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UV SPECTROSCOPIC ESTIMATION OF LEVOSULPIRIDE IN BULK DRUG AND FORMULATIONS

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ABSTRACT

A simple and sensitive uv spectrophotometric method has been developed for the estimation of Levosulpiride in tablet dosage form was described. From the solubility data phosphate buffer (pH 8) was used as solvent and shows absorption maximum at 291 nm. The Beer's Law range is 10-100 µg/ml. The linear regression for method found to be 0.999. When tablet dosage forms where analyzed, the results obtained by the proposed methods are in good agreement with the labelled amount and the developed method was validated statistically as per ICH guidelines. Conclusion: The developed method is simple, sensitive, specific and can be successfully employed in routine analysis of Levosulpiride Pharmaceutical dosage forms.

KEYWORDS: Levosulpiride, UV spectroscopy, validation, ICH Guideliness, Qutantification.

INTRODUCTION

Levosulpiride is chemically known as N-[(2S)-1-ethylpyrrolidin-2-yl]-2-methoxy-5-sulfamoylbenzamide. It is used for the treatment of the signs and symptoms of, antipsychotic agent anti-angina, antidepressant, medication that has the dual properties of a nitrate and antagonist of dopamine D2 receptors. In humans, the action dopamine is to stop brain from sending signals to the body from which human stop acting as antipsychotic behaviour. D2 dopamine act on both central and peripheral levels. A literature survey revealed no spectrophotometric methods for the estimation of levosulpiride in pure and tablet dosage form. HPLC and LC-MS methods were reported for the estimation of Levosulpiride. In the present report, the paper describes a simple and sensitive UV spectroscopic method for the determination of levosulpiride in pure and tablet dosage form.

MATERIALS AND METHODS

Pharmaceutical grade of was kindly Levosulpiride gifted from Lupin Pharmaceuticals, Pune. The brand of tablets used was Levosulpiride and procured from a local Pharmacy. All the solvents and chemicals used were of analytical reagent grade and procured from Qualigens fine Chemicals (Mumbai).

Instruments

Kerron P5 Series Precision Electronic Balance, Model Bl -3003, T60 UV-Visible spectrophotometer with 1 cm matched quartz cells, Sonicator Sonica.

Method – Simple UV- Spectroscopy[1-3]

Ultrasonic cleaner model 2200 MH. The solubility of levosulpiride was determined in a variety of solvent ranging from nonpolar to polar using essentially a method of Schefter and Higuchi.[6] The drug was found to be very soluble in phosphate buffer (pH 8), chloroform, glacial acetic acid, ethanol, Distilled Water and freely soluble in 0.2 N methanolic hydrochloric acid. Considering the economic factor and the drug were stable in phosphate buffer (PH 8) for 3 h, phosphate buffer (PH 8) was selected as the solvent for method.

Preparation of standard stock solution[4-10]

10 mg Levosulpiride was accurately weighed and transferred into a 50 ml standard flask and dissolved with minimum quantity of phosphate buffer (pH 8) and made up to 50 ml with more phosphate buffer (pH 8) (100 µg /ml).

Selection of λ_{max} and stability studies

The standard stock solution was further diluted with phosphate buffer (pH 8) to get 10 µg/ml concentration (1 ml to 100 ml). The solution was scanned between 200 and 400 nm using phosphate buffer (pH 8) as blank. From the spectrum obtained, 291 nm was selected as λ_{max} for the analysis of levosulpiride. Stability studies were performed and levosulpiride was found to be stable for 3 hrs.

Calibration graph and linearity

In this method, the aliquots (0.5–2.5 ml) of standard stock solution of levosupiride were transferred into 100 ml standard flasks and made up to the mark with phosphate buffer (pH 8). The absorbance was measured

at 291 nm against phosphate buffer (pH 8) as blank. The sample solutions were found to be linear from 10-100µg/ml. The calibration curve was plotted between concentration and absorbance.

Quantification of formulations

Thirty tablets of formulation containing 5 mg of levosulpiride were accurately weighed to find out the average weight and powdered. Transferred the powdered tablets equivalent to 50 mg of levosulpiride into a 50 ml conical flask, extracted with phosphate buffer (pH 8) for three times (3 x 10 ml), sonicated for 15 min and produced to 50 ml with phosphate buffer (pH 8) using a standard flask. Half of the solution was filtered using Whatmann filter paper No. 41. From this clear solution, 5 ml was transferred to a 25 ml standard flask and produced to obtain 100 µg/ml solution with phosphate buffer (pH 8). The absorbance was measured at 291 nm using phosphate buffer (pH 8) as blank. The amount of levosupiride present in each formulation was calculated from the slope and intercept of respective calibration curve.

Recovery studies

From each of the preanalyzed formulation, known quantities were taken (2.5 µg/ml) and the raw material solution was added in ascending amounts (2.5, 7.5, 12.5, 17.5 and 22.5 ml) to 100 ml standard flasks. The contents were mixed well, finally made up to the mark and filtered. The absorbance was measured at 291 nm using phosphate buffer (pH 8) as blank and the amount of drug recovered from each formulation was calculated by the mathematical relation followed by Sane.

Statistical Validation[11-12]

The obtained results were treated for statistical validation parameters like Standard Deviation (SD) and Percentage Relative Standard Deviation (% RSD).

RESULTS AND DISCUSSION

The solubility profile of levosulpiride was determined as per procedure followed by Schefter and Higuchi. Using various polar to nonpolar solvents and from the solubility studies the category of solvents for Rasagiline was hereby confirmed as freely soluble in phosphate buffer (pH 8), Dist. Water, very soluble in 0.1 M Hydrochloric acid, Acetonitrile, Acetic acid, Chloroform, Ethanol, and 0.1 M methanolic Hydrochloric acid.

Phosphate buffer (pH 8) was selected as solvent for simple UV-method because of its easy availability, cost factor and high stability. The proposed method for estimation of levosulpiride in pure and in tablet dosage form were found to be simple and sensitive. The drug in phosphate buffer (pH 8) shows λ_{max} at 291 nm, with linearity range of 10 – 100 µg/ml.

The optical parameters like Beer's law limits (05-25 µg/ml), Sandel's sensitivity (0.159776521), correlation coefficient (0.99998), slope (0.0062), intercept (0.004), limit of detection (0.8244), and limit of quantification (2.4983) were calculated for levosulpiride in phosphate buffer (pH 8) and produced in Table 1. Quantification of levosulpride.

3 from tablets dosage form was performed and the amount present was determined by average of six replicate analysis and the amount in percentage purity is found to be 100.94 and shown in table 1s.

To evaluate the accuracy of the method and for knowing the interference from excipients recovery study was performed. The Recovery of Levosulpiride by UV-Spectroscopic method was found to be 99.88 and the results are shown in Table 3. The values of co-efficient of variance were satisfactorily low and recovery was close to 100 % indicating reproducibility of the methods. The excipients in the formulation did not interfere in the accurate estimation of levosulpiride in tablet dosage form.

From the results, the UV-Spectroscopy method was found to be more precise. Since none of the spectroscopic method is reported for the estimation of phosphate buffer (pH 8) in tablet dosage form, this developed method can be applied in industries for routine analysis of the levosulpiride in tablet dosage form.

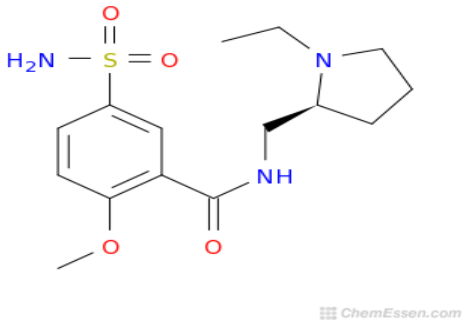

Fig. 1: Structure of Levosulpiride.

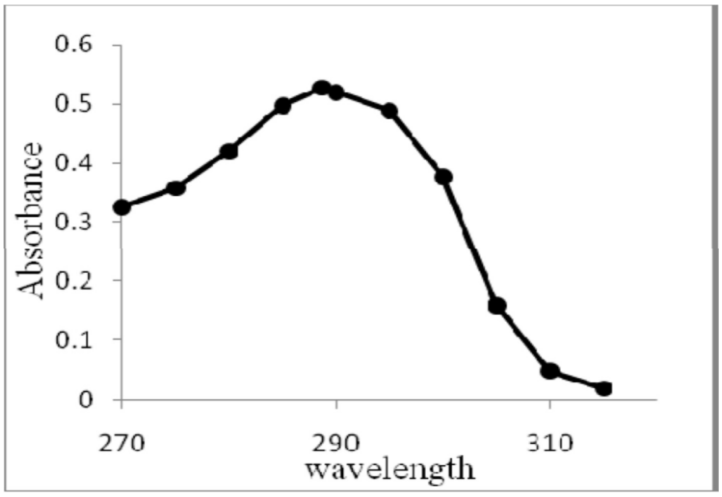

Fig. 2: UV Spectrum of Levosulpiride in Phosphate Buffer (10µg/ml).

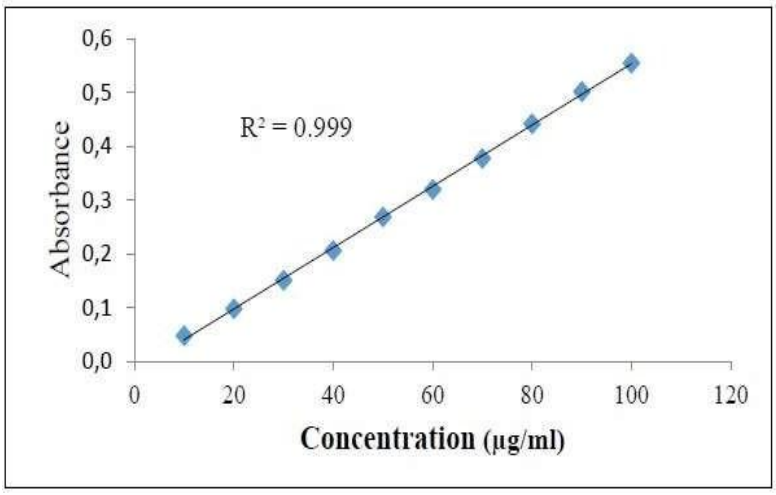

Fig. 3: Calibration Curve of Levosulipiride in Phosphate Buffer (pH 8) (10µg/ml).

Absorption VS Concentration

Table 1: Optical Characteristics of Levosulpiride.

Parameters	Method
λmax (nm)	291
Beers law limit (µg/ml)	10-100
Correlation coefficient (r)	0.999
Régression équation (y=mx+c)	Y=(0.0062X + 0.004)
Slope(m)	0.0062
Intercept(c)	0.004
LOD (µg/ml)	0.8244
LOQ (µg/ml)	2.4983
Standard error of mean of Regression line	0.1758658

Table 2: Results of Analysis of Commercial Formulations.

S. No.	Label claim (mg/Tab)	Amount found (mg)*	Percentage purity*	Average	S.D	% R.S.D	S. E
1	50	49.95	99.96				
2	50	50.28	100.18				
3	50	49.42	99.61	99.88	0.399561	2.66374	0.178580
4	50	49.51	99.67				
5	50	49.98	99.98				

SD is standard deviation, % RSD percentage relative standard deviation

*Average of six determinations

Table 3: Results of Recovery Studies.

S. No.	Amount Present (µg)	Amount Added *(µg)	Amount Found* (µg)	Amount Recovered* (µg)	Recovery%
1	1.5	1.5	2.9542	1.4542	96.94
2	1.5	4.5	5.7346	4.2346	94.00
3	1.5	7.5	8.8210	7.321	97.60
4	1.5	10.5	12.1021	10.6021	100.95
5	1.5	13.5	14.9342	13.4342	99.48
6	1.5	16.5	17.0683	15.5683	94.30

*Average of six determinations

SUMMARY AND CONCLUSION

The proposed analytical methods are simple, reliable, rapid, sensitive, reproducible and accurate for the estimation of Oseltamivir.

The method adopted for our studies are Simple UV-Spectroscopic method

The drug samples were analysed by UV spectroscopy using phosphate buffer as solvent and the average content of drug present in the formulation was found to be 99.56 mg (99.56%).

The above method does not suffer from any interference due to common excipients. Therefore, it was shown that the proposed method could be successfully applied to estimate commercial pharmaceutical products containing Oseltamivir. Thus, the above studies and findings will enable the quantification of the drug for future investigation in the field of analytical chemistry.

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REFERENCES

1. Beckett, A.H. and Stenlake, J.B. Practical Pharmaceutical Chemistry, part B. 4th edn.,CBS publishers and Distributors, New Delhi, 2002; 279-298,158-316.
2. Chatwal, R. Gurdeep and Sham, K. Anand. Instrumental Methods of Chemical Analysis.5th Revised edn., Himalaya publishing House, Mumbai, 2000; 2: 160.
3. Sharma, Y. R. Elementary Organic Spectroscopy.4th Revised and enlarged edn., S.Chand and Company Ltd., New Delhi, 2007; 11.
4. Alexeyev, V.N. Quantitative Chemical Semi micro Analysis. 1st edn., Satish Kumar Jain For CBS Publishers and Distributors, New Delhi, 1994; 15-16.
5. Anonymous. The Indian Pharmacopoeia volume-I. The controller of publication, NewDelhi, 1996; A-44.
6. Anonymous. The Indian Pharmacopoeia. The controller of Publication, New Delhi, II, Appendix 13.1,A-145.sir, 1996.
7. Anonymus. The Science and Practice of Pharmacy. 21st edn., Wolters Klower Health Pvt. Ltd., New Delhi., 2007; 623.
8. A Rapid RP-HPLC Method Development And Validation For The Quantitative Estimation of Levosulpride in capsules, D. Vijaykumar, K. Balaraju, A. Ashokkumar, *International Journal of pharmacy and pharmaceutical science*., 2015; 7: 10.
9. UV Spectrophotometric assay method development and validation of Levosulpride in capsules Syed Shashed Hussain, G. Bhavani, A. Ashok Kumar, *International Journal of Pharmacy and Pharmaceutical science*., 2015; 7: 8.
10. A simple and a cheap UV Spectrophotometric assay method development and validation of Levosulpridein capsules, P. Soundarya, Mounika, Laxmi Prasanna, K. Sandhya, Sandhya, A. Ashok Kumar, *International Journal of Pharmacy and Pharmaceutical science*., 2015; 7: 8.
11. Rajesh Kumar e*tal*, Development and Validation of spectroscopic method for estimation of Levosulpiride in bulk drug and tablet dosage form.
12. ICH, Q2A, Text on Validation of Analytical Procedures, International Conference on Harmonization, Geneva, October, 1991; 1-5.
13. ICH, Q2B, Validation of Analytical Procedures: Methodology, International Conference on Harmonization, Geneva, November, 1996; 1-8.