

SPECTROPHOTOMETRIC ASSAY OF PROMETHAZINE HYDROCHLORIDE VIA OXIDATIVE COUPLING REACTION WITH 2-AMINOPYRIMIDINE IN THE USING OF SODIUM PERSULFATE

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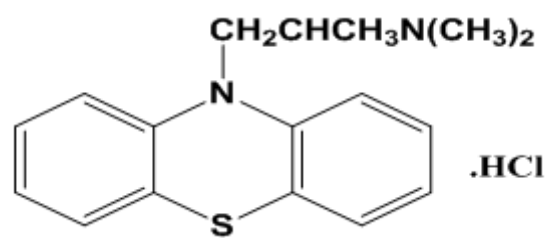
ABSTRACT : A simple, accurate and rapid spectrophotometric method has described for determination of promethazine.HCl in pharmaceutical preparation. The method is based on oxidative coupling reaction of promethazine.HCl with 2-Aminopyrimidine in the presence of sodium persulfate as an oxidant reagent to produce an intense yellow-orange coloured, water-soluble and stable for at least 55 min, which exhibit maximum absorption at 422 nm. The calibration graph showed that Beer's law is obeyed over the range 5-55 µg.ml⁻¹ of promethazine HCl with a molar absorptivity of 6.89×10^4 L.mol⁻¹.cm⁻¹, limit of detection (LOD) of 0.0735 µg.ml⁻¹ and limit of quantification (LOQ) of 0.2451 µg.ml⁻¹, a relative standard deviation of $\pm(0.19-0.81)\%$ depending of the concentration level. The recommended method has been successfully applied to the assay of promethazine hydrochloride in different pharmaceutical formulations.

Key words : Promethazine hydrochloride, sodium persulfate, 2-aminopyrimidine.

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INTRODUCTION

Promethazine hydrochloride appears as a white to faint yellow crystalline powder, which is practically odorless, it is soluble in alcohol and in methylene chloride. It is characterized of promethazine. HCl by the molecular formula and chemical structure as shown below (British pharmacopia, 2013).



Dimethyl[1-(10H-phenothiazin-10-yl)propan-2-yl]amine hydrochloride

Molecular Formula C₁₇H₂₀N₂S.HCl

Molecular Weight = 320.9 g/mol

Promethazine Hydrochloride is a derivative of phenothiazines, it is a specific antihistamine H₁ and has a hypnotic and antiemetic effect and is used to treat the symptoms associated with permanent and muscular

allergic rhinitis, runny nose and sneezing as well as for sedation, anxiety relief and sleep aid (British pharmacopia, 2013; World Health Organization, 2015). Several methods used for determination of PMH include, spectrophotometric methods (Mezal, 2010; Al-Saidi and Hammza, 2014; Qader and Fakhre, 2017; Mahmood *et al*, 2018; Baker and Jalal, 2018; Abdulaziz *et al*, 2019; Taqi *et al*, 2019; Alrazzak, 2019; Ahmed *et al*, 2020; Al-Rufaie, 2021), titrimetric method (Pandey *et al*, 2017), flame emission and molecular absorption spectrophotometric (Al-khadimy, 2016), chemiluminescence (Sultan *et al*, 2003; Jabbar *et al*, 2015), flow injection analysis (Daniel and Gutz, 2003; Mezal ~ Hassan *et al*, 2011; Karim *et al*, 2012), chromatographic (Bosakova *et al*, 2002; Tesarova and Bosakova, 2003; Kumazawa *et al*, 2011; Huang *et al*, 2012), ion-selective electrode (Lima *et al*, 1997; Al-Saidi and Ahmed, 2011), voltammetric (Xiao *et al*, 2007), chemometric (Muthukutty *et al*, 2021), fluorimetric (Ensafi *et al*, 2018) and electrochemical (Ribeiro *et al*, 2008; Chen *et al*, 2014; Arumugam *et al*, 2020).

The aim of the present work is to provide facile, rapid,

Table 6 : The comparison of methods.

Analytical parameters	Present method	Literature method (Baker and Jalal,2018)	Literature method (Abdulaziz et al.,2019)
λ_{max}	422	490	592
Reagent	2-Amino Pyrimidinein + sodium persulfate	2-Nitroso-1-Naphthol-4-Sulfonic Acid+ N-Bromosuccinimide	m-amino benzoic acid+ N-Bromosuccinimide
R^2	0.9991	0.9934	0.9991
Linearity ($\mu\text{g.ml}^{-1}$)	5-55	8-112	2-26
ϵ ($\text{L.mol}^{-1}.\text{cm}^{-1}$)	6.89×10^4	5390	9.754×10^3
Sandel index ($\mu\text{g.cm}^{-2}$)	0.04651	0.05953	0.03289
L.O.D($\mu\text{g/ml}$)	0.0735	1.979×10^{-6}	0.1949
Notes	Sensitive and does not need to adjust the pH or temperature	These need to adjust the pH and adjust the temperature	These need to adjust the pH

Method applications

Direct method

Three various concentrations of solution (Phenergan 25 mg) 20, 30, 40 $\mu\text{g/ml}$. The solution were treated with the same proceeding as the calibration curve, then absorption was measured at 422nm. The result shown in Table 4.

Standard additions method

Promethazine.HCl has been estimate in pharmaceutical preparation (Phenergan 25 mg) by standard additions method. The curve shown in Fig. 6 and Table 5.

Comparison of methods

Table 6 shows the comparison between the various analytical parameters found in suggested work with the same for method literature.

CONCLUSION

The developed method described, simple, an easy, rapid and low coast method for determination of Promethazine.HCl in pharmaceutical preparation, based on the reaction of promethazine.HCl with 2-Aminopyrimidinein the presence of sodium persulfate as an oxidant reagent to produce an intense yellow-orange coloured. This method was applied successfully for the estimating the drug on it's pure condition or in pharmaceutical preparations (Phenergan 25 mg) with high accuracy and precision. An important feature of this work is that it requires no extraction and is practical at room temperature.

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