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EVALUATION AND VALIDATION OF A UPLC METHOD FOR THE ESTIMATION OF DULOXETINE IN BULK DOSAGE FORM

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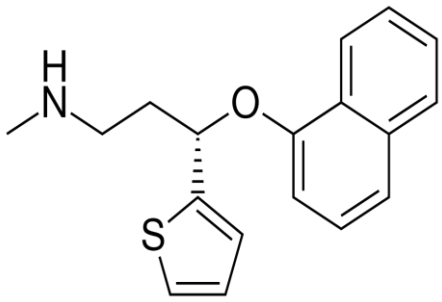
ABSTRACT

Duloxetine is a potential dual inhibitor of the reuptake of serotonin and norepinephrine. It has been approved by the US Food and Drug administration (USFDA) for the treatment of major depressive disorder and for the diabetic peripheral neuropathic pain. There has been comprehensive validation of the disclosed technique for its specificity, system appropriateness, linearity, accuracy and precision.

KEYWORDS: Duloxetine, USFDA and validation.

INTRODUCTION

Duloxetine HCl (+) - (s)-N-methyl-3-(1napthyloxy)-3-(thiophen-2-yl)-propan-1-amine (The Merck Index, 2001) is a potential dual inhibitor of the reuptake of serotonin and norepinephrine (SSNRI). It has been approved by the US Food and Drug administration (USFDA) for the treatment of major depressive disorder and for the diabetic peripheral neuropathic pain. It belongs to the class narcoleptics.



Chemical Structure of Duloxetine
Weight: 297.42 g·mol−1
Chemical Formula $C_{18}H_{19}NOS$
IUPAC (+)-(S)-N-Methyl-3-(naphthalen-1-yloxy)-3-(thiophen-2-yl) propan-1-amine

Experimental
Methodology
Method Validation
What we mean when we talk about "the analytical technique" is the method by which the analysis is carried out. All of the analytical procedures should be spelled out in great detail. The sample, the reference standard, and the reagents, as well as their preparations, the use of the equipment, the development of the calibration curve, the application of the formulas for the calculation, etc. There has been comprehensive validation of the disclosed technique for its specificity, system appropriateness, linearity, accuracy, precision, limit of detection, limit of quantification, and robustness.

RESULTS

Preparation of Standard Stock Solution
Preparation of Diluent
The Dope was measured out at a weight of 10 mg and weakened with a volume of 100 ml of versatile stage to form a 100 µg/ml stock arrangement of working arrangement. That had been measured to get ready for disintegration in versatile stage is included to the jar, and the Droxoled, and permitted to blend, taken after by sonication, which causes it to break down. In this case, the arrangement was sonicated for 10 minutes and after that sifted through a 0.2µ channel.

System Precision

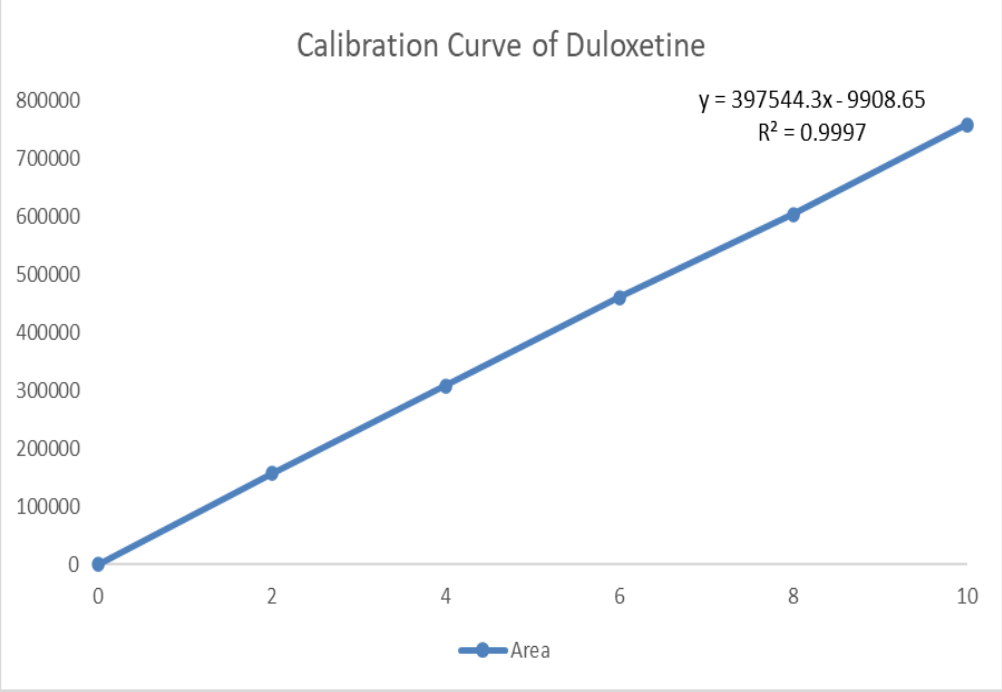
Parameters	Duloxetine
Theoretical plates ± % RSD	6055.11 ± 0.50
Asymmetry ± % RSD	1.08 ± 0.05
Repeatability (% RSD)	0.07

Method Precision

Replicate	*Duloxetine*		
S. No.	**Concentration Taken (µg/ml)**	**Area**	**%LC**
1	04.00	437888	99.98%
2		437973	99.96%
3		437947	99.97%
4		437846	99.99%
5		438248	99.90%
6		437849	99.99%
Average			99.96%
Std. Dev			0.03391
% RSD			0.03%
Standard weight			4mcg
Standard potency			99.99%

Linearity

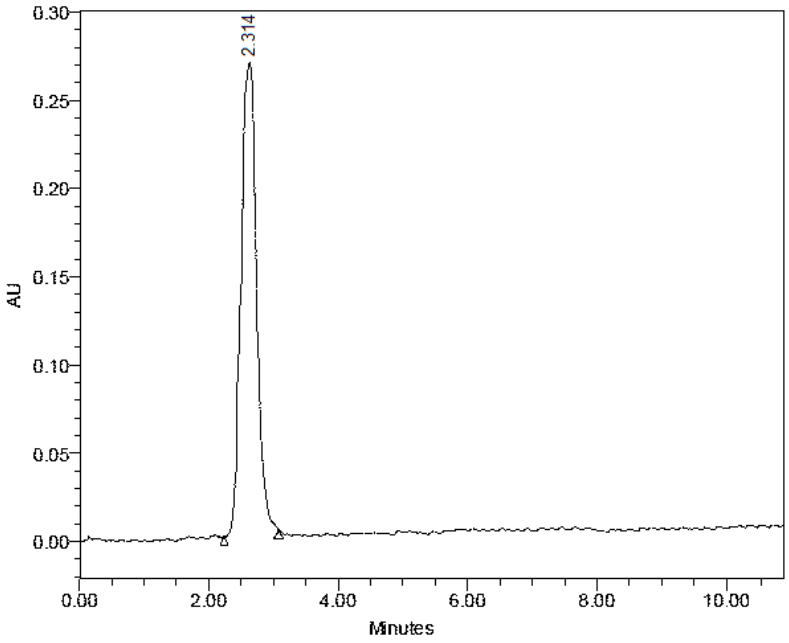
Duloxetine		
Linearity level	**Concentration in µg/mL**	**Area**
1	2 µg/mL	156447
2	4 µg/mL	307832
3	6 µg/mL	459588
4	8 µg/mL	603329
5	10 µg/mL	757785
Correlation co-efficient	0.9973	
Slope	9908.65	
Intercept	397544.3	



Ruggedness

Robustness Studies			
Parameter	**Value**	**Peak Area**	**% RSD**
Flow Rate	**Low**	438364	0.02%
	Actual	438425	
	Plus	438536	
Temperature	**Low**	438734	0.07%
	Actual	438856	
	Plus	439339	
Wavelength	**Low**	438638	0.10%
	Actual	438741	
	Plus	439436	

Assay Studies
Sample Control



Calculation formula for DULOXETINE

$$\%\ Assay = \frac{AT}{AS} \times \frac{W1}{100} \times \frac{1}{25} \times \frac{100}{W2} \times \frac{25}{1} \times \frac{AW}{LC} \times P$$

Sample Control (DULOXETINE)

$$\%\ Assay = \frac{437947}{439863} \times \frac{04.15}{100} \times \frac{1}{25} \times \frac{100}{04.24} \times \frac{25}{1} \times \textbf{Error!} \times$$

99.99 = 97.50%

CONCLUSION

Duloxetine was proven to be selective in boosting the accuracy and sensitivity in measurement, and a simple, accurate, and sensitive quantification technique was discovered for the detection of drug-related impurities in pharmaceutical serum powders. After the stress tests were done, only Duloxetine and its impurities remained, proving the procedure's stability-confirming potential. The specificity, linearity, limit of detection, accuracy, ruggedness, and/or robustness of the method were all evaluated, and determined to be in accordance with the new ICH requirements.

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