

EXTRACTIVE SPECTROPHOTOMETRIC METHODS FOR NEBIVOLOL HYDROCHLORIDE

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ABSTRACT: Two simple and sensitive spectrophotometric methods have been developed for the estimation of Nebivolol hydrochloride in pure and pharmaceutical dosage forms. Method 1 is based on Ion-association complex formation of the drug with (SBT λ_{\max} 515 nm). Method 2 is based on Ion-association complex formation of the drug reacts with (BTB λ_{\max} 410nm). These methods have been statistically evaluated and found to be precise and accurate.

Key words: Nebivolol hydrochloride , spectrophotometric methods , Solochrome black- T , Bromothymol blue

INTRODUCTION:

Nebivolol Hydrochloride (NBH) is an anti hypertensive agent. Nebivolol, chemically α, α' -[Iminobis (methylene)] bis [6-fluoro-3, 4-dihydro-2H-1-benzopyran-2- methanol]. It is a beta-adrenergic blocker. Nebivolol selectively blocks the β_1 - adrenoceptor. Nebivolol reduces heart rate, rate of myocardial contractility and systemic blood pressure while increasing diastolic pause. β - blockers are useful prophylactic agents in stable and unstable types of angina. Nebivolol is preferable in patients with bronchospasm, diabetes, peripheral vascular disease or Raynaud's phenomenon. The literature survey reveals that only few methods⁴⁰⁻⁵⁵ are reported for the determination of NBH in biological fluids. A set of thirteen spectrometric methods have been developed by utilizing the reactions of various analytically important functional groups. All these methods have been extended for the analysis of pharmaceutical formulations of NBH.

INSTRUMENTATION:

A Systronics Double beam UV visible spectrophotometer 2201 with 1 cm matched quartz cells was used for all spectral and absorbance measurements. A systronics digital p^H meter was used for all p^H measurements.

EXPERIMENTAL

Preparation of Reagents:

1. SBT solution: Prepared by dissolving 100 mg of solochrome black - T in 100 ml of distilled water.
2. HCl : 4.425 ml of concentrated hydrochloric acid was diluted to 100 ml with distilled water.
3. BTB: Prepared by dissolving 100 mg of Bromothymol blue in 100 ml of distilled water.
4. Standard drug preparation: The working standard solution (1.0 mg/ ml) of NBH was prepared by dissolving 100 mg of the drug in 100 ml of Ethanol. This stock solution was further diluted with the same solvent to get 100 µg/ml of working standard solution.

ASSAY PROCEDURES

Method 1

Aliquots of standard NBH solution (100µg/ml) ranging from 0.6 to 1.4 mL were transferred into a series of 125 ml separating funnels. A volume of 2.0 ml of 0.1 N HCl and 1.0 ml of Methyl orange (SBT) dye solutions was added to all separating funnels. The total volume of aqueous phase in each separating funnel was adjusted to 10.0 ml with water. To each separating funnel 10.0 ml of chloroform was added and shaken for 3 minutes. The absorbance of separated chloroform layer was measured at λ_{\max} 515nm. The amount of NBH was calculated from the corresponding Beer-Lambert's plot.

Method 2

Aliquots of standard NBH solution (100µg/ml) ranging from 0.2 to 1.0 mL were transferred into a series of 125 ml separating funnels. A volume of 2.0 ml of 0.1 N HCl and 1.0 ml of Methyl orange (BTB) dye solutions was added to all separating funnels. The total volume of aqueous phase in each separating funnel was adjusted to 10.0 ml with water. To each separating funnel 10.0 ml of chloroform was added and shaken for 3 minutes. The absorbance of separated chloroform layer was measured at λ_{\max} 410nm. The amount of NBH was calculated from the corresponding Beer-Lambert's plot.

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, Molar Extinction coefficient, percent relative standard deviation, percent range of error (0.05 and 0.01 confidence limits) were calculated for all the methods and results are summarized in Table 1. The values obtained for the determination of Nebivolol Hydrochloride in Pharmaceutical formulations (Tablets) by the proposed methods are presented in Table 2. Studies reveal that the common excipients and other additives usually present in the Tablets did not interfere in the proposed methods.

CONCLUSION : The proposed methods are simple, selective, and reproducible and can be used in the routine analysis of Nebivolol Hydrochloride in bulk drug and formulations with reasonable accuracy and precision.

Table-1: Optical characteristics, precision and accuracy of the proposed method NBH

Parameter	Method 1	Method 2
λ_{\max} (nm)	515	410
Beer's law limits ($\mu\text{g}/\text{ml}$)	6-14	2-10
Molar absorptivity ($\text{L. mole}^{-1} \text{cm}^{-1}$)	19.91×10^3	32.84×10^3
Sandell's sensitivity ($\mu\text{g}/\text{cm}^2/0.001$ absorbance unit)	0.0205	0.0123
Optimum photometric range ($\mu\text{g}/\text{ml}$)	5-12	4-8
Regression equation ($Y = a + bc$): Slope (b)	0.0492	0.0796
Intercept (a)	-0.0022	0.0057
Correlation coefficient (r)	0.9998	0.9998
% Relative standard deviation*	0.83	1.235
% Range of Error (Confidence limits)* 0.05 level	0.694	1.032
0.01 level	1.027	1.528

* $Y = a + bx$, where 'Y' is the absorbance and x is the concentration of Nebivolol Hydrochloride $\mu\text{g}/\text{mL}$

**For six replicates

Table-2: Estimation of Nebivolol in Pharmaceutical Formulations NBH

Formulations	Labelled Amount (mg/ml)	Amount found* by proposed method		% recovery** by proposed method	
		Method 1	Method 2	Method 1	Method 2
Tablet 1	5	4.5	4.2	99.6	99.3
Tablet 2	10	9.6	9.3	99.9	99.5

* Average of six determinations**Recovery of amount added to the pharmaceutical formulation (Average of three determinations)

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