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FULL PAPER

Ultra violet estimation of promethazine HCl in pharmaceutical formulation and industrial waste water sample

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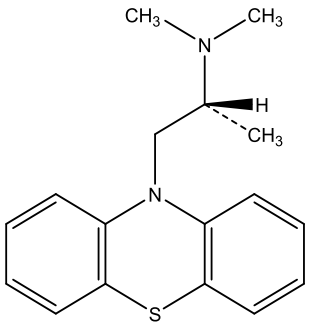
A new method is proposed to detect and precisely determining of promethazine HCl. This procedure is easy, straightforward, quick, and cost-effective technique. It is applicable to a wide range of samples, environmental, municipal wastewater, and of course, pharmaceutical preparations (for both tablets and injections). The highest absorbance value was obtained at 248 nm of a uniform content in distilled water. This procedure obeys Beer-Lambert low at a range of 0.5-15 µg/mL, while the registered molar absorptivity is 2.8X104 $L.mol^{-1}.cm^{-1}$, whereas the relative standard deviation is less than 2%, and the accuracy (average recovery%) is 100 ± 0.9. This technique was substantiated by sensitivity and precision which confirms appropriation for regular analysis of promethazine HCl in actual samples.

KEYWORDS

Promethazine.HCl; waste water; spectrophotometry.

Introduction

Promethazine hydrochloride (P.HCl) (Figure 1), is a white, odorless powder that is soluble in water, alcohol, and chloroform. It dissolves hardly in diethyl ether, acetone, and ethyl acetate. It turns reddish-blue when exposed to air or moisture for a long time. Therefore, it is kept away from light, and placed in closed containers. It belongs to a class of medicines called phenothiazines, and acts as an antihistamine by blocking the effects of histamine on the body, so it may be used in the treatment of allergy symptoms, allergic reactions, for the treatment of nausea and vomiting, and prevention of vertigo. For insomnia treatment in adults and a sedative for children, it has side effects as it causes blurred vision, drowsiness, dry mouth, rapid or slow heart rate, and high or low blood pressure [1]. Its molecular weight is (320.88 mg/mol) and its melting point is (232-230) °C. The chemical formula for (P.HCl) is (RS)-N, N-dimethyl-1-(10H-phenothiazine-10-yl) propan-2-amine hydrochloride, it is now used as a sedative, emetic, hypnotic, analgesic, and antihistaminic medicine [2,3].



· HCl

($C_{17}H_{20}N_2S.HCl$: 320.880 $g.mol^{-1}$)

FIGURE 1 Chemical composition of (P.HCl)

In contrast, (P.HCl) can be as a chromogenic agent material hypochlorite and iodate ions spectrometric determination.[4,5]

Several methods for determining (P.HCl) have been proposed in the literature, including indirect titration [6] pectrophotometrically [7-9], spectro-fluorometrically, [10] based on turbidimetric analysis, [11] or Chemiluminescence [12] volta metric, [13] implementation RP-HPLC methods [14-17]. Nevertheless, efforts are being taken to advance straightforward and efficient experimental techniques for quantitative measurement of promethazine since the pharmaceutical industry urgently needs a simple yet effective approach to characterize the drug. Thus, the innovative methods for quantifying promethazine's effectiveness as a pharmaceutical active component, straightforward, efficient, less time-consuming, sensitive, affordable, and accurate analytical methods are required. We estimate the dosages of promethazine hydrochloride in bulk and its tablet dosage forms are estimated using straightforward, delicate, accurate, quick, and affordable spectrophotometric methods in the current study.

Experimental

Apparatus

Shimadzu UV-1700 pharmaceutical aspect spectrophotometer (two beams) was used. This device has a (1.0 cm) broad quartz curette and a dual beam light path.

Reagents

The chemicals used in this experiment are of high analytical purity. (P.HCl) was offered as a standard material and pharmaceutical preparations, by [AL-Hokamaa business of pharmaceutical industries) (HPI) (Mosul-Iraq] (i.e. tablets), while promethazine ampules (50 mg/2 mL) were supplied by Oubari-Oubari Pharma-Syria, a state company. The distilled water was used as a solvent.

Preparation of (p.HCl) standard solution 100 mg/L

In volumetric flask calibrated previously (P.HCl), the weight of (10 mg) was dissolved in a small amount diluted in D.W, and then the volume finalized to (100 mL) using D.W.

Absorption spectrum peaks determination

The (P.HCl) standard solution (10 µg/mL) was examined in the scanning mode of the instrument over a wavelength range of (210-300 nm) to get a spectrum peak at (248 nm). With D.W as the blank treatment, this peak will be used to produce curve calibration on range of (0.5-15 g.mL^{-1}), as displayed in Figure 2.

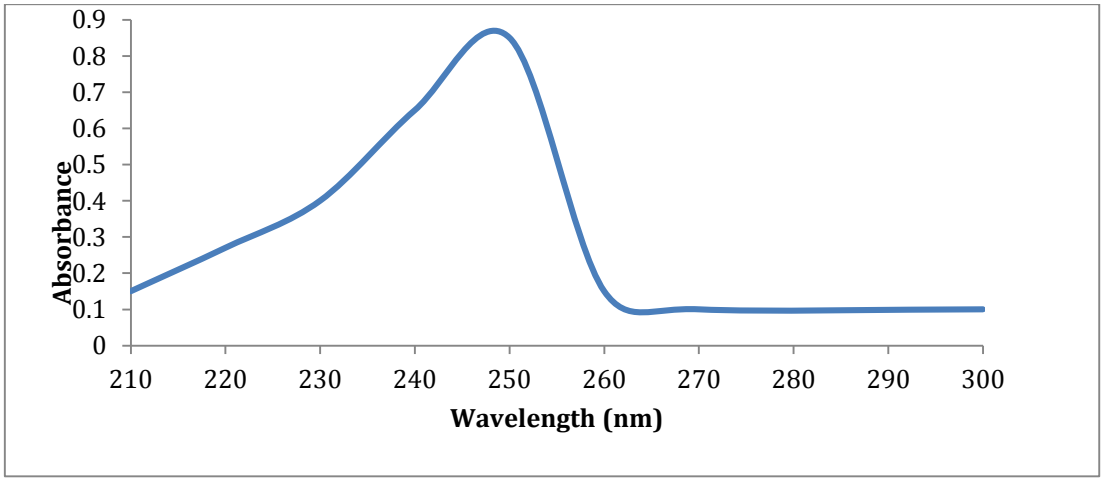


FIGURE 2 Absorption spectrum of 10 µg.mL^{-1} of promethazine hydrochloride

This curve may then be used to figure out the sample's unknown concentration. In terms of pharmaceutical preparation, variations in tablet composition containing (5.0 mg) of promethazine hydrochloride per tablet, supplied by [AL-Hokamaa business of pharmaceutical industries, (HPI) Iraq-Mosul] are quite likely to occur and can be reduced. After grinding 10 tablets and weighing their contents, (10 mg) of (P.HCl) equivalent powder was added to around (70.0 mL) of distilled water, the mixture was well agitated for half an hour, and filtering was performed using Whatman® paper (No. 42) as a filter. The filtrate had been then dilute to (100 mL) with (D.W). Various volumes of this solution were handled in the same way as the general technique described before. Finally, the regression analysis was used to determine the amount of drug in the sample.

Injections of (50 mg P.HCl/2 mL) injection samples were utilized in injectable formulation, which is a component of the pharmaceutical business. In a (250 mL) beaker, the contents of 5 ampoules were combined, and an aliquot of (10 mg) of P.HCl was carefully pipetted into volumetric flask (100 mL), which was then filled to (100 mL) with (D.W). (20 mL) of the solution was diluted with (D.W) to a final volume of (100 mL) to prepare it for subsequent measurement of its absorbance

Industrial waste water examination

To show that this procedure can be used to detect (P.HCl) in industrial wastewater, a sample of such water was obtained from the [Al-Hokamaa Company for pharmaceutical industries (HPI) in Mosul, Iraq], and later analyzed. It was spiked with a concentration of promethazine hydrochloride in the range of (0.5-15 g/mL). For the indicated method, it was treated as mentioned above.

Results and discussion

Spectrophotometry in the visible and ultra violet ranges of the electromagnetic spectrum is a cost-effective and effective method of detecting medicines [18-20]. The technique for detecting P.HCl in pharmaceutical preparations and wastewater utilized in this study is sensitive, accurate, and repeatable. Beer's law was applied to a concentration range that includes (0.5-15 $\mu g.mL^{-1}$) (Figure 3) connection of the coefficient (0.6916), a slope of (0.0875), and an intercept of (0.002). The molar absorptive condition is ($2.8X10^4$ $l.mol^{-1}.cm^{-1}$).

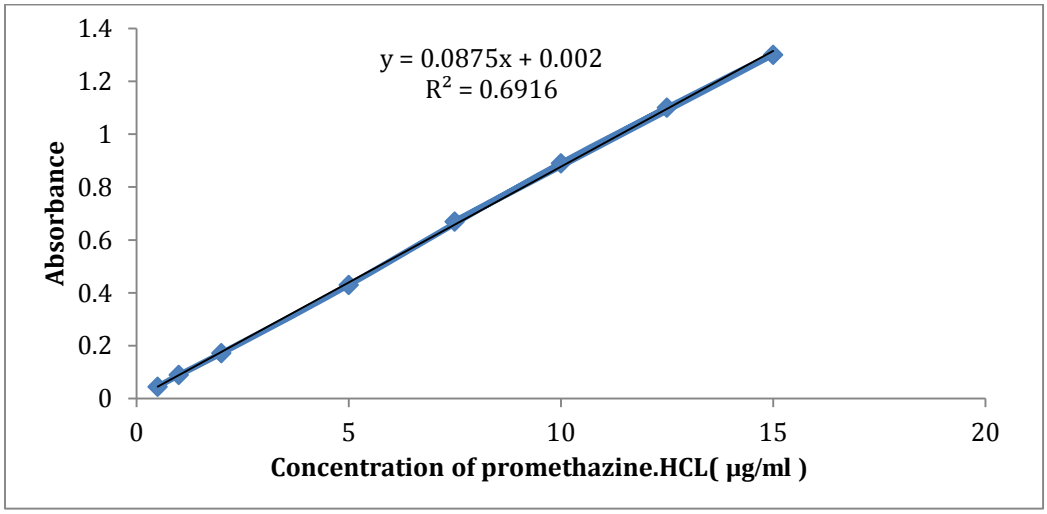


FIGURE 3 Calibration curve of promethazine HCL

The precision and accuracy of this procedure as well as a pure solution of the provided medication were tested. Three concentrations of the drug solution were

calculated, and each calculation was repeated ten times. We can observe from (Table 1) that relative error values (percent) and relative standard deviation values are adequate, whereas recovery studies were carried out. Near to (100.0 percent). The RSD percent score is (1.80 percent), which indicates that the operation was accurate. The limit of detection and limit of quantification are evaluated as [7]: (LOD= Intercept/Slope X10) and (LOQ= 3.30LOD). The limit of detection was (0.2290 µg/mL) and the limit of quantification (LOQ=0.754 µg/mL) as the lowest Standard Concentration which could be determined with the acceptable accuracy.

TABLE 1 The precision and accuracy of the recommended method

Promethazine.HCL taken (µg/mL)	Er (%) [a]	R.S.D (%)	S
5.0	0.810	1.50	0.0020
10.0	0.90	1.750	0.0030
15.0	0.820	1.90	0.0050

[a]Mean of ten estimations

Analytical application

The proposed solution was implemented effectively for quantitative detection of (P.HCl) in pharmaceutical formulation (tablets and injection vials) along with spiked wastewater samples. The outcome of a pharmaceutical formulation analysis (Table 2) shows there is close harmony as a result of the findings achieved by the given procedure and the label claim, and those of industrial wastewater samples (Table 3) demonstrate that the recovery rates attained were close to 100%.

TABLE 2 Assay for Promethazine .HCL formulations of pharmaceuticals

Pharmaceutical formulation	Amount of Promethazine. HCL* Proposed method	Label- claim	Recovery%
Tablet 5 mg (supplied by HPI) Injection ampoule Oubari Pharma-Syria	4.98 mg 25.06	5 mg 25 mg/mL	99.6 100.24

*Mean of ten determinations

Samples of industrial effluent yielded the following findings. The recovery values achieved were in the (100 percent) range, as listed in Table 3.

TABLE 3 Determination of (P.HCL) in industrial wastewater samples.

Water as sample	P .HCL(µg /mL) * Taken	Found	Recovery%
Industrial waste water	5	5	100
	10	10.06	100.6
	15	15.1	100.66

*= ten determinations

Utilization of the suggested technique for content uniformity [21-23]

The consistency degree of the amount of active ingredient among dosage units is known as content uniformity or dosage unit uniformity. The risk assessment technique that underpins content uniformity testing is based on the notion that there are some predetermined boundaries beyond which security and effectiveness results may be affected if content uniformity fails. The proposed method successfully passed the content standardization test, which needed a large no. of tests on individual tablets.

Table 4 presents that the suggested approach can quantitatively measure promethazine.HCL in commercially available tablets with accuracy and precision. The labeled claim's mean percentage (with RSD) detected in ten tablets was (100.1) (0.432 percent), which is within the United States Pharmacopeia's content uniformity guidelines [22].

TABLE 4 Testing tablet content uniformity using the proposed technique

Parameter	% claim
1	100.8
2	99.9
3	100.2
4	100.2
5	99.8
6	100.2
7	99.8
8	100.2
9	100,2
10	99.8
(X)	100.1
%R.S.D	0.432
Max. allowed unit value [22]	±15.0%

Conclusion

The approach under review appears to be more time-saving, highly susceptible, precise, and inexpensive, making it a good candidate for routine drug quality control analysis in pharmaceutical formulations, industrial effluent, and the use of content uniformity testing.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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