

Simple UV Spectrophotometric method development and Validation for determination of Lacosamide in bulk and its Tablet Dosage Form

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Abstract

A simple and reproducible UV spectroscopic methods have been developed and validated for the determination of lacosamide (LCM) in bulk and tablet dosage forms of two different brands. The standard and sample solutions were prepared using methanol: water (50:50 % v/v) as solvent. The maximum absorbance was obtained at 257 nm. Beer's Lambert's law was obeyed at the concentration range of 400 – 600 µg/ml and the correlation coefficient was found to be 0.9996. The developed method was validated according to ICH guidelines and was found to be accurate and precise for the determination of lacosamide in bulk and its tablet dosage form.

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Key words:

Lacosamide, UV spectrophotometry, method development, tablet formulation.

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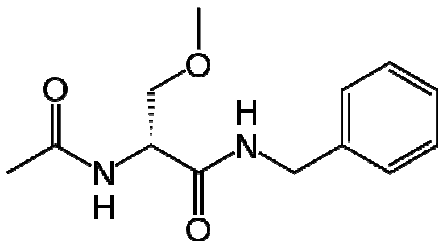
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INTRODUCTION

Lacosamide is the latest AED approved by US- FDA for adjunctive use in partial-onset seizures in patients 17 years of age and older [1,2]. It differs from all other approved AEDs in that it has two novel mechanisms of action and favourable pharmacokinetic and safety profiles. The potential for drug interactions with other AEDs and currently prescribed medications is very low. Overall there is a minimal dosing and clinical monitoring requirement with lacosamide. Lacosamide is (R)-2-acetamido-N-benzyl-3-methoxypropionamide[3]. The structure of lacosamide is given Fig.1. Lacosamide is a member of functionalized aminoacids. It occurs as a white to slight yellow crystalline powder with a molecular

weight of 250.294 g/mol. It is soluble in organic solvents such as ethanol, DMSO and dimethyl formamide, slightly soluble in acetonitrile, soluble in phosphate buffered saline at pH 7.2.

Fig 1: Structure of Lacosamide

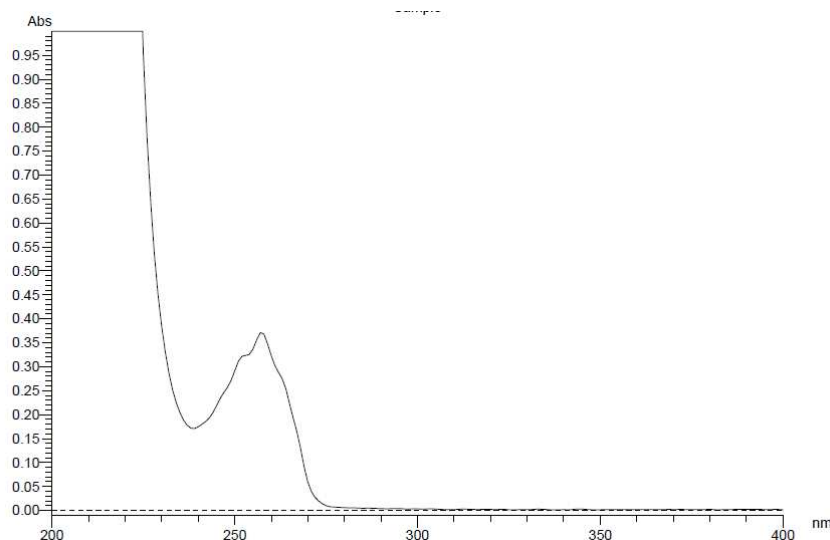


Spectroscopic method using zero order method and under curve method have been reported so far^[4,5]. Literature also reveals HPLC^[6,7] and LC-MS in tablet dosage form and in human and rat serum^[8,9].

The aim of the present study is to develop a simple, sensitive and reproducible UV spectroscopic method for Lacosamide in bulk and its tablet dosage form. The developed method was validated according to ICH guidelines.

MATERIALS AND METHODS

Fig. 2: UV spectrum of Lacosamide



Preparation of sample solution

Sample solution was prepared using two different brands of lacosamide tablets by taking 20 tablets

Chemicals and reagents

Lacosamide pure drug was obtained as a gift sample from Micro Labs, Chennai. Lacosamide tablets were procured from local pharmacy. The chemicals used for analysis are of analytical grade. Milli-Q water (Millipore Corporation, USA) was used. Methanol used was obtained from Merck Ltd. Mumbai.

Instrumentation

The analysis was carried out in Techcomp UV-2301 Spectrophotometer using methanol : water (50:50%v/v) as diluents at a maximum absorbance of 257 nm.

Preparation of standard stock solution

Standard stock solution of LCM was prepared by dissolving 312.5 mg in 25 ml methanol and 1 ml of this solution is further diluted to 25 ml using methanol : water, (50:50 v/v) to get a concentration of 500 µg. The resulting solution was scanned between 200 - 400 nm. The maximum absorbance was obtained at 257 nm. The UV spectrum of Lacosamide is given in Fig. 1.

from each separately and accurately weighed and powdered. The powder weight equivalent to the label claim was transferred to 25 ml standard flask and to

this 25 ml of methanol was added and the solution was ultrasonicated for 15 minutes. The 1 ml of this solution is transferred to 25 ml standard flask and made up to the volume using methanol : water mixture (50:50 v/v). The sample stock solution was filtered through Whatmann filter paper no.40 prior to use. The absorbance of the resulting solution was scanned at 257 nm. The amount of LCM present in each tablet is calculated using the absorbance value obtained. The assay results were given in Table 1.

Table 1: Assay of Lacosamide Formulation (Brand A and Brand B)

S. No.	Dosage Form	Label Claim (mg)	* Amount found (mg)		Amount (%)	
			Brand A	Brand B	Brand A	Brand B
1.	Tablet	100	99.98	100.15	99.98	100.15

*mean of three observations.

RESULTS AND DISCUSSION

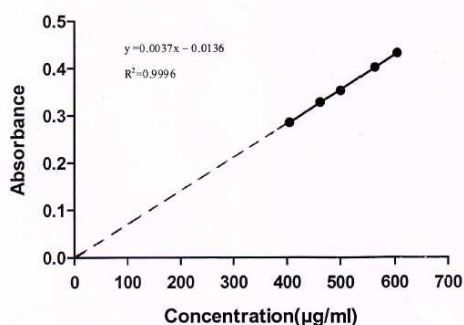
Method Validation

After the method development of UV Spectroscopy method, it has been validated according to ICH guidelines [10].

Linearity

Approximate volume of stock solution of 0.8, 0.9, 1.0, 1.1, 1.2 ml was diluted to 25 ml get a series of solutions containing 404.75, 462.55, 500.40, 562.90 and 604.60 µg/ml respectively. The solutions were scanned at 257 nm and a standard graph was drawn using absorbance versus concentrations. The graph was given in Fig.2.

Fig. 3: Calibration curve of Lacosamide



Accuracy

Accuracy was established using nine determinations over three concentration levels which cover the specified range in triplicates. Results were given in Table 2.

Table 2: Accuracy results of Lacosamide Formulation (Brand A and Brand B)

Level (%)	Amount added (mg/ml)	Brand A		Brand B	
		Amount Recovered (mg/ml)*	% Recovery	Amount Recovered (mg/ml)*	% Recovery
110	10	9.95	99.50	9.89	98.09
120	20	20.00	100.00	19.86	98.60
130	30	29.76	99.20	30.09	100.30

* each value corresponds to the mean of three determinations

Precision

Precision is the degree of agreement among individual test results when procedure is applied repeatedly with multiple samplings of a homogenous sample. Precision of Lacosamide was evaluated and the percentage relative standard deviation (%RSD) was found to be less than 1% which proves that the method was precise. Results were given in Table 3.

Table 3: Precision of Lacosamide Formulation (Brand A and Brand B)

Sample No.	Brand A		Brand B	
	Absorbance	% Amount	Absorbance	% Amount
1.	0.357	99.98	0.377	100.47
2.	0.359	100.07	0.371	99.86
3.	0.362	100.47	0.375	100.33
4.	0.362	99.98	0.376	100.53
5.	0.361	100.12	0.374	100.44
6.	0.368	100.36	0.367	99.90
	% Mean	100.16	% Mean	100.25
	SD	0.2	SD	0.3
	% RSD	0.19	% RSD	0.27

CONCLUSION

A rapid, accurate, precise and reproducible UV Spectroscopy method has been developed. The sample recoveries from the formulation was in good agreement with their respective label claims and the precision studies showed % RSD not less than 2.

Hence this method can be used for the routine analysis of Lacosamide in bulk and its tablet dosage form.

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