The Pharmaceutical and Chemical Journal, 2019, 6(1):49-52

Available online www.tpcj.org

Research Article

ISSN: 2349-7092
CODEN(USA): PCJHBA

Comparative Utilization of Potentiometric Titration and HPLC Methods for Content Determination of Propranolol Raw Material

Derouicha Matmour[1,3], Fatima Zohra Hadjadj Aoul[2], Toumi Houari[3]

[1]Therapeutic Chemistry Laboratory, Pharmacy Department, 22000 Sidi Bel-Abbes, Algeria
[2]Medicinal Chemistry Laboratory, Pharmacy Department, 16000 Algiers, Algeria
[3]Research Laboratory in Pharmaceutical Development. EHUO 1st November, 31000 Oran, Algeria

Abstract This study describes an application and comparative evaluation of a HPLC and potentiometric titration methods to quantify the content of Propranolol in raw material. HPLC analysis were carried out using a C18 column and mobile phase composed of 1.6 g sodium lauryl sulfate, 0.31 g tetrabutylammonium dihydrogen phosphate, 1 ml sulfuric acid, 450 ml of water and 550 ml acetonitrile, with a flow rate of 1.8 ml/min and UV detection at 292 nm. The titration method of Propranolol was carried out using sodium hydroxide 0.1M as titrant and ethanol as solvent. The end point was potentiometrically determined. The content obtained by potentiometry is 100.49%, by HPLC is 100.01%. These results meet the required standard.

Keywords potentiometric titration, HPLC, content, propranolol, raw material

1. Introduction

In recent decades a lot of attention has been paid to the quality of pharmaceutical products entering the market. The major challenge for the pharmaceutical industry is to produce quality medicines, which require rigorous quality controls to maintain the quality, efficacy and safety of these products [1]. The accuracy and reliability of the analytical results are critical in ensuring quality, safety, and efficacy of pharmaceutical products. However, to ensure these criteria, the choice of appropriate analytical method is required [2]. Propranolol is a B-blocker, belongs to the chemical family aryloxypropanolamine used as an antihypertensive, anti-arrhythmic and anti-angina [3].

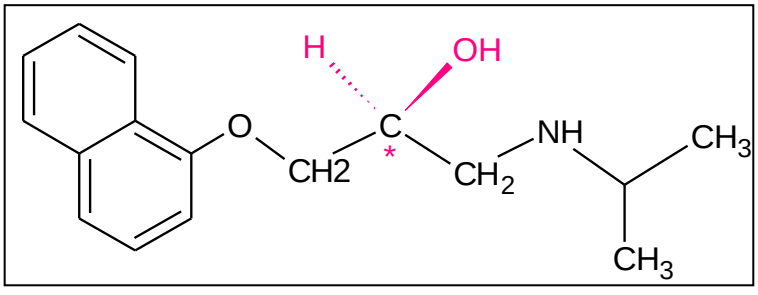


Figure 1: Chemical structure of propranolol [4].

This study describes an application and comparative evaluation of HPLC, and potentiometric Titration methods to quantify the content of Propranolol in raw material.

2. Materials and Methods

2.1. HPLC Content Determination

A HPLC brand WATERS 2695 was used, the chromatographic conditions were regled at injection volume: 20 µl, Flow: 1.8 ml/min, temperature: 25°C, Column: C_{18} (5µm x 4,6mm x 250mm) and the wavelength λ : 292 nm. The mobile phase is composed of 1.6 g of sodium lauryl sulfate, 0.31 g of tetrabutylammonium dihydrogenophosphate in a mixture of 1 ml sulfuric acid, 450 ml water and 550 ml acetonitrile, the pH was adjust to 3.3. The SCR control and test solutions were prepared at 2 mg/ml [4,5].

2.2. Potentiometric Titration Content Determination

A potentiometer brand METTLER TOLEDO DL50 was used, titrant solution of sodium hydroxide 0,1M, potassium phthalate acid standard solution 0,1 M. The test solution was prepared at 5mg/ml in ethanol [4,6].

3. Results and Discussion

3.1. HPLC Content Determination

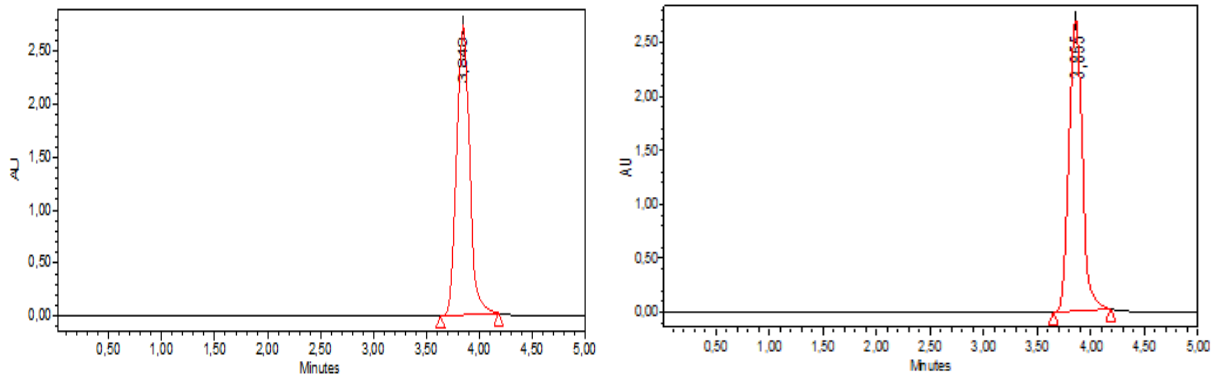


Figure 2: Control solution chromatograms of first and second injection

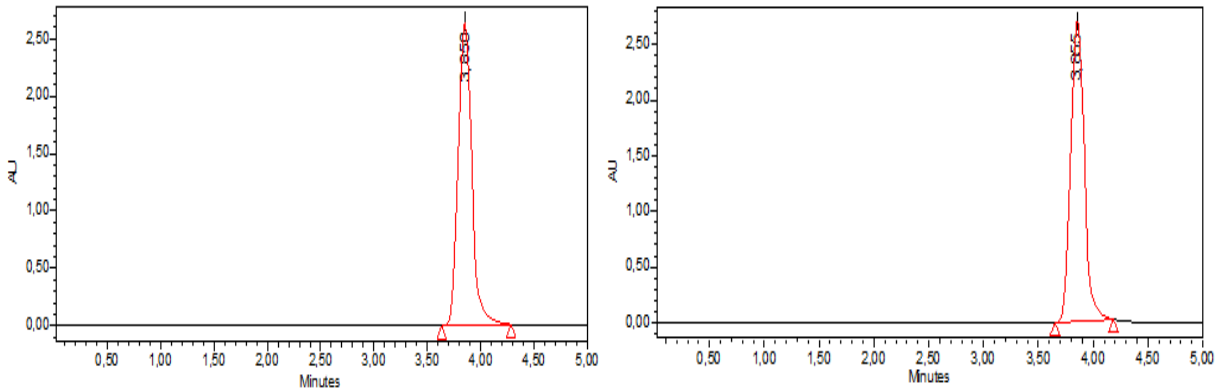
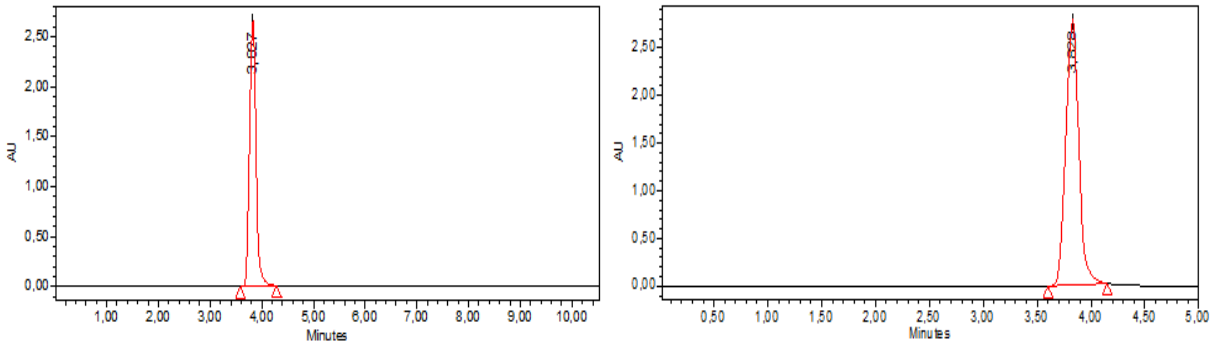


Figure 3: Control solution chromatograms of third and fourth injection



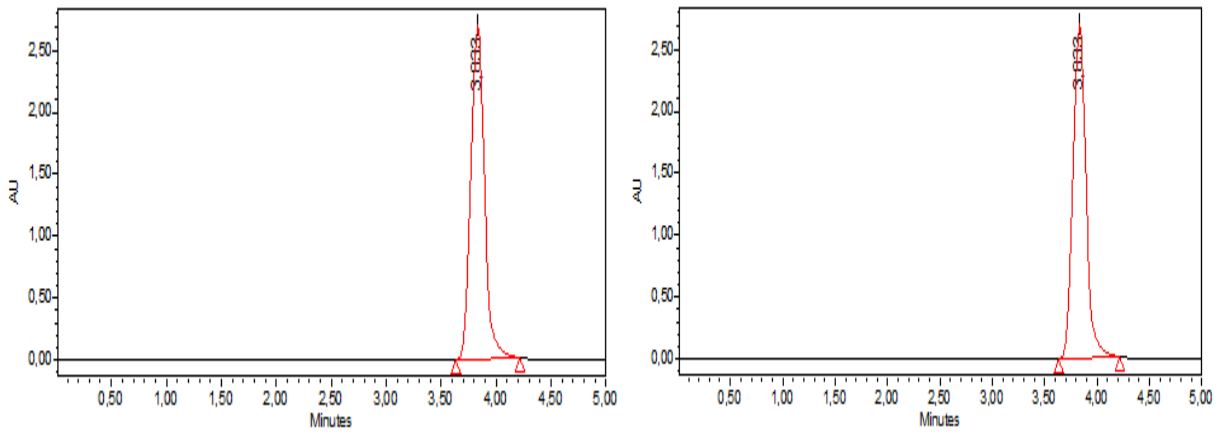


Figure 4: Test solution chromatograms of first, second, third and fourth injection

Table 1: HPLC Content Determination Results

Name	Retention Time (min)	Area Average (mAu.min)	Content (%)	Normes (%)
SCR	3.851	23345968.33	100	99-101
API_Sample	3.829	23347844.67	100.01	

According to the chromatogram, the retention time of propranolol hydrochloride is 3.85 min. Value close to that required by the European Pharmacopoeia. The content of propranolol hydrochloride anhydrous is 100.01%, it meets the required standard.

3.2. Potentiometric Titration Content Determination

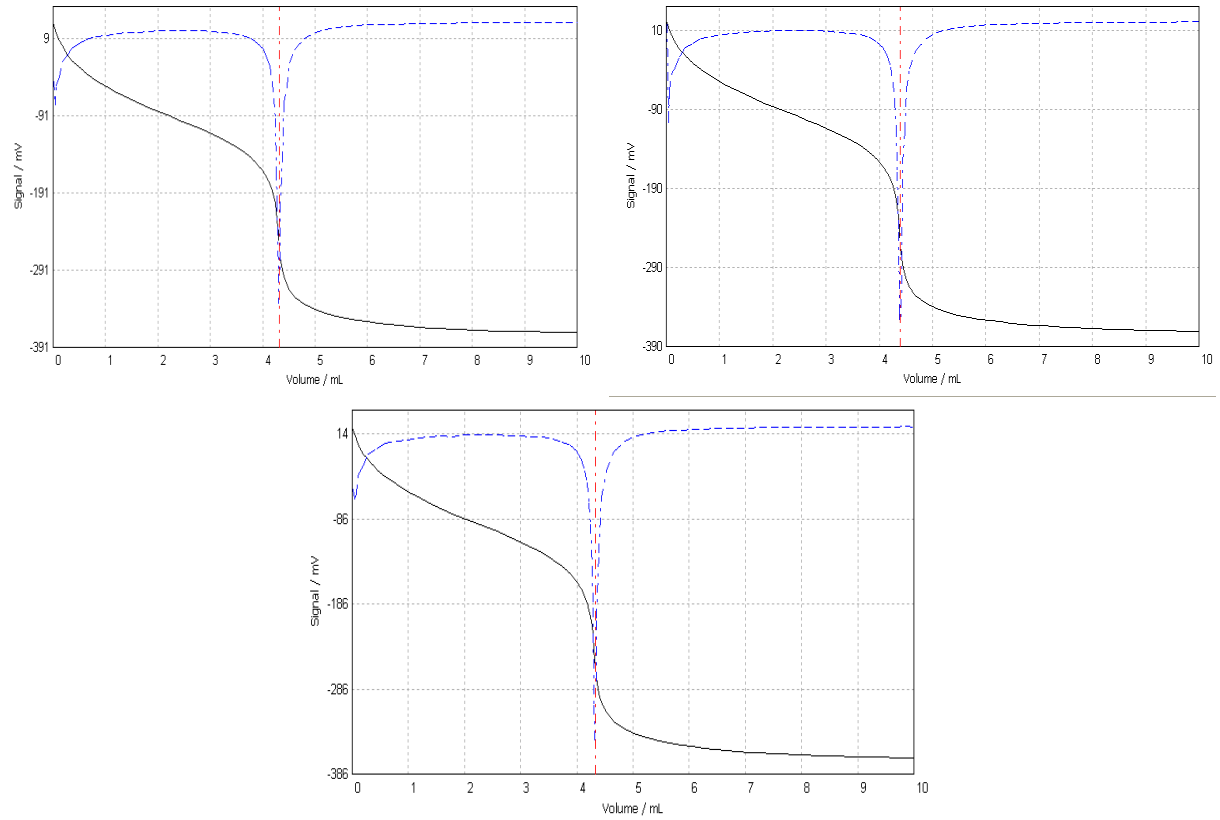


Figure 5: Test solution titration Graphics

Table 2: Potentiometric Titration Content Determination

Assay Number	NaOH Volume (ml)	Correction factor	Content (%)	Average	Normes (%)
1	4.345	0.9758	100.33	100.49	99-101
2	4.379		100.95		
3	4.340		100.21		

The content of propranolol hydrochloride anhydrous is 100.49 %, it meets the required standard.

4. Conclusion

The evaluated methods showed to be adequate to quantify Propranolol Hydrochloride in raw material. The potentiometric titration doesn't require the use of a reference substance. The manipulation is rapid, but the error margin is important than the HPLC.

References

[1]. Varpe D, Ayre A, Nayak R and Vasa N. Impurity profiling of pharmaceuticals. Advanced Research in Pharmaceuticals and Biologicals. December 2011; 1(2):76-90.

[2]. Bari SB, Kadam BR, Jaiswal YS and Shirkhedkar AA .Impurity profile: Significance in active pharmaceutical ingredients. Eurasian Journal of Analytical Chemistry. 2007; 2(1):32-53.

[3]. Brion J D, Buxeraud J, Castel J, Cussac M. Drugs of the cardiovascular system. Treaty of therapeutic chemistry (vol.3), Paris: Tec and Doc; 1992.

[4]. European Pharmacopoeia 8th edition. Propranolol hydrochloride. Strasbourg: EDQM; 2015: 2979- 80.

[5]. European Pharmacopoeia 8th edition. Council of Europe. Physical and physicochemical methods. Liquid chromatography. Strasbourg, France; 2015: 48-50.

[6]. European Pharmacopoeia 8th edition. Council of Europe. Physical and physicochemical methods. Potentiometric titration. Strasbourg, France; 2015: 35.