled water.

Recommended procedure

After a systematic and detailed study of the various parameters involved, as described under results and discussion in this chapter, the

following procedure is recommended for the determination of TPH in bulk samples.

Into series of 10 ml calibrated tubes, aliquots of standard drug solution, 240 µg/ml concentration ranging from 0.1 to 0.6 ml were transferred into a series of calibrated tubes, and the volume in each tube was brought to 3.0 ml with distilled water. 1.0 ml of SNP and 1.0 ml of hydroxylamine solutions were successively added to each tube and shaken for 2 min. Then, 1.0 ml of sodium carbonate solution was added and shaken for 15–25 min. Then, contents were diluted to 10 ml with distilled water, and the absorbance was measured after 10 min at λ_{max} 447 nm (Fig. 4) against the reagent blank. The amount of TPH was computed from its calibration graph (Fig. 5)

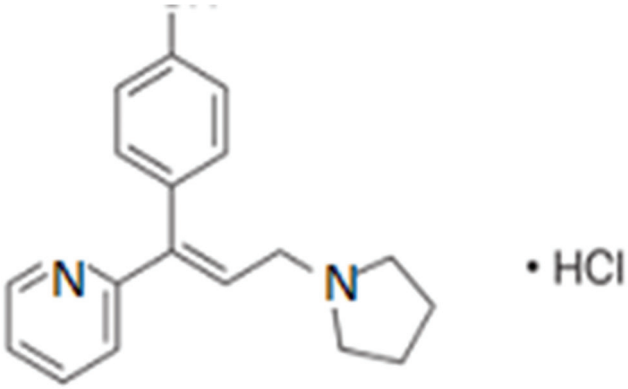


Fig. 1: Chemical structure of Triprolidine Hydro Chloride

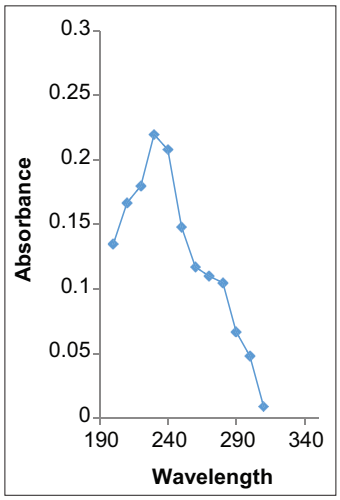


Fig. 2: Absorption spectra of triprolidine hydrochloride in methanol (ultraviolet reference method)

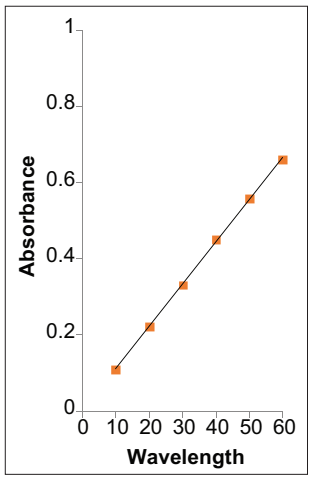


Fig. 3: Beer's law plot of triprolidine hydrochloride in methanol (ultraviolet reference method)

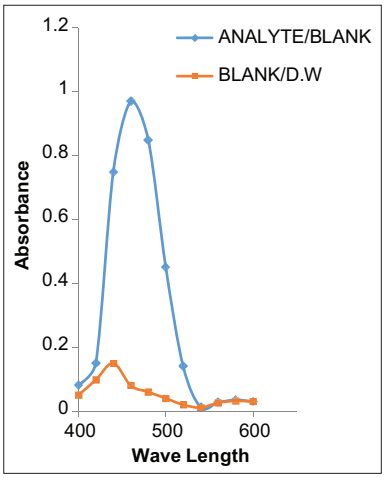


Fig. 4: Absorption spectra of triprolidine hydrochloride: Sodium nitroprusside/HA

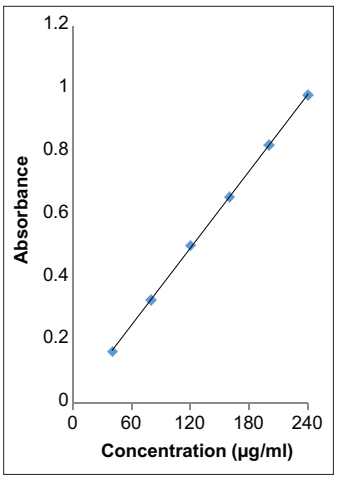


Fig. 5: Beer's plot of triprolidine hydrochloride: Sodium nitroprusside/HA

Table 1: Optical and regression characteristics, precision, and accuracy of the proposed methods for TPH

S.no	Parameter	Values
1.	Wavelength λ_{max} (nm)	447
2.	Beer's law limits (µg ml^{-1})	40–240
3.	Detection limits (µg ml^{1})	5.9481
4.	Molar absorptivity (1 mole cm^{-1})	1.1938×10^{4}
5.	Sandell's sensitivity (µg cm^{-2}/0.001 absorbance unit)	2.6373×10^{-2}
6.	Regression equation (Y=a+bC) Slope (b)	0.0038
7.	Standard deviation of slope (S_b)	4.8366×10^{-5}
8.	Intercept (a)	0.0082
9.	Standard deviation of intercept (S_a)	7.5343×10^{-3}
10.	Standard error of estimation (S_e)	8.0932×10^{-3}
11.	Correlation coefficient (r^2)	0.9994
12.	Relative standard deviation (%)*	0.3379
13.	% Range of error (confidence limits) 0.05 level*	0.3546
14.	% Range of error (confidence limits) 0.01 level	0.5562
15.	% Error in bulk samples**	0.256

Table 2: Assay and recovery of TPH in pharmaceutical formulations

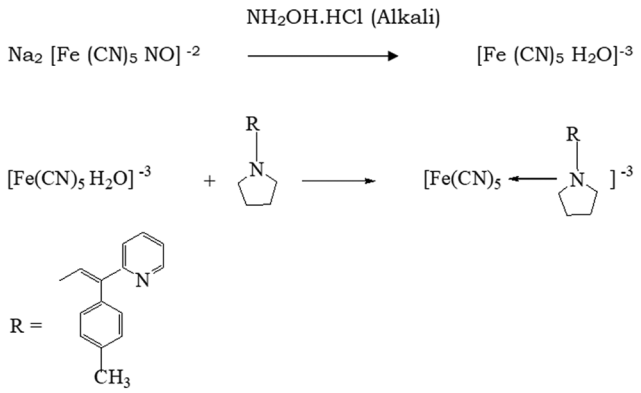
Sample	Amount taken (mg)	Amount found by proposed method	Amount found by reference method	Percentage recovery by the proposed method
Tablet I	2.5	2.490±0.0025 F=1.44 t=0.43	2.495±0.003	99.708±0.15
Tablet II	2.5	2.492±0.0022 F=1.1 t=1.04	2.496±0.002	99.786±0.16

*: Average ± standard deviation of six determinations; the t- and F-values refer to a comparison of the proposed method with the reference method. Theoretical values at 95% confidence limit t=2.57, F=5.05. **: After adding two different amounts of the pure labeled to the pharmaceutical formulations, each value is an average of three determinations

Chemistry of the colored species in the present investigation

TPH possesses different functional moieties such as tertiary amino group and indole of varied reactivity. An attempt has been made to indicate the nature of colored species formed in each proposed method for TPH determination tentatively based on analogy.

In the presence of hydroxylamine and alkali, SNP exists as $[Fe(CN)_5 H_2O]^{-3}$. The color obtained with amino groups presence, which is basic, may be due to the formation of inner complex replacing H_2O by a tertiary amino group. The reactions of TPH with SNP/HA are described in scheme given below.



RESULTS AND DISCUSSION

Optimum operating conditions used in the procedure were established adopting a variation of one variable at a time method. The effect of various parameters such as the effect of volume of SNP solution on colored species, volume of NH_2OH, volume of Na_2CO_3 solution on color product, reaction time, order of addition of reagents on color development, solvent for final dilution, and stability of the colored species after final dilution was studied and the results are summarized in Table 1. Commercial formulations containing TPH were successfully analyzed by the proposed method. The values obtained by the proposed and reference method for formulations were compared statistically by the t-test and F-test and found not to differ significantly. These results are summarized in Table 2.

CONCLUSION

The proposed method for TPH determination has many advantages over other analytical methods due to its rapidity and lower cost. Unlike HPLC, LC procedures and the instrument are simple and are not costly. Economically, all the analytical reagents are inexpensive and available in any analytical laboratory. The proposed method reports a new way for the determination of TPH in pharmaceuticals

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