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NOTE

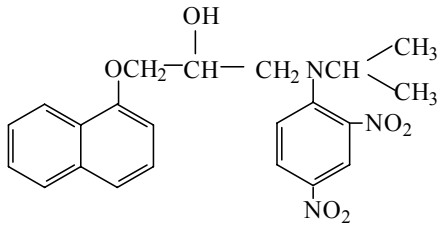
Spectrophotometric Estimation of Propranolol in Tablet Dosage Form

ANIL BHANDARI*, BRIJESH KUMAR and RAKESH PATEL†
Jodhpur Pharmacy College, Jhanwar Road, Narnadi, Boranada, Jodhpur-3420 01, India
E-mail: asthwal@rediffmail.com

A simple and accurate spectrophotometric method has been developed for the quantitative estimation of propranolol in bulk and tablets. The method is based on the reaction of propranolol with 1-chloro-2,4-dinitrobenzene, forming a complex, which is analyzed by spectrophotometry. The absorbance maxima (λ_{max}) was found to be 314.6 nm. Optimization of reaction was carried out with the factors, temperature, time, stability of complex, molar ratio of drug: reagent. The proposed method was validated as per ICH guidelines.

Key Words: Propranolol, Spectrophotometry, 1-Chloro-2,4-dinitrobenzene.

Chemically, propranolol is (2RS)-1-[(1-methylethyl)amino]-3-(naphthalene-1-yloxy)propan-2-ol hydrochloride (**1**). Propranolol is a cardio selective β-adrenergic blocker, mainly used in hypertension, angina pectoris and myocardial infarction. Propranolol is official in IP[1] 1996, USP[2] 2003 and BP[3] 1993. The USP 2003 recommends HPLC method for pure and dosage forms. The BP 1993 recommends potentiometeric titration method for analysis of propranolol in bulk and spectrophotometeric method for dosage forms. Literature survey[4-6] reveals that numerous methods are available for the estimation of propranolol. This paper presents a simple, accurate, sensitive, reproducible and economic method for determination of propranolol in bulk and tablet form.



(**1**) Propranolol-reagent complex

†GRY Institute of Pharmacy, Borowan, Khargone-451 228, India.

The pure drug sample was obtained from ONS Pharmaceuticals, Jaipur. 1-Chloro-2,4-dinitrobenzene (AR Grade) and methanol (spectroscopic grade) were obtained from Loba. The instruments include, UV-Visible spectrophotometer (Elico SL 160) and FTIR- 8300 (Shimadzu).

Procedure for bulk drug: Accurately weighed 100 mg of propranolol pure drug was dissolved in methanol to give a stock solution of 1000 mg/mL concentration. From this stock solution, working standard solutions of drug (4-16 µg/mL) were prepared by appropriate dilutions. Working standard solutions were scanned in the entire UV-visible range (200-800 nm). Standard solutions were prepared having concentration 4, 6, 8, 10, 12, 14 and 16 µg/mL. In these solutions, 1 mL of 0.01 % (w/v) 1-chloro-2,4-dinitrobenzene solution was added and kept for 0.5 h to complete the reaction. The absorbance maxima (λ_{max}) of propranolol: reagent complex was found to be 314.6 nm. The absorbances of these samples were measured at 314.6 nm and calibration curve was plotted. The absorptivity coefficient was determined using calibration curve.

Procedure for tablet formulations: 20 Tablets were weighed and ground to fine powder. An accurately weighed powder equivalent to 10 mg of propranolol was transferred in 100 mL volumetric flask. The powder was dissolved in 60 mL methanol and heated the resulting solution to 60 ºC and shaken for 15 min. After cooling, this was diluted to 100 mL with methanol and filtered through a sintered glass funnel (porosil G3). From this stock solution, working sample solutions were prepared by appropriate dilutions and analyzed by developed method.

The reaction occurred at room temperature. Optimization of reaction time was done by measuring the absorbance at an interval of 5 min up to 1 h. The optimum reaction time was found to be 0.5 h. Stability of complex was observed up to 120 min and it remained stable for 15 min.

All method validation parameter of ICH guidelines were applied. The results of analysis of tablet formulations are recorded in Table-1. Recovery studies (Table-2) carried out gave satisfactory results. The optical characteristics and regression equation is given in Table-3. The molar absorptivity and Sandell's sensitivity values show the sensitivity of method while the precision is confirmed by % relative standard deviation. The proposed method can be successfully applied for the estimation of propranolol in tablets.

TABLE-1
RESULTS OF ASSAY

Formulation	Label/claim (mg/tab)	Found (%)	Mean ± SD
X	40	99.3	
Y	40	98.7	99.27 ± 0.73
Z	40	99.8	

Average of 3 measurements.

TABLE-2
RECOVERY DATA

Amount of drug added (mg)	Recovery (%)	Mean ± SD
1	100.6	99.39 ± 0.68
2	99.8	
3	98.5	

TABLE-3
OPTICAL CHARACTERISTICS AND PRECISION

Parameters	Values
Beer's law limit (µg/mL)	4-16
Sandell's sensitivity (µg/cm/0.001 abs. unit)	0.1702
Stability of colored species (min)	15
Molar extinction coefficient (1 mol^{-1} cm^{-1})	2.713×10^3
Correlation coefficient	0.9986
Regression equation (y*)	
Slope (a)	0.0413
Intercept (b)	0.0651

*b + ac, where C is concentration in µg/mL and y is absorbance unit.

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