INTERNATIONAL JOURNAL OF PHARMACEUTICAL RESEARCH AND DEVELOPMENT (IJPRD)
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# VALIDATED SPECTROPHOTOMETRIC ESTIMATION OF LACOSAMIDE IN BULK AND TABLET DOSAGE FORMS

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***ABSTRACT***

*Two Simple, precise and economical UV methods have been developed and validated for the quantitative determination of Lacosamide in bulk and tablet dosage forms. The solutions of standard and sample were prepared in distilled water. Lacosamide has the absorbance maxima at 257 nm. Beer's law was found to be obeyed in the concentration range of 300-900 µg/mL. The developed method was validated according to ICH guidelines and was found to be accurate and precise. The proposed methods can be successfully applied for the estimation of Lacosamide in bulk and tablet dosage forms. Results of the analysis were validated statistically and by recovery studies.*

***KEYWORDS:*** *Lacosamide, Water, Zero order, AUC, Tablets.*

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## INTRODUCTION

Lacosamide [1,2] is a functionalized amino acid specifically synthesized as an anticonvulsant drug. It is chemically (2R) - 2 - (acetylamino) - N - benzyl - 3 - methoxypropanamide. It is uses an adjunctive therapy in the treatment of partial-onset seizures it is being investigated as a treatment for diabetic neuropathic pain.From the literature survey, it was found that Lacopsamide estimated by analytical method such as spectrophotometric methods, high-performance liquid chromatographic[3,4]. Apart from the above no other methods such as zero order derivative spectrophotometric method and area under curve method were reported for the quantitative determination of Lacopsamide in tablet dosage forms. The developed method was simple, precise, specific and accurate. The statistical analysis proved that method is reproducible and selective for the analysis of Lacosamide in bulk drug and tablet formulations.

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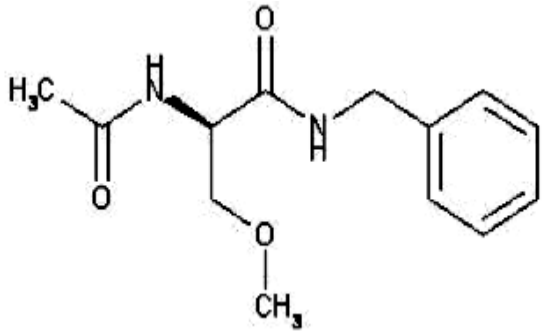



**Chemical structure of Lacosamide**

**OBJECTIVES**

The target of this study is to develop new, simple and fast analytical methods by UVSpectrophotometry[5] to quantify Lacosamide in bulk and its tablet dosage forms together with its latter validation study. This validation study is defined as the laboratory studies by which it is established that the performance characteristics of the method meet requirements for the intended analytical application. This work describes the validation parameters stated by the International Conference on Harmonization[ICH] guidelines includes specificity, linearity, range, accuracy, precision, robustness to achieve analytical methods with acceptable characteristics of suitability, reliability and feasibility

## EXPERIMENTAL WORK

**Materials:**

Spectral runs were made on a Shimadzu UV Visible spectrophotometer, model-1800 (Japan) with spectral bandwidth of 0.5 nm, wavelength accuracy of }0.3 nm with automatic wavelength corrections using a pair of 10 mm quartz cells. All Spectral measurements were done using UV-Probe 2.33 software. Glassware's used in each procedure were soaked overnight in a mixture of chromic acid and sulphuric acid rinsed thoroughly with double distilled water and dried in hot air oven. Lacosamide reference standard was kindly provided by Ranbaxy Pharma, Ahmedabad. Commercial tablet formulations vimpat were used for present study containing 50mg 100 and 200mg of Lacosamide, respectively. Water was used as solvent for dilutions. All the solutions were analyzed on the day of preparations.

**Preparation of working standard drug solution**

The standard Lacosamide (100 mg) was weighed accurately and transferred to volumetric flask (100 ml). It was dissolved properly and diluted up to the mark with water to obtain final concentration of 1000 µg/ml and the resulting solution was used as working standard solution.

**Analysis of marketed formulations**

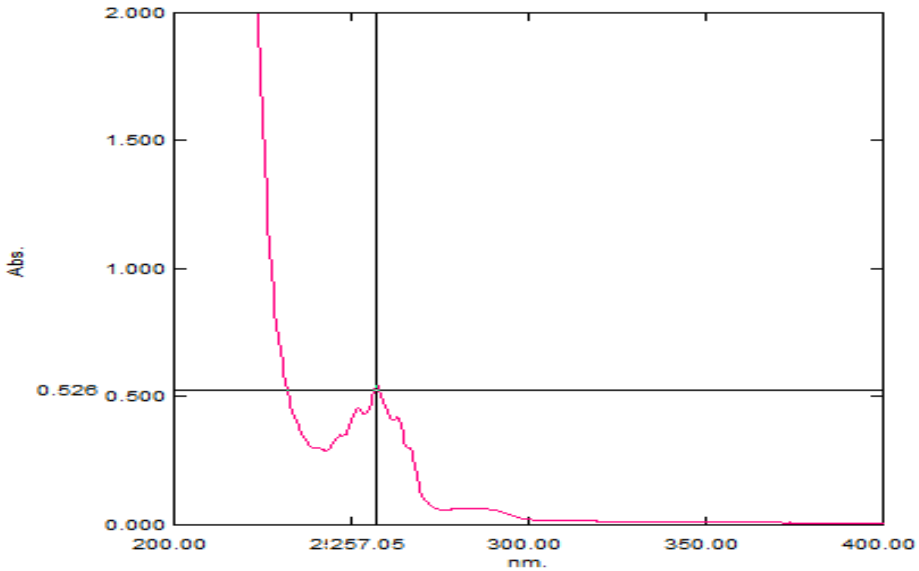
For the estimation of Lacosamide in tablets formulation, 20 tablets were weighed and triturate to fine powder. Tablet powder equivalent to 100 mg of Lacosamide for each was weighed and transfer into 100 ml volumetric flask than dissolved with water and further diluted with water. It was kept for ultra-sonication for 30 min; this was filtered through Whatman filter paper No. 41 and then final dilution was made with methanol to get the final stock solution of 1000 µg/ml. From this stock solution, various dilutions of the sample solution were prepared and analysed.

**Zero order spectrophotometry:**

The solutions were scanned in the range 400- 200 nm using water as blank to obtain zero order UV-Spectra of Lacosamide (Fig. 1). The peak was observed at 257 nm which was used as an analytical wavelength for measurement of

absorbance. Calibration curve was obtained by plotting absorbance at 257nm against the concentration of Lacosamide. The regression equation and correlation coefficient were determined. Beer's- Lamberts law was obeyed in the concentration range of 300-900 µg/ml. The concentration of the sample solution was determined using the regression equation.

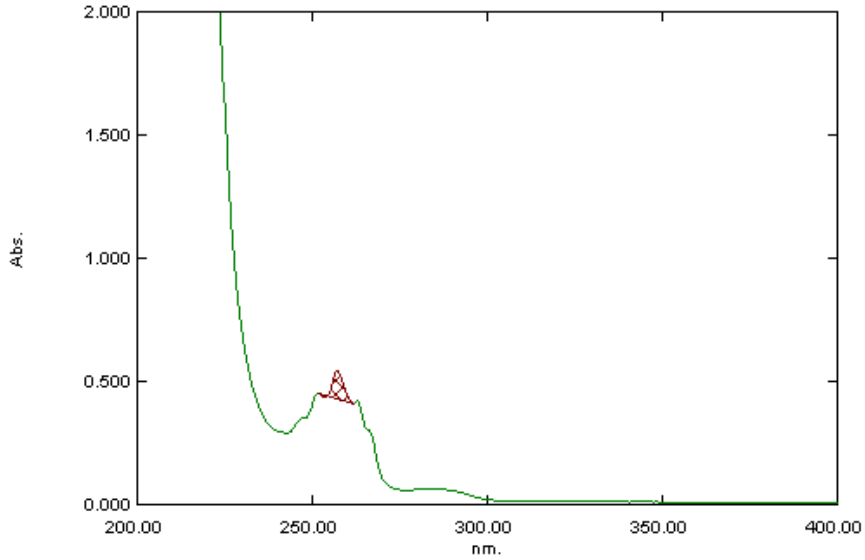
**Figure-1:** Zero order spectra of Lacosamide showing absorbance at 257 nm




**AUC spectrophotometry:**

In this method, Zero order UV-Spectra were obtained and Area Under the Curve [AUC] between the range 252-262 nm were measured using UV-Probe as illustrated in Fig. 2. Calibration curve was obtained by plotting AUC between 252-262 nm against the concentration of Lacosamide. The regression equation and correlation coefficient were determined. Beer's- Lamberts law was obeyed in the concentration range of 300-900 µg/ml. The concentration of the sample solution was determined using the regression equation.

**Figure-2:** Zero order spectra of Lacosamide showing Area Under Curve [AUC] from 252 to 262 nm




**VALIDATION**

The objective of method validation is to demonstrate that the method is suitable for its intended purpose as it is stated in ICH guidelines[6,7,8] Q2A and Q2B. Recommend validation characteristics depend on the type of

analytical procedure. Method validation characteristics were tested in accordance with ICH guidelines for each method. Linearity (correlation coefficient) was tested in the given range for each method. Repeatability and Intermediate precisions were obtained as % Relative Standard Deviation [% RSD] using six replicates per day. We have established method accuracy (% Recovery and SD) by spiked placebo recovery method. Limits of detection and quantification were provided for Lacosamide using standard deviation of intercept. To establish ruggedness of the proposed methods, assays for two different brands of Lacosamide tablets were performed by two different analysts on two different days.

**RESULTS AND DISCUSSION**

Lacosamide has the absorbance maxima at 257 nm Zero order derivative spectra, showed sharp peak at 257 nm. The polynomial regression data for the calibration plots showed good linear relationship in the concentration range of 300-900 µg/ml and given in Table 1. Recovery studies were carried out at three different levels i.e. 50 %, 100 %, and 150 % by adding the pure drug to the previously analysed tablet powder sample. Percentage recovery for Lacosamide was determined by all the methods and they were found to be under acceptance criteria which are 98% to 102 % according to ICH guidelines. The results are in Table 1. The percentage recovery value indicates non interferon from excipients used in formulation. The result of analysis of marketed formulation is shown in Table 2. The reproducibility and accuracy of the method was found to be good, which was evidenced by low standard deviation.

**Table-1:** Validation parameters.

| Validation Parameters | Zero-order method | AUC method |
|---|---|---|
| *Absorption Maxima (nm)* | 257 | 252-262 |
| *Beer's-Lambert's range (µg/ml)* | 300-900 | 300-900 |
| *Regression equation (y)** | | |
| *Slope (b)* | 0.000915 | 0.000622 |
| *Intercept (a)* | 0.00021 | 0.001143 |
| *Correlation coefficient* | 0.999 | 0.999 |
| *Sandell's sensitivity (mcg / $cm^2$-0.001 absorbance units)* | 1.10294 | 1.6042 |
| *Precision (% RSD)* | | |
| *Intraday precision* | 0.1383 | 0.20118 |
| *Interday precision* | 0.1644 | 0.239152 |
| *Accuracy* | 98.41 | 99.54 |
| *Limit of detection (µg / ml)* | 1.1222 | 1.65244 |
| *Limit of quantification (µg /ml)* | 3.4009 | 5.70441 |

* Mean ± SD are obtained from 6 determinations.

**Tabel-2:** Analysis of formulations.

| Tablet | Label claimed (mg) | Amount found (mg) | | %Recovery ± SD** | |
|---|---|---|---|---|---|
| VIMPAT | 100mg | Zero-order method | AUC method | Zero-order method | AUC method |
| | | 99.45 | 98.289 | 100.605 ± 0.104 | 98.360± 0.114 |

* Obtained from 6 determinations

**CONCLUSION**

The proposed analytical methods are rapid, accurate, precise and reproducible and hence can be used for the routine analysis of Lacosamide in bulk, tablet dosage forms. The sample recoveries from the formulation was in good agreement with their respective label claims, which suggested non-interference of excipients in the estimation. The most striking features of these methods are its simplicity and rapidity, not requiring tedious sample preparations such as extraction of solvents, heating, degassing which are may needed for HPLC procedure. All the above result indicates that, the methods employed here are very simple, accurate, economic and rapid for routine analysis of the Lacosamide.

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