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NOTE

UV Spectrophotometric Determination of Duloxetine Hydrochloride

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Simple and sensitive UV spectrophotometric method for the determination of duloxetine hydrochloride having absorption maximum at 290 nm and method have been extended to pharmaceutical preparations. There is no interference from any common pharmaceutical additives and diluents. The method has been statistically evaluated and found to be precise and accurate.

Key Words: Spectrophotometry, Duloxetine hydrochloride.

Duloxetine hydrochloride a selective serotonin norephinephrine receptor blocker is chemically N-methyl-3-naphthalen-1-yloxy-3-thiophen-2-yl-propan-1-amine (Fig. 1). It is a potent dual reuptake inhibitor of serotonin, norephinephrine possessing comparable affinities in binding to norephinephrine transporter and serotonin transporter sites. Duloxetine works by preventing serotonin, norephine-phrine and to a lesser extent dopamine from being reabsorbed into the nerve cells in the brain specifically on the 5-HT_3, NE and D_2 receptors, respectively. It is used to treat major depressive disorders and general anxiety disorders. A survey of literature revealed few analytical methods of the drug in blood plasma as well as pharmaceutical formulations include HPLC[1,2] and LCMS[3,4]. An attempt has been made to develop a simple, rapid and reproducible UV spectrophotometric[5] method with greater precision, accuracy for the analysis of duloxetine hydrochloride in pure as well as pharmaceutical dosage forms.

All the chemicals used were of analytical grade. Spectral and absorbance measurements were made on UV-visible spectrophotometer-1700 with 10 mm matched quartz cells.

Preparation of standard solutions: Accurately weighed 100 mg of duloxetine hydrochloride was dissolved in 100 mL of methanol: water mixture (50:50 % v/v) and the solutions were diluted quantitatively with methanol: water mixture (50:50 % v/v) to obtain a final concentration of 40 µg/mL.

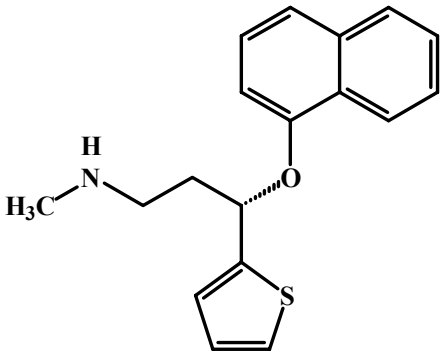

Fig. 1. Structure of duloxetine

Preparation of sample solutions: An accurately weighed amount of capsule powder of duloxetine hydrochloride equivalent to 100 mg was dissolved in 100 mL of methanol:water mixture (50:50 % v/v) and filtered. This solution was further diluted with methanol:water mixture (50:50 % v/v) so as to obtain a concentration of 40 µg/mL.

Proposed method for duloxetine hydrochloride: Aliquots of solution 1 to 5 mL (40 µg/mL) were transferred into of series of 10 mL volumetric flasks and the volume was brought up to 10 mL with methanol:water mixture (50:50 % v/v). The absorbance was measured at 290 nm against a blank. The amount of duloxetine hydrochloride present in sample solution was computed from its calibration curve.

The optical characteristics such as Beer's law limits, molar extinction coefficient per cent relative standard deviation, regression equation, correlation coefficient, % range of error were calculated and the results are summarized in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PERPOSED METHOD

Parameters	
λ_{max} (nm)	290
Beer's law limit (µg/mL)	4-20
Molar absorptivity (L mol^{-1} cm^{-1})	4.9×10^3
Sandell's sensitivity (µg cm^{-2}/0.001 absorbance unit)	0.066
Regression equation (Y = a + bC)	
Slope (b)	0.0239
Intercept (a)	-1.5×10^{-3}
Correlation coefficient (r)	0.9986
Relative standard deviation (%)*	0.69
% Range of error (confidence limits)*	
0.05 level	0.07
0.01 level	0.16

*Average of five determinations.

To evaluate the validity and reproducibility of the methods, known amounts of pure drug were added to previous pharmaceutical preparations and the mixtures were analyzed by the proposed method and the results are presented in Table-2. These results indicate that the method was simple rapid with reasonable precision and accuracy and applicable to various formulations of duloxetine hydrochloride.

TABLE-2
ESTIMATION OF DULOXETINE HYDROCHLORIDE IN PHARMACEUTICAL FORMULATIONS

Sample	Labelled amount (mg)	Amount found (mg) Proposed method	Recovery (%)*
Capsules I	40	39.86	99.65
Capsules II	40	39.48	99.45

*Recovery amount was average of five determinations.

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