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Research Article

# SPECTROPHOTOMETRIC ESTIMATION OF LEVOSULPIRIDE IN BULK DRUG AND FORMULATIONS

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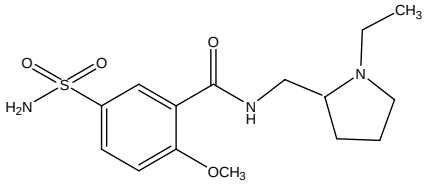
**ABSTRACT**

Three new, simple, precise and economical Spectrophotometric methods have been developed for the estimation of Levosulpiride in bulk and pharmaceutical formulations. Levosulpiride was estimated at 291 nm in 0.1N NaOH (Method A), 288.7 nm in Methanol (Method B) and first order derivative spectrum in Methanol at 282.4 nm with n=1 (Method C). Linearity range was found to be 25-125 µg/ml in all the three methods. The apparent molar absorptivity was found to be 2.14 X $10^3$ $lmol^{-1}cm^{-1}$ (Method A), 2.39 X $10^3$ $lmol^{-1}cm^{-1}$ (Method B) and 2.07 X $10^3$ $lmol^{-1}cm^{-1}$ (Method C). The proposed methods were successfully applied for the determination of Levosulpiride in pharmaceutical formulations. The results demonstrated that the procedure is accurate, precise, reproducible (relative standard deviation < 2%), while being simple, economic, less time consuming, can be validated statistically, by recovery studies and were found to be satisfactory.

**keywords:** Levosulpiride, UV spectrophotometry, Derivative spectroscopy, Pharmaceutical dosage form.

## INTRODUCTION

Levosulpiride, a purified levo-isomer of sulpiride, chemically it is 5-(aminosulfonyl)-N-[(1-ethyl-2-pyrrolidinyl)methyl]-2-methoxy benzamide. It is not official in any pharmacopoeia. It is listed in The Merck Index[1] and Martindale, The Complete Drug Reference[2].




Levosulpiride

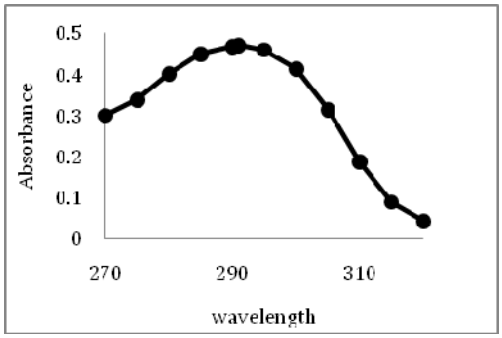
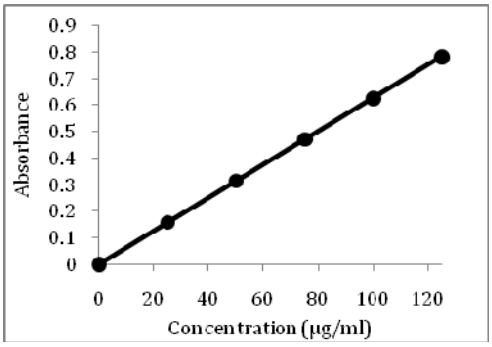



**Fig. 1: Wavelength range selection of Levosulpiride (Method A)**

## MATERIALS AND METHODS

Pure sample of Levosulpiride was obtained from Sun Pharmaceuticals Industries., Jammu as a gift sample. All chemicals used were of analytical grade 0.1N NaOH and Methanol. Shimadzu 1700 UV-Visible Spectrophotometer and Systronics 119 UV-Visible spectrophotometer was used with quartz cell of 10mm path length. Tablets of 100mg strength were procured from local pharmacy of commercial brand that is Nexipride (SUN PHARMA). About 100 mg of Levosulpiride (pure or formulation) was accurately weighed and dissolved in 100 ml of their respective solvents (1 mg/ml). The final concentration of Levosulpiride was made to 500 µg/ml in their respective solvents. In case of formulations twenty tablets were

Levosulpiride is a $D_2$-dopamine receptor antagonist and commonly prescribed to patients with psychosis, depression and functional dyspepsia. At low doses, levosulpiride increases dopaminergic neurotransmission, primarily by the blocking of the dopamine autoreceptors, which inhibits the pre-synaptic dopamine synthesis and release of dopamine[3]. Compared with racemic and dextro-forms, the levo-form of sulpiride has greater central antidopaminergic activity[4], antiemetic and antidyspeptic effects and lower acute toxicity[5]. A survey of literature has revealed simple UV-Spectrophotometric method in 0.1N HCl and RP-HPLC method for estimation of Levosulpiride in bulk drug and formulation[6]. The objective of the present study is to develop simple, precise, accurate and economic analytical methods for estimation of Levosulpiride.




**Graph 1: Calibration Curve of Levosulpiride (Method A)**

accurately weighed and powdered and then 100 mg of Levosulpiride equivalent was taken for the study. For preparation of different concentrations, aliquots of stock solutions were transferred into a series of 10ml standard flasks and volumes were made with respective solvents. Five different concentrations were prepared in the range of 25-125 µg/ml of Levosulpiride in two solvents. The solution were scanned in the spectrum mode from 400 nm to 200 nm wavelength range Levosulpiride was estimated at 291 nm in 0.1N NaOH (Method A), 288.7 nm in Methanol (Method B), and 282.4 nm in the first order derivative spectra were obtained in Methanol at n=1 (Method C) respectively. The method was applied for the sample solution of known concentration and was found to be satisfactory for the analysis of tablet formulations.

**Table 1: Summary of validation parameters**

| Parameters | Method A | Method B | Method C |
|---|---|---|---|
| λ max | 291nm | 288.7nm | 282.4nm |
| Beer's law limits(C) | 25-125µg/ml | 25-125µg/ml | 25-125µg/ml |
| Molar Absorptivity | | | |
| Lit $mol^{-1}$ $cm^{-1}$ | 2.149 X $10^3$ | 2.399 X $10^3$ | 2.07 X $10^3$ |
| Sandell's Sensitivity | | | |
| (mcg/cm2 – 0.001 absorption units) | 0.018 | 0.025 | 0.0424 |
| Regression equation | | | |
| Slope b | 0.0062 | 0.007 | 0.0060 |
| Intercept a | 0.004 | 0.001 | 0.001 |
| Correlation coefficient(r) | 1.0008 | 1.0004 | 1.0007 |
| Limit of Detection (LOD) | 0.8244 | 0.6142 | 0.3602 |
| Limit of Quantification (LOQ) | 2.4983 | 1.8614 | 1.0916 |
| % RSD or CV | 0.3281 | 0.2472 | 0.1436 |
| Range of Errors | | | |
| Confidence limits with 0.05 level | 0.00129 | 0.00108 | 0.00054 |
| Confidence limits with 0.01 level | 0.00191 | 0.00161 | 0.00080 |

**Table 2: Result of assay**

| Label claim | Amount obtained (mg) Proposed method. | | Percentage recovery | |
|---|---|---|---|---|
| | 0.1N NaOH | Methanol | 0.1N NaOH | Methanol |
| 100mg | 99.80 | 99.60 | 99.8 | 99.6 |

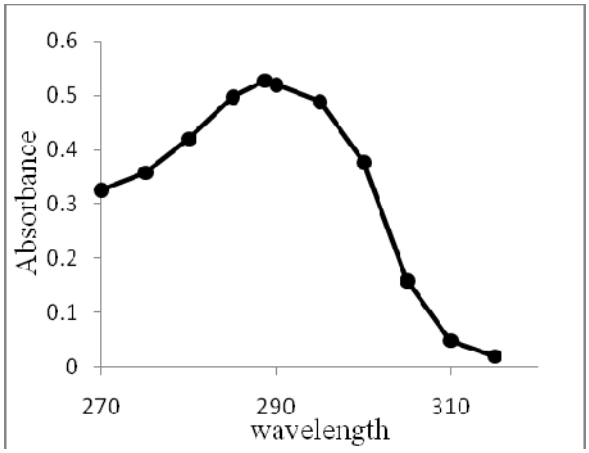
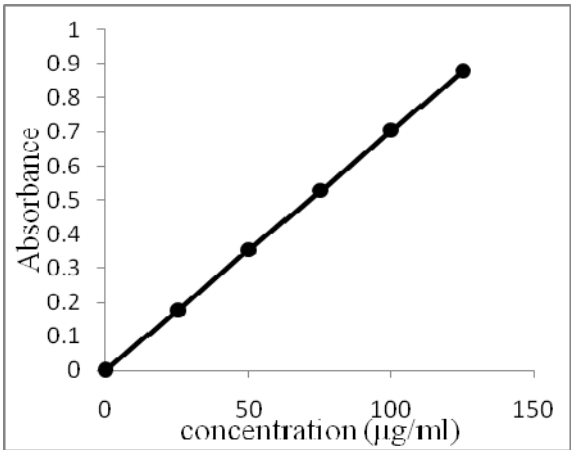



**Fig. 2: Wavelength range selection of Levosulpiride (Method B)**




**Graph 2: Calibration curve of Levosulpiride (Method B)**

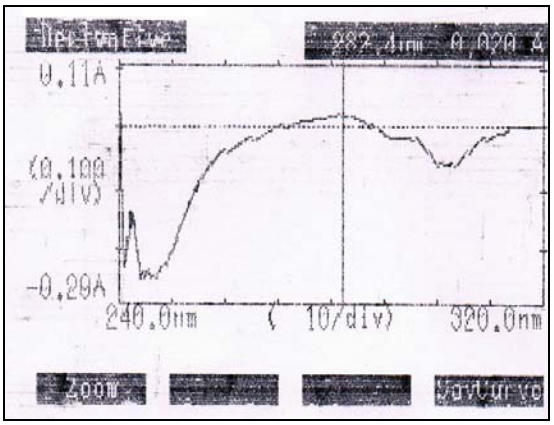
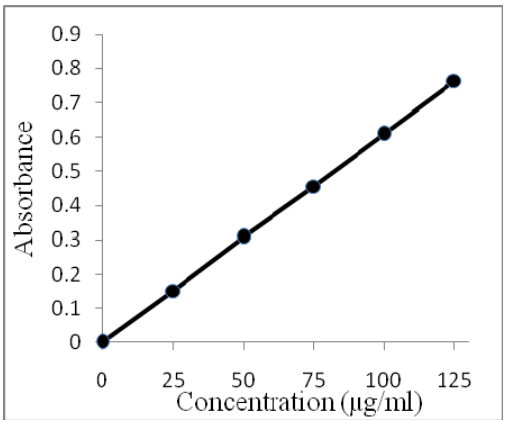



**Fig. 3: Wavelength range selection of Levosulpiride (Method C)**




**Graph 3: Calibration curve of Levosulpiride (Method C)**

**RESULTS AND DISCUSSION**

The UV spectrum of Levosulpiride was found to be at 291 nm in 0.1N NaOH, 288.7 nm in Methanol and first order derivative spectrum in Methanol at 282.4 nm with n=1. The derivative spectroscopy method applied has the advantage that it locates the hidden peaks in the normal spectrum when the spectrum is not sharp and it also eliminates the interference caused by the excipients and the degradation products present, if any, in the formulation. The methods were validated for accuracy, precision, ruggedness and robustness. The % RSD values less than 2 indicate the methods are accurate and precise. Ruggedness of the proposed methods was studied with the help of two analysts. Robustness of the methods was studied in two different laboratories using two different UV-visible spectrophotometers. The results did not show any statistical difference between operators and environmental conditions, suggesting that methods developed were rugged and robust. The results from validation studies are shown in table 1. The amount of drug determined was in good agreement with the label claim as shown in table 2.

**ACKNOWLEDGEMENT**

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