Available online at **www.joac.info**

ISSN: 2278-1862

Journal of Applicable Chemistry

2019, 8 (4): 1909-1915

(International Peer Reviewed Journal)

Validated Stability-Indicating High-Performance Liquid Chromatographic Method for Determination of Duloxetine HCl Drug

Pravinsing S. Girase*

Department of Chemistry, JET's Z. B. Patil College, Dhule (MS), **INDIA**

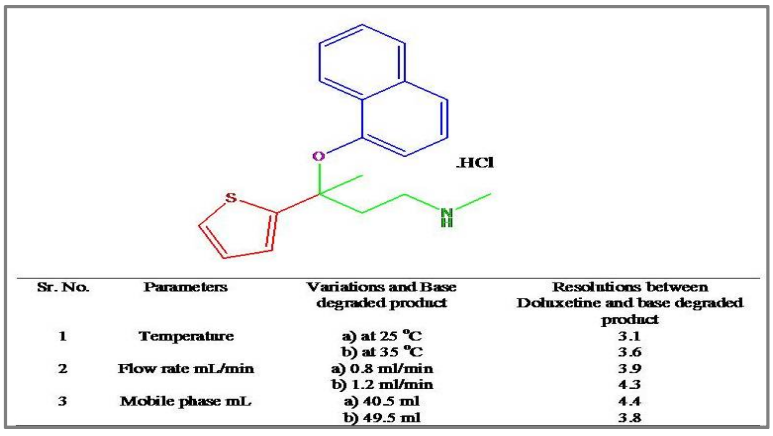
Email: psgirase65@gmail.com

Accepted on 21st June, 2019

ABSTRACT

A Green economic, rapid, sensitive reversed phase stability-indicating high- performance liquid chromatographic (HPLC) green economic validation assay method was developed and validated for quantitative determination of duloxetine hydrochloride in bulk drugs and the degradation products generated from forced decomposition. A gradient, reversed phase HPLC method was developed to separate the drug from the degradation on products, using a Kromasil C8 (150mm x 4.6 mm), 3u column and the mixture of 0.1% Triethyl amine and acetonitrile was used as mobile phase. The detect ion was carried out at wavelength 230 nm. The chromatographic resolution between its degraded products was found to be greater than three. The duloxetine hydrochloride was subjected to stress conditions of hydrolysis acid, base, oxidation (30% H_2O_2), and thermal degradation. The degradation was observed for duloxetine hydrochloride in base and in thermal hydrolysis. The mass balance was close to 100 in all the stress conditions. The degraded products were well resolved from main peak. The developed method was validated with respect to linearity, accuracy, recovery, precision, system suitability, selectivity, robustness and forced degradation studies prove the stability indicating ability of the method.

Graphical Abstract



Sr. No.	Parameters	Variations and Base degraded product	Resolutions between Doluxetine and base degraded product
1	Temperature	a) at 25 °C	3.1
		b) at 35 °C	3.6
2	Flow rate mL/min	a) 0.8 ml/min	3.9
		b) 1.2 ml/min	4.3
3	Mobile phase mL	a) 40.5 ml	4.4
		b) 49.5 ml	3.8

Keywords: Green economic Validation, Duloxetine hydrochloride, Stability indicating, RP-H PLC, Kromasil C8, Forced degradation.