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Spectrophotometric Estimation of Promethazine Hydrochloride In Bulk and Pharmaceutical Formulations

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ABSTRACT

Two simple, accurate, rapid and sensitive methods (A and B) have been developed for the estimation of Promethazine Hydrochloride in its pharmaceutical dosage form. The method A and B are based on the formation of chloroform extractable complex of Promethazine Hydrochloride with Bromothymol Blue (method A) and bromocresol green (method B), which shows absorbance maxima at 416 nm and 414 nm respectively. The absorbance-concentration plot is linear over the range of 4-20 mcg/ml and 2-10 mcg/ml for method A and B respectively. Results of analysis for all the methods were validated statistically and by recovery studies. The proposed methods are economical and sensitive for the estimation of Promethazine Hydrochloride in bulk drug and in its tablet dosage form.

Keywords: Ultraviolet-Visible Spectrophotometry, Promethazine Hydrochloride, Bromocresol Green (BCG).

INTRODUCTION

Promethazine Hydrochloride is chemically (RS) -N, N-dimethyl-1- (10H-phenothiazin-10-yl) propan-2-amine [1]. Promethazine is a first-generation antihistamine of the phenothiazine family. The drug has anti-motion sickness, antiemetic, and anticholinergic effects, as well as a strong sedative effect and in some countries is prescribed for insomnia [1]. The official methods proposed by BP [2] and USP [3] for the assay of Promethazine Hydrochloride. Various other methods have been described for the assay of Promethazine Hydrochloride in dosage forms. Survey of literature reveals that the drug is determined by using High Performance Liquid Chromatography [4-7] only. No spectrophotometric methods are reported. The present study describes simple, sensitive, accurate, rapid and economical spectrophotometric methods for the estimation of Promethazine Hydrochloride in bulk & its tablet dosage forms [8].

EXPERIMENTAL

Instrument

Analytical Technology Solution Ultraviolet-Visible double beam spectrophotometer with 1 cm matched quartz cells was used for all spectral measurements.

Reagents

All the chemicals used were of analytical reagent grade. All the solutions were freshly prepared.

1. Acid phthalate buffer pH 3
2. Bromothymol Blue -BTP (0.1%)
3. Acid phthalate buffer pH 2.4
4. Bromocresol Green-BCG (0.1%).
5. Chloroform AR grade.

Procedure

A standard stock solution containing 1 mg/ml was prepared by dissolving 100 mg of Promethazine Hydrochloride in 100 ml of distilled water for method A and B. From this, a working standard solution containing 20 µg/ml was prepared for method A and B.

Assay procedure

Method A

Accurately measured portion (0.5-3.0 ml, 100 $\mu g.ml^{-1}$) of standard solutions Promethazine Hydrochloride were taken in different 125 ml

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separating funnels. To each of the separating funnels BTB dye solution (5.0 ml), buffer solution (5.0 ml, pH-3.0) and chloroform (10.0 ml) were added and the separating funnels were shaken for 2min. The layers were allowed to separate. The separated layers were collected in dry test tubes containing anhydrous sodium sulphate. The absorbance of each organic layer was measured in 1.0 cm cell at 515 nm against blank. The concentration of the unknown was read from the calibration graph or computed from the regression equation.

Method B

Accurately measured portion (0.5-3.0 ml, 100 $\mu g.ml^{-1}$) of standard solutions Promethazine Hydrochloride were taken in different 125ml separating funnels. To each of the separating funnels BCG dye solution (5.0 ml), buffer solution (5.0 ml, pH-3.0) and chloroform (10.0 ml) were added and the separating funnels were shaken for 2 min. The layers were allowed to separate. The separated layers were collected in dry test tubes containing anhydrous sodium sulphate. The absorbance of each organic layer was measured in 1.0 cm cell at 512 nm against blank. The concentration of the unknown was read from the calibration graph or computed from the regression equation.

Preparation of sample solution

Twenty tablets of Promethazine Hydrochloride tablets, Phenergan12.5 mg, 25 mg, and 50 mg, were from Victory Pharma. Were accurately weighed and powdered. Tablet powder equivalent to 25 mg of Promethazine Hydrochloride was dissolved in 50 ml of distilled water, sonicated for 15 mins, filtered and washed with distilled water. The filtrate and washings were combined and the final volume was made to 100 ml with distilled water. The solution was suitably diluted and analyzed as given under the assay procedure for bulk samples. The results are represented in Table1. Similar to the 50mg none of the excipients usually employed in the formulation of tablets interfered in the analysis of Promethazine Hydrochloride, by the proposed methods.

Recovery Studies

To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analyzed formulated samples and these samples were reanalyzed by the proposed method and also performed recovery experiments. The percentage recoveries thus obtained were given in Table 1.

Table 1. Assay and recovery of Promethazine Hydrochloride in tablet dosage form

Tablet formulation	Labeled Amount (mg)	Amount obtained by proposed method,mg*	**%recovery by the Proposed method
1	25 **mg**	24.81	99.24
2	50 **mg**	49.96	99.92

Table 2. Optical characteristics and precision data Parameters Method A Method B

Parameter	Method A	Method B
λ_{max} (nm)	515	512
Beer's law limits (μg/ml)	4.0 – 20.0	2.0 – 10.0
Detection limit (μg/ml)	0.00405	0.003662
Molar absorptivity (1 $mol^{-1}.cm^{-1}$)	3.283×10^{5}	1.341×10^{5}
Optimum photometric range (μg/ml)	5.0 – 15.0	3.0 – 9.0
Regression equation (Y=a+bc) slope (b)	0.0123	0.0196
Standard deviation on slope (S_b)	2.886×10^{-5}	5.773×10^{-5}
Intercept (a)	-0.0004	-0.0004
Standard deviation on intercept (S_a)	1.663×10^{-5}	3.033×10^{-5}
Standard error on estimation (S_e)	3.615×10^{-4}	3.615×10^{-4}
Correlation coefficient (r)	0.9999	0.9999

RESULTS AND DISCUSSION

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen**.** In the present work method A and B have been developed for the estimation of Promethazine Hydrochloride from tablet formulation.

The developed methods A and B are based on formation of chloroform extractable colored complexes with bromothymol blue and bromocresol green respectively. The conditions required for the formation of colored complexes to form colored species were optimized. Statistical analysis was carried out and the results were found to be satisfactory. Relative standard deviation values were low that indicates the reproducibility of the proposed methods. Recovery studies were close to 100 % that indicates the accuracy and precision of the proposed methods. The optical characteristics such as absorption

maxima, Beer's law limits, molar absorptive and Sand ell's sensitivity are presented in Table 2.

CONCLUSION

The new procedure for the spectrophotometric determination of Promethazine Hydrochloride described in this work is simple, rapid and cost-effective with high accuracy and precision when compared with previously reported procedures. It could find application as a convenient technique for the in-process control of Promethazine Hydrochloride.

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