

Analytical Determination of Antihistamine drugs Pure and its pharmaceutical Preparation with NBSA reagent

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Abstract: A quick and convenient method has been developed for the micro estimation of antihistamine drugs. 1-5 mg of sample is allowed to react with 10 ml of 0.02 M, N-bromosaccharin solution. Unconsumed reagent can be accurately titrated with 5 ml of 15% KI and 0.02N sodium thiosulphate solution using starch as indicator. SD and CV was calculated for reproducible and accurate result. The accuracy of the method is within ± 1 % and possible course of reaction was suggested on the basis of stoichiometry as well as find reaction product.

Keywords: Determination, Antihistamine, NBSA, Pharmaceutical preparation

I. Introduction

Antihistamine drug^{1,4} is one that inhibits, sharpens or alters nature of emotional and behavioral responses. These drugs have also been employed for the symptomatic treatment of neurotic and psychotic conditions. These drugs are administered orally because of the great medicinal importance the analysis and assay of antihistamines need prime attention. Several workers have reported the pharmacology and determination of phenothiazine derivatives⁵⁻¹² the N-halo saccharin reagents are stable and determine different compounds¹³⁻¹⁵ in different reaction conditions. Singh *et al.*¹⁶ determine antihistamine drugs pure and its pharmaceutical preparations with BrCl reagent in acetic acid medium. The present method is better than the existing methods and does not require a catalyst and sophisticated instrumentation.

II. Materials & Method

2.1 Reagent: 0.05240 of N-bromosaccharin (NBSA) was accurately weighed and dissolved in 40 ml of glacial acetic acid by shaking thoroughly in 100 ml volumetric flask. The solution was made up to the mark with distilled water and standardized iodometrically.¹⁷

A stock solution of sodium thiosulphate was prepared by dissolving 4.9604. g of sodium thiosulphate in distilled water in a 1L volumetric flask. The solution was standardized with 0.02N copper sulphate iodometrically.

2.2 Sample solution: Stock solution of all phenothiazine derivatives were prepared by dissolving 50 mg accurately weighed amount of the sample in distilled water in 50 ml standard volumetric flask.

2.3 Method: At aliquots containing 1-5 mg of sample from the stock solution was transferred to a 100 ml glass stopper conical flask. 10 ml of N-Bromosaccharin solution was added. The flask was Stoppard and contents shaken thoroughly. The reaction was allowed to proceed for 10 minutes at room temperature with occasional shaking The stopper was washed with 5 ml of distilled water followed by addition 5 ml of 15% KI solution. The contents were shaken thoroughly and liberated iodine was titrated against standard sodium thiosulphate solution using starch as indicator. A blank experiment was also run under identical experimental conditions.

$$(V_B - V_S) n \times W.$$

Recovery of sample (mg)

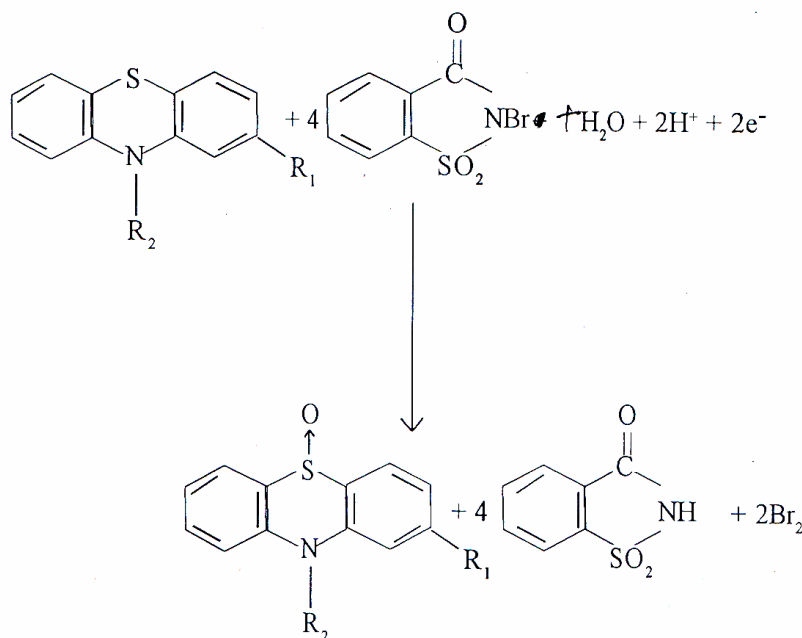
2N

Where VB = Volume of sodium thiosulphate solution required to titrate blank (ml)
VS = Volume of sodium thiosulphate solution required to titrate samples (ml)
N = Normality of sodium thiosulphate solution.
W = Molecular Weight of sample
N = Stoichiometry

With recommended procedure the determination of Prochloroperazine Maleate (Pure) Promethazine hydrochloride (Pure), Trifluopromazine hydrochloride (pure), Trifluoperazine (Pure) & eskazine (tab) has been successfully achieved on 1-5 mg of sample within an accuracy of $\pm 1\%$ (Table-1) in most of the cases.

III. Figures & Tables

A quick and convenient method has been developed for the micro estimation of antihistamine drugs. 1-5 mg of sample is allowed to react with 10 ml of 0.02 M, N-bromosaccharin solution. Unconsumed reagent can be accurately titrated with 5 ml of 15% KI and 0.02N sodium thiosulphate solution using starch as indicator. SD and CV was calculated for reproducible and accurate result. The accuracy of the method is within $\pm 1\%$ and possible course of reaction was suggested on the basis of stoichiometry as well as find reaction product.



Where $R_1 = \text{Cl}$, $R_2 = -\text{CH}_2(\text{CH}_2)_2 - \text{N}(\text{CH}_3)_2$

TABLE - 1
Determination of Antihistamine drugs with 0.2M NBSA

S. No.	Sample	Amount taken (mg)	Reaction time (min)	Amount recovered (mg)	Stoichiometry	Error (%)	SD	CV		
1	Prochloroperazine maleate (pure)	1.0000	10	0.9960	4	-0.40	0.0045	0.4494		
		3.0000		3.0072		+0.24			0.0130	0.4660
		5.0000		5.0155		+0.31			0.0137	0.2735
2	Promethazine hydrochloride (Pure)	1.0000	10	1.0014	4	+0.14	0.0060	0.5990		
		3.0000		3.0075		+0.25			0.0115	0.3712
		5.0000		4.9885		-0.29			0.0114	0.2279
3	Trifluopromazine hydrochloride (Pure)	1.0000	10	0.9974	4	-0.26	0.0016	0.1604		
		3.0000		3.0108		+0.36			0.0120	0.0398
		5.0000		5.0155		+0.31			0.0137	0.2735
4	Trifluoperazine (Pure)	1.0000	10	1.0051	4	+0.51	0.0094	0.0934		
		3.0000		3.0108		+0.23			0.0091	0.3030
		5.0000		5.0155		+0.36			0.0137	0.2735
5	Eskazine (Tab)	1.0000	10	1.0054	4	+0.34	0.0070	0.0698		
		3.0000		3.0114		+0.38			0.0028	0.0561
		5.0000		5.0180		+0.36			0.0168	0.3350

In each case three determinations were done.

IV. Conclusion

The effect of variables such as reaction time, concentration of reagent and temperature were studied. It was found that the recommended concentration of NBSA reagent is suitable to achieve quantitative reaction. It was observed that the reaction was completed at room temperature. Accurate and constant results were obtained when the reaction was carried out at room temperature and normally the reaction is completed with 10 minutes. Considering the stoichiometry and the available literature it may be believed that prochlorperazine maleate forms their monosulphoxide derivative with NBSA reagent.

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