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NOVEL ESTIMATION OF TRIPROLIDINE HYDROCHLORIDE IN PHARMACEUTICAL PREPARATIONS AND ENVIRONMENTAL WASTEWATER SAMPLES

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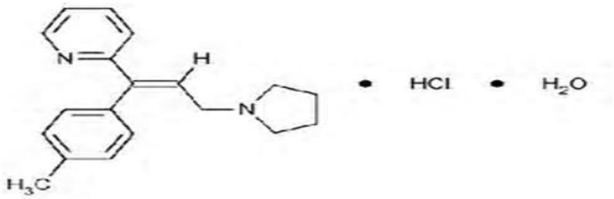
ABSTRACT

A simple, rapid, accurate and sensitive spectrophotometric method for determination of triprolidine hydrochloride has been developed. The proposed method is based on the reaction between chloride ion and mercuric thiocyanate, formation of a colored complex by the reaction between released thiocyanate and ferric ions to form red soluble product with maximum absorption at 460 nm. Beer's law is obeyed over the concentration range of 2-28µg/ml, with molar absorptivity of $0.932x10^4$ l/mol.cm. The present method is considered to be simple because it does not need either heating or hydrolysis or solvent extraction steps. The ingredients often formulated with triprolidine hydrochloride have been shown not to interfere, and the proposed method is suitable for the routine determination of triprolidine hydrochloride. The method has been successfully applied for the determination of triprolidine hydrochloride in pure form, pharmaceutical preparations (Tablets) and environmental wastewater sample.

KEYWORD: Triprolidine Hydrochloride, Mercuric thiocyanate, Environmental Wastewater, Pharmaceutical Preparations.

INTRODUCTION

Triprolidine hydrochloride (Figure.1) is a pyridine derivative with the properties of antihistamine.



C19H22N2, HCl, H2O = 332.9

Figure [1]: Chemical Structure of Tripolidine Hydrochloride.

It is a potent histamine H1-receptor antagonist (H1-blocker), with a rapid onset and long duration action, almost up to 12 hours. It is probably effective for the symptomatic treatment of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to allergens, foods and prevention of allergic reactions to blood or plasma.[1-3] Triprolidine hydrochloride, an alkylamine derivative, is a sedating antihistamine with antimuscarinic and mild sedative effects. It is used for the symptomatic relief of allergic conditions including urticaria and rhinitis and in pruritic skin disorders.[4] It is given orally, the usual dose for adults being 2.5 mg up to four times daily. Triprolidine hydrochloride has also been applied topicallyto the skin although, as with other antihistamines, The most common side effects are sedation, dizziness, incoordination, gastrointestinal disturbances, nausea,vomiting and diarrhea. It may also produce blurred vision, dryness of mouth, tightness of chest, blood disorders including agranulocytosis and haemolytic anaemia[1,4] Several methods for the determination of triprolidine hydrochloride have been described in the literature, including spectrophotometric methods[5-8], Kinetic spectrophotometric methods[9], derivative spectrophotometric methods[10], liquid chromatography methods.[11,12] High performance liquid chromatographic methods[13,14], and ion selective electrodes method.[15] The present work describes a new, simple spectrophotometric method for the determination of triprolidine hydrochloride in pure form, pharmaceutical formulations and in industrial wastewater samples. The method is based on reaction between chloride ion and mercuric thiocyanate, formation of a colored complex by the reaction between released thiocyanate and ferric ion.

EXPERIMENTAL

Apparatus

Shimadzu UV- 1700 pharmaspec (double beam) spectrophotometer with 1.0 cm quartz cells was used for absorption measurements.

Reagents

All chemical used were of analytical or pharmaceutical grade and triprolidine hydrochloride standard material was provided from AL-Hokamaa company for pharmaceutical industries (HPI) Mosul-Iraq.

Triprolidine hydrochloride standard solution: 0.01**% (3.0x10^{-4}M)**

This solution was prepared by dissolve 0.01 gm of triprolidine hydrochloride in 100 mL of distilled water in volumetric flask.

Ferric ammonium sulphate solution: 5%

5g of ferric ammonium sulphate [FeNH4(SO4)2.12H2O] was dissolved in 50 ml double distilled water and 20ml of concentrated nitric acid was added and diluted with double distilled water to 100ml.

Mercuric thiocyanate solution: 0.5%

0.5g of mercuric thiocyanate was dissolved and diluted to 100 ml with ethanol. Mixed and filtered through filter paper.

General procedure

Different aliquots of standard triprolidine hydrochloride solution equivalent 50-700 µg(0.5-7 ml) were transferred into a series of 25ml volumetric flasks, and 2mL of ferric ammonium sulfate solution were added and2ml of saturated solution of mercuric thiocyanate were added to each flask and mixed well with occasional shaking. This was diluted to 25ml with double distilled water and mixed well. Let stand for 5 min, the absorbance of each solution was measured at 460 nm against a reagent blank.

Procedures for pharmaceutical preparations (Tablets)

To minimize a possible variation in the composition of the tablets (containing 2.5mg of triprolidine hydrochloride tablet were provided from AL-Hokamaa company for pharmaceutical industries (HPI) Mosul-Iraq.The mixed content of 20 tablets were weighed and grounded, then the powder equivalent to 10 mg of triprolidine hydrochloride in about 70 ml of distilled water was stirred well for 30 min and then filtered through whatman No. 42 filter paper and the filtrate solution was diluted to 100ml by distilled water and different volume of this solution was treated as described above under general procedure.

Procedure for industrial wastewater samples

To demonstrate the practical applicability of the proposed method, real industrial wastewater samples from Al-Hokamaa company for drug industries (HPI) Mosul-Iraq were analyzed by spiked with the concentrations ranging from 2-20 µg /ml of triprolidine hydrochloride and aliquot of this solution was treated as described above under general procedure.

RESULT AND DISCUSSION

Spectrophotometric methods development for the determination of drugs is a very valuable technique and has been increased considerably in recent years because of their features like simplicity, economical, suitable for wide range of importance in pharmaceutical analysis.[16,17] A new method has been developed for the spectrophotometric determination of triprolidine hydrochloride. The method depends upon the displacement of thiocyanate ion from mercury (I1) thiocyanate by chloride ion in the Triprolidine hydrochloride. The free thiocyanate then complexes with Fe III at room temperature resulting in formation of red colored complex which absorbed at 465nm (Fig. 2).and the intensity of its color is proportional to the original chloride ion.[18]

$$2Cl^- + Hg(SCN)_2 + 2Fe^{3+} \longrightarrow HgCl_2 + 2[Fe(SCN)]_2^+$$

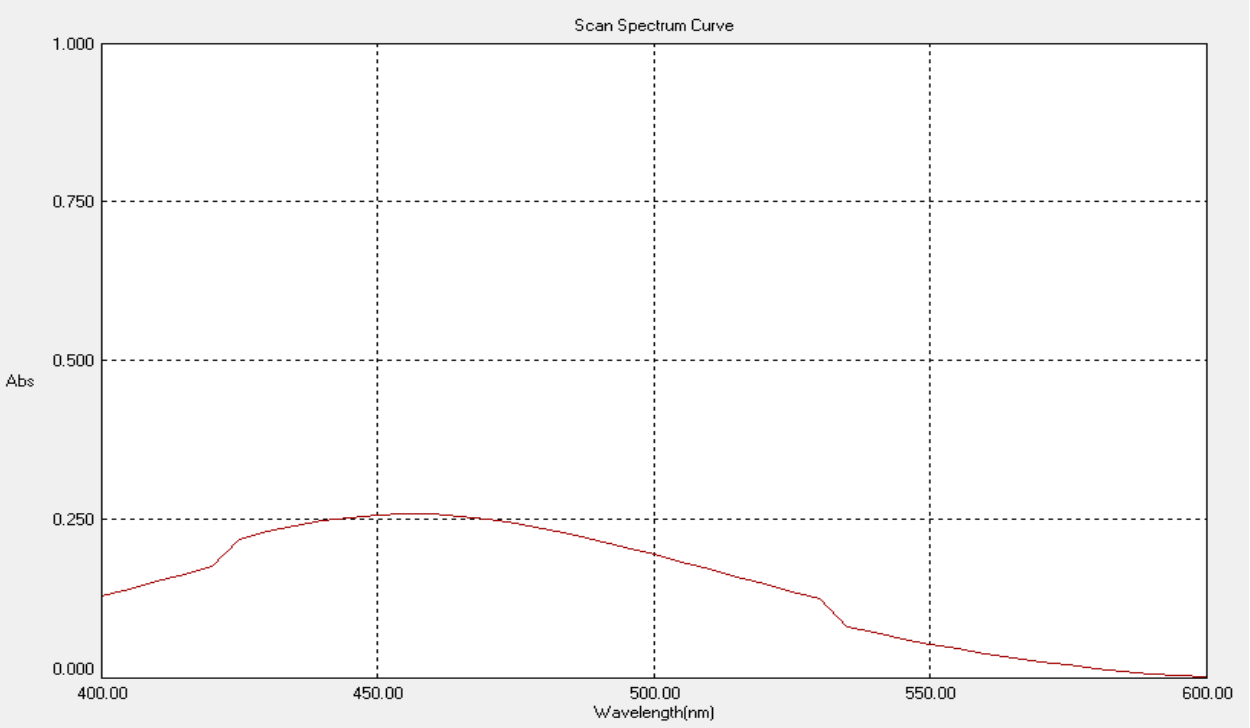


Figure [2]: Absorption Spectra of 12 3µg /ml of Triprolidine Hydrochloride.

The various experimental affecting the development and stability of the reaction product was optimized by changing each variable in turn while keeping all other variables constant.

Effect of ferric ammonium sulfate solution

The amount of ferric ammonium sulfate solution (5%) for maximal color intensity was examined the maximum constant intensity was reached at 1 ml of reagent solution and remained constant up to 5ml. However 2 ml of the reagent solution was selected for the subsequent work.

Effect of mercuric thiocyanate solution

The amount of mercuric thiocyanate solution (0.5%) for maximal color intensity was examined the maximum constant intensity was reached at 1 ml of reagent solution and remained constant up to 5ml. However 2 ml of the reagent solution was selected for the subsequent work.

Effect of temperature and time

The results obtained indicated that complete color formation occurred immediately and not affected by temperature therefore, room temperature was selected as suitable temperature. The absorbance remained constant for 6 hours at least, and 5 min was selected as a suitable time.

Effect of order of addition

To test the effect of order of the addition of the reagents on the absorbance of the product, different order was tested. The selected order was sample solution, ferric ammonium sulphate followed by mercuric thiocyanate solution which was gave high absorbance value.

Calibration graph

Employing the conditions described in the general procedure a linear calibration graph of triprolidine hydrochloride which obeys Beer's law in the concentration range of 2-28 µg/ml(Fig.3). Linear regression equation: Y= 0.028X-0.001 (r=0.999). Where Y is the absorbance and X is concentration in µg/ml. The apparent molar absorptivity was 0.932×10^{4} $l.mol^{-1}.cm^{-1}$ and sandell's sensitivity was $0.0357\mu g.cm^{-2}$. The limit of detection and quantification were evaluated as.[19]

$$LOD = 3.3\frac{S_0}{b} \qquad LOQ = 3LOD$$

Where b is the stop and S_0 is the standard deviation of the regression line. The limit of detection was 0.127 µg .ml^{-1} and the limit of quantification as the lowest standard concentration which could be determine with acceptable accuracy, and precision was 0.419 µg.ml^{-1}. The applied method can be used routinely for the estimation of pure drug salts through their chloride concentration.

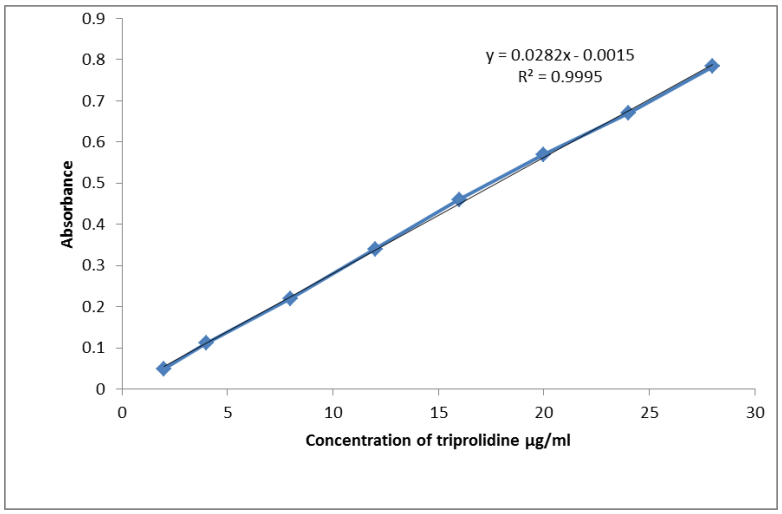


Figure [3]: Calibration Graph of Triprolidine Hydrochloride.

Accuracy and precision

The accuracy and precision of the method were established by analyzing the pure drug solution at three different levels. The average recovery which is a measure of accuracy is 100 ±0.89% revealing high accuracy of the method. The relative standard deviation (RSD), which is an indicator of precision, is less than 1.5%, the result are complied in (Table .1).

Table [1]: Optical Characteristics and Statistical Data for Regression Equation of the Proposed Method.

Parameters	Value
λ max (nm)	460
Beer's law limits (µg.ml^{-1})	2-28
Molar absorptivity (L.mol^{-1}.cm^{-1})	0.932×10^{4}
Limit of detection (µg.ml^{-1})	0.127
Limit of quantification (µg.ml^{-1})	0.419
Sandell's sensitivity (µg.cm^{-2})	0.0357
Correlation coefficient (r)	0.999
Regression equation (Y=C+bX)	
Intercept (C)	0.0015
Slope (b)	0.0282
Recovery	100±0.89
Relative standard deviation (%)	< 1.5

Effect of interferences

The interfering effect of foreign species often accompanied with triprolidine hydrochloride in the pharmaceutical preparations were studied by adding different amounts of foreign species to 300µg/25ml of triprolidine hydrochloride in solution and the recommended procedure for the determination of triprolidine hydrochloride was followed . The species are considered to interfere seriously if the cause aching of more than 2% in the absorbance obtained for triprolidine hydrochloride a lone.[20] Results of the recovery analysis are presented in (Table.2). Excipients at the concentration show in (Table.2). Do not interfere with the assay .In addition recoveries in most cases were around 100%.

Table [2]: Determination of Triprolidine Hydrochloride in Presence of Excipients.

Excipients	Amount taken, (µg/ml)	Average recovery, * %
Talc	700 1000	99.95 100.08
Mannitol	800 1000	100.09 99.95
Mg – stearate	600 1000	100.05 100.09
Starch	500 1000	100.08 100.03
Microcrystalline cellulose	500 1000	99.98 99.94

*****Average of five replicate determinations.

Application of the proposed method

The proposed method was successfully applied to the analysis of triprolidine hydrochloride in tablets and industrial waste water sample. The result of analysis for pharmaceutical formulations revels that there is close agreement between the results obtained by the proposed method and the label claim(table. 3), And the results of water samples (table.4) show that the recovery values obtained were close to 100%.

Table [3]: Assay of Triprolidine Hydrochloride in Pharmaceutical Formulations.

Pharmaceutical formulation supplied by HPI	Amount of triprolidine hydrochloride * Proposed method	Label claim	%Recovery
Tablet 25mg	24.9 mg	25 mg	99.6

*Mean of ten determinations.

Table [4]: Determination of Triprolidine HCL in Spiked Industrial Wastewater Sample.

Water samples	Triprolidine.HCL(µg/ml) * Taken	Found	Recovery %
Industrial wastewater	**4.0**	**4.0**	**100.0**
	10	**10.05**	**100.5**
	16	**16.03**	**100.187**

*Mean of ten determinations

CONCLUSION

The applied method was simple, rapid, accurate, precise, sensitive and low economical cost. Furthermore, the proposed method doesn't require elaboration of procedures, which are usually associated with chromatographic methods. The proposed method could be applied successfully for determination of triprolidine Hydrochloride in environmental water samples, pure form as well as in different dosage forms.

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