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# Determination of Propranolol HCL in Pharmaceutical Preparations and Environmental Wastewater Samples Application to Content Uniformity Testing

**Ghfran Naif Rahman[1] and Nief Rahman Ahmad[2]***

[1]Student at Medical College, University of Mosul, Mosul-Iraq1

[2]College of Environmental, University of Mosul-Iraq

**ABSTRACT**

A Newly developed analysis method for the simple, accurate, precise, rapid, economical and sensitive Ultraviolet spectrophotometric method has been developed for the determination of Propranolol Hydrochloride in pharmaceutical preparations and environmental wastewater samples, which shows maximum absorbance at 290 nm in methanol. Beer's law was obeyed in the range of 2.5 -50 µg/ ml, with molar absorptivity of 5.92×103 L.mol-1.cm-1, relative standard deviation of the method was less than 1.5%, and accuracy (average recovery %) was 100 ± 0.9. No interference was observed from common excipients and additives often accompany with Propranolol Hydrochloride in pharmaceutical preparations. The method was successfully applied to the determination of Propranolol Hydrochloride in some pharmaceutical formulations (tablets) and industrial wastewater samples. The proposed method was validated by sensitivity and precision which proves suitability for the routine analysis of Propranolol Hydrochloride in true samples.

***Corresponding author**

Nief Rahman Ahmad, College of Environmental, University of Mosul-Iraq.

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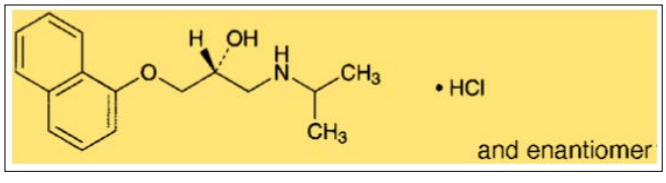
## Introduction

Propranolol Hydrochloride is Beta-adrenoceptor antagonist., White or almost white powder, Soluble in water and in ethanol (96 per cent), with M.P about 164°. Propranolol Hydrochloride (ATNL), chemically identified as 2-[4-[(2RS)-2-hydroxy-3-[(1-methylethyl) amino] proxyphenyl] acetamide (Figure 1).

Propranolol Hydrochloride (ATEN), a beta-blocker is used to treat angina and high blood pressure. Hydrochlorothiazide (HCTZ) is a thiazide diuretic that increases the urine flow and prevents the retention of fluid in the body. It is used to treat high blood pressure [1-4].




**C16H21NO2.HCl: 295.80**

(2RS)-1-(1-Methylethyl)amino-3-(naphthalen-1-yloxy)propan-2-ol mono hydrochloride

**Figure 1:** Propranolol Hydrochloride Chemical Structure

In this paper the Determination of propranolol hydrochloride in pharmaceutical preparations. The literature survey reveals that various methods has been reported for estimation of Propranolol Hydrochloride by Titrimetric method [5, 6]. Spectrofluorometric methods Spectrophotometric methods RP-HPLC methods Square-wave voltammetry Flow-injection chemiluminescence analysis method Capillary electrophoresis continuous flow injection analysis via turbid metric method, second derivative spectroscopy method Atomic absorption spectrophotometric method and colorimetric [7-12]. In the view of the need in the industry for routine analysis of Propranolol Hydrochloride, attempts are being made to develop simple and accurate instrumental methods for quantitative estimation of Propranolol Hydrochloride [13-16]. Thus there is need for the development of new, simple, sensitive and accurate analytical method for the quantitative estimation of Propranolol Hydrochloride as an active pharmaceutical ingredient [17,18]. The present work describes simple and accurate Spectrophotometric methods for the estimation of Propranolol Hydrochloride in bulk, dosage form and environmental wastewater samples: Application to content uniformity testing [19,20].

## Experimental

### Apparatus

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

### Reagents

All chemical used were of analytical or pharmaceutical grade and Propranolol Hydrochloride standard material was provided from the state company of drug industries and medical appliance (NDI) Nineveh – Iraq.

**Propranolol Hydrochloride Stock Solution (1000 ppm)** was prepared by dissolving 0.1g of Propranolol Hydrochloride in 100 ml methanol in a volumetric flask.

**Propranolol Hydrochloride Standard Solution (100 ppm)** was prepared by diluting10 ml of stock solution to 100 ml by methanol in a volumetric flask.

**Determination of Absorption Maxima**

The standard solution of Propranolol Hydrochloride (20µg/ml) was scanned in the range of 220-350 nm which shows maxima located at 290 nm Figure 2. Therefore ,290 nm wavelength was selected for the construction of calibration curve.

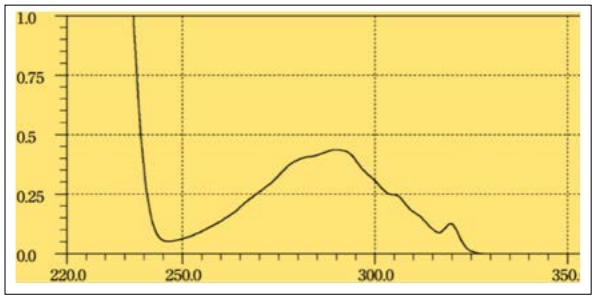



**Figure 2:** Absorption Spectra of 20 (µg/ml) Propranolol Hydrochloride against Methanol.

**Recommended Procedure**

From the absorption maxima, calibration curve was prepared in the concentration range of 2.5-50 µg/ml. The absorbance was measured at 290 nm against methanol as a blank .The concentration of the sample solution can be determined by using the calibration curve.

**Procedure for Real Water Samples**

To demonstrate the practical applicability of the proposed method, real water samples were analyzed by this method. Industrial waste water from the state company of drug industries and medical appliance (NDI) Nineveh – Iraq, were fortified with the concentrations in the range of 10,30,50 µg/ml of Propranolol Hydrochloride. The fortified water samples were analyzed as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

**Procedure For Pharmaceutical Preparations (Tablets)**

Weight and powder 10 tablets [BECARDIN-40] Tablets 40 mg (NDI)]. Dissolve a quantity of the powdered tablets containing 0.01 gm. of Propranolol Hydrochloride in about 100 ml methanol and mixed for 20 mint and then filtered. The filtrate was mad up to 1000 ml with methanol and aliquot of this solution was treated as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

**Result and Discussion**

UV visible spectrophotometry is still considered to be a convenient and low cost method for the determination of pharmaceuticals [21-25]. The method used for the determination of Propranolol Hydrochloride in pharmaceutical preparations and environmental wastewater samples was found to be sensitive, simple, accurate, and reproducible. Beer s law was obeyed in the concentration range of 2.5-50 µg/ml .Figure 3 with correlation coefficient of 0.998 ,intercept of -0.001 and slope of 0.02 .The conditional molar absorptivity was found to be 5.92 x$10^3$ l/mol.cm.

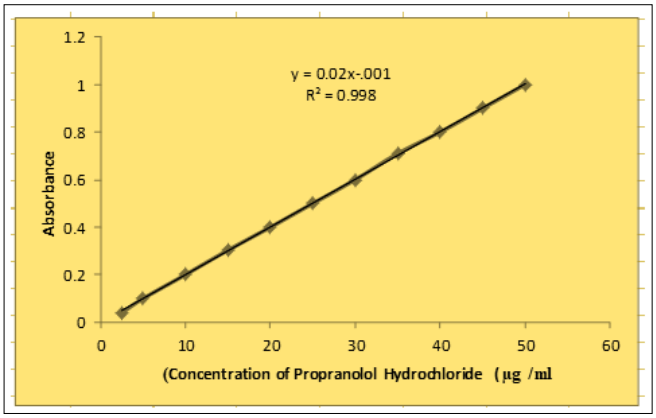



**Figure 3:** Calibration Curve for Propranolol Hydrochloride.

The accuracy and precision of the method, a pure drug solution was analyzed at three different concentrations, each determination being repeated ten times. The relative error(%) and relative standard deviation values are summarized in table 1.From table 1 the values of standard deviation were satisfactory and the recovery studies were close to 100%,.The RSD% value is less than1.5 indicative of accuracy of the method.

**Table 1: Accuracy and Precision of the Proposed Method.**

| Propranolol Hydrochloride taken( µg/ml) | Er (%) a | RSD(%) |
|---|---|---|
| 5 | 1.1 | 1.4 |
| 15 | 1.1 | 1.3 |
| 50 | 1.2 | 1.3 |

Average of Ten Replicate Determinations

**Analytical application**

The proposed method was satisfactorily applied to the determination of Propranolol Hydrochloride in its pharmaceutical preparations tablets 40 mg (NDI)] and wastewater samples, the results of the assay of the pharmaceutical preparations revels that there is close agreement between the results obtained by the proposed method and the label claim Table 2, and the results of water samples Table 3 show that the recovery values obtained were closed to 100%.

**Table 2: Assay of Propranolol Hydrochloride in Pharmaceutical Formulations.**

| Pharmaceutical formulation supplied by NDI | Amount of Propranolol Hydrochloride* Proposed method | Label claim | %Recovery |
|---|---|---|---|
| Tablet 40 mg | 40.1mg | 40mg | 100.25 |

*Mean of ten determinations.

**Table 3: Determination of Propranolol Hydrochloride in Spiked Industrial Wastewater Sample.**

| Water samples | Propranolol Hydrochloride (µg/ml) * Taken Found | Recovery% |
|---|---|---|
| Industrial wastewater | 10 10.01<br>30 30.04<br>50 49.95 | 100.1<br>100.13<br>99.9 |

Mean of ten determinations.

**Application of the Method to Content Uniformity [26-31].**

The proposed method proved to be suitable for the content uniformity test, where a great number of assays on individual tablets are required [4]. Data presented in Table indicate that the proposed method can accurately and precisely quantitate Propranolol Hydrochloride in its commercially available tablets. The mean percentage (with RSD) of the labeled claim found in ten tablets was (0.518%) which fall within the content uniformity limits specified by the USP 33 [ 29].

| Table 4: Content uniformity testing of Propranolol Hydrochloride tablets using the proposed method Parameter | % of the label claim |
|---|---|
| Tablet NO. 1 | 100. 18 |
| Tablet NO. 2 | 100. 21 |
| Tablet NO. 3 | 99. 86 |
| Tablet NO. 4 | 100.41 |
| Tablet NO. 5 | 99.38 |
| Tablet NO. 6 | 99. 55 |
| Tablet NO. 7 | 99.72 |
| Tablet NO. 8 | 100. 35 |
| Tablet NO. 9 | 100.46 |
| Tablet NO. 10 | 99.96 |
| Mean ( x ) | 100.008 |
| % RSD | 0.518 |
| Max. allowed unit [29] | ±15% |

## Conclusion

In this work, a simple, rapid, precise and accurate spectrophotometric method was developed and validated for the determination of Propranolol Hydrochloride in pharmaceutical preparations and industrial waste water samples. The method free from such experimental variables as heating or solvent extraction step. The method rely on the use of simple and cheap chemicals and techniques and can be used for rapid routine determination and quality control of Propranolol Hydrochloride in pure form, bulk sample, pharmaceutical preparations and real industrial waste water sample.

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