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UV SPECTROPHOTOMETRIC DETERMINATION OF LEVOCETERIZINE IN BULK AND DOSAGE FORMS

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ABSTRACT

In the present study, a simple, precise, accurate and low cost U.V. spectrophotometric method is developed for the determination of Levoceterizine in bulk and dosage forms. The absorbance of aqueous Levoceterizine solutions are measured by UV- visible spectrophotometer at a wave length of 230 nm. This method obeys Beer's Law in the concentration range of 5-17.5 µg/mL in aqueous media. As per linearity studies, the correlation coefficient, slope and standard deviations are 0.9998, 0.029 and 0.1772 respectively. The % recovery of the assay of the drug in the sample in this method is 99.2 and the method is sensitive in presence of the excipients in the dosage form. According to ICH guidelines the linearity, accuracy, precision, LOD, LOQ are studied and the method is validated. Hence, the present method is suitable for the accurate, precise, sensitive and low cost determination of Levoceterizine in pure and formulations.

Key words: Levoceterizine, Dosage form, UV-spectrophometry, Method development, Validation

INTRODUCTION

The IUPAC name of Levoceterizine is [2-{4-[R]-(4-chlorophenyl) phenylmethyl] piperazinyl]ethoxy]-acetic acid .Its molecular formula is $C_{12}H_{25}ClN_2O_3$ and molecular mass is 388.88 gms/mole . The structure of of Levoceterizine is represented by Fig .1 . It is a non- sedative anti- histaminic agent H-1 receptor antagonist and used in the treatment of allergic rhinitis . The UV spectra of Levoceterizine is shown in Fig.2. Levoceterizine is available as **Vozet** tablets of dosage 5mg/tablet in the local market. As per literature, Levoceterizine is determined individually by liquid chromatography-electrospray tandem mass spectrometry[1] , HPLC method [2] and simultaneously with other drugs by HPLC methods [3-7]. It is also determined by visible spectrophotometric method individually [8] and simultaneously with other drugs [9-13]. But, no U.V.spectrophotometric method is reported in the literature for the determination of Levoceterizine in bulk and pharmaceutical dosage forms. Hence, the authors report an useful UV method for the determination of Levoceterizine in pure and pharmaceutical dosage form.

MATERIALS AND METHODS

Instruments: Sartorious balance model –TTA225D, ID NO QC1 017 electronic balance is used for weighing .A Shimazdu UV-2450 PC series UV – visible spectrophotometer with slit width 2.0 nm, light source change wave length 360.0nm and wave length range of 200-400nm with sampling interval 1.2 is used for measuring the absorbance of the solutions.

Chemicals and reagents: Levoceterizine is a gift sample from Esteem formulations Hyderabad. All the chemicals used in the validation process are of analytical grade and supplied by Bharat Scientifics, Hyderabad.

Prepartion of solutions: Standard stock solution preparation (100µg/mL): Accurately 10mg of

Levoceterizine is weighed and transferred into 100 mL volumetric flask , some distilled water is added , sonicated to dissolve, filtered and made upto to the mark by water.

Standard solution preparation (10µg/mL): In to a 100mL volumetric flask 10mL of the stock solution is pippetted out , some distilled water is added , sonicated to dissolve , filtered through filter paper and made upto the mark by water. The resulting solution is used for UV spectrophotometric determinations.

Sample solution preparation: Nearly 20 **Vozet** tablets are grind to powder and accurately powder equivalent to 10mg of Levoceterizine is transferred in to 100mL volumetric flask, some distilled water is added, sonicated to dissolve, filtered and made upto the mark by water.10mL of the above solution is transferred into 100mL volumetric flask, some water is added, sonicated to dissolve, filtered and made up to the mark by water. This solution is used for the assay determination of the sample.

METHOD VALIDATION:

The present UV spectrophotometric method is validated as per ICH guidelines for accuracy, precision, linearity, ruggedness and sensitivity

Recovery studies (Accuracy): By the addition of standard API of Levoceterizine to the pre-analyszed sample and the subsequent recovery of the total assay by the present method, the accuracy of the method is determined. To the standard solutions of Leveceterizine, 80 %, 100% and 120 % of API`s of Levoceterizine are added and the resulting solutions are analyzed by the present method . The amounts of Levoceterizine present in the solutions and the amounts recovered are shown in Table 1 . %Recovery of Levoceterizine is 100 ± 2 indicating that the method is accurate.

Precision: The precision of a method is in agreement with the results obtained when the method is applied to different aliquots of a homogeneous solution .Samples are analyzed within a day and within different days. Intraday precision is determined by analyzing solutions of 8 µg/mL, 10µg/mL and 12µg/mL concentration three times within a day (Table 2). Inter day precision is determined by analyzing the samples daily once in a day in 3days.

Linearity: The linearity of the method is determined by taking the absorbance of six linear solutions of different concentrations and a calibration curve is constructed between concentration and absorbance. In this method linearity is observed in the concentration range of 5-17.5 µg/mL with correlation coefficient of 0.9998. The amounts of Levoceterizine present in the linear solutions are shown in Table 3 and the calibration curve is shown in Fig.3

Ruggedness: The ruggedness of an analytical method is determined by the analysis of the same sample under different conditions such as by different analysts, by different instruments etc. Presently the ruggedness of the method is determined by the analysis of the samples by different analysts under identical conditions. The results of ruggedness are shown in Table 4.

Repeatability: Repeatability is determined by the analysis of six solutions of Levoceterizine six times. The results of repeatability are shown in Table 5.

Determination of the assay of the sample VOZET : Six identical solutions of sample vozet are taken and their absorbances are measured. By statistical methods the % RSD is determined. The result of analysis of the dosage form Vozet is shown in Table 6.

Students 't'-test and variance ratio test or F-test:

The % Assay determination of the sample by the present method with that of the reference method is compared by student "t"-test and F-test for its accuracy and precision and the values are given in the Table 7.

RESULTS AND DISCUSSION

The absorbances of different Levoceterizine solutions are taken at 230 nm wave length. Levoceterizine solutions obeys Beer`s Law in the concentration range 5-17.5µg/mL with correlation coefficient of 0.9998.The optical characteristics of Levoceterizine are shown in Table 8.By the present method the sample solutions are analyzed and the % of the drug found is 99.2, which is in the range 100±1. The accuracy of the method is determined by the addition of known amounts of API`S of Levoceterizine to the pre-analyzed sample and the total amounts of assay present in the solutions are determined by the present method. The %RSD of the determinations of accuracy are less than 2, hence the method is accurate .By the inter day and intraday precision analysis of the Levoceterizine solutions under identical conditions the precision of the method is determined. The %RSD of the precision studies is less than 2, hence the method is precise. The ruggedness is determined by analyzing the samples by different

analysts under identical conditions. The % RSD is less than 2, hence the method is rugged. Solutions of Levoceterizine are analyzed six times and the repeatability is determined. The %RSD of the repeatability studies is less than 2, and hence the method is repeatable. The LOD and LOQ are determined, they are in the limits and hence the method is sensitive. Same solutions of the sample **VOZET** tablets are analyzed six times, found that the % recovery of the assay of the sample is within the limits 100 ±1. In the students t-test $t_{cal} < t_{table}$, the null hypothesis is substantiated i.e the % amounts of the drugs determined by the two methods are the same with a certain probability. In the variance ratio test or F-test, $F_{cal} < F_{table}$, then the two standard deviations are not significantly different. Hence, the method may be used for the determination of Levoceterizine in dosage forms.

CONCLUSION: The U.V-Spectrophotometric method presently developed is simple, accurate, precise, cost effective and sensitive for the determination of Levoceterizine in bulk and dosage forms without any interference from the excipients present. Hence, this method may be used for the routine analysis of Levoceterizine in quality control laboratories.

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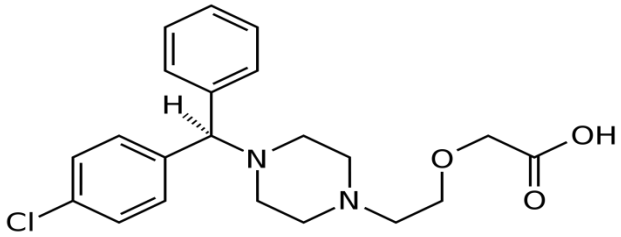

Fig. 1 Chemical structure of Levoceterizine

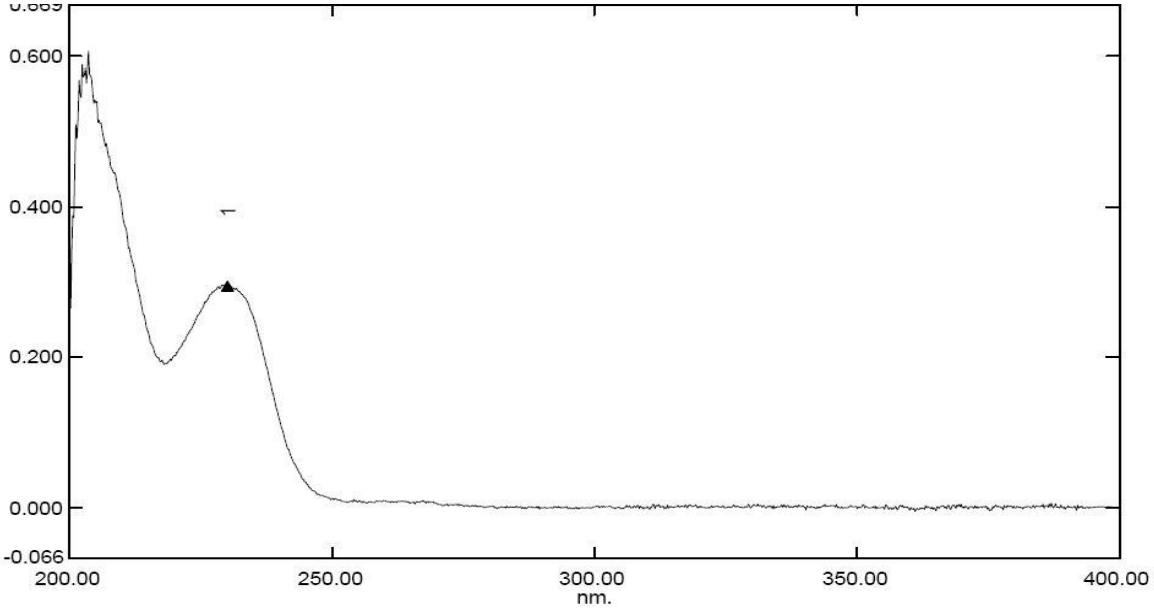

Fig. 2 U.V spectrum of Levoceterizine

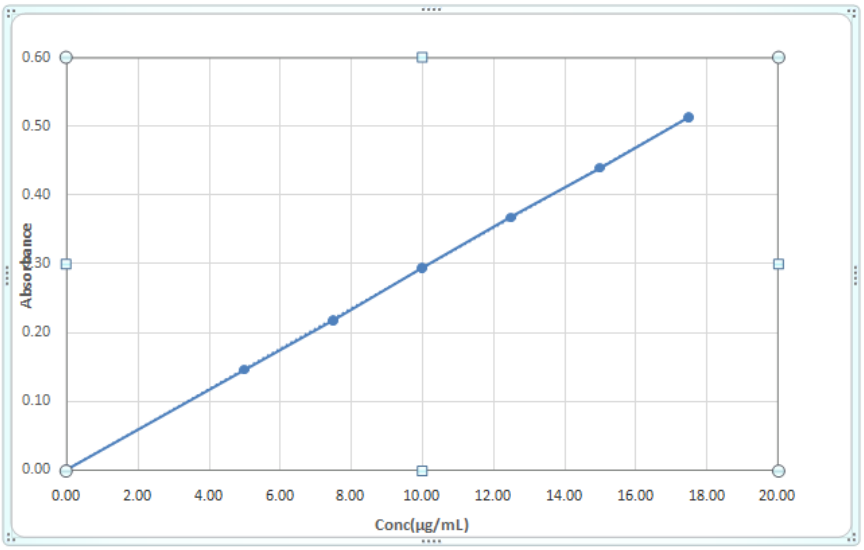

Fig.3 Linear curve of Levoceterizine

Table 1 Amounts of Levoceterizine recovered

Sl.No.	Level of the solution%	Amount taken µg/mL	Amount of API added µg/mL	Total amount present µg/mL	Amount recovered	% of recovery
1.	80	10	8	18	17.95	99.72
2.	100	10	10	20	19.94	99.7
3.	120	10	12	22	21.94	99.72

Table 2 Results of precision studies

Sl.No.	Level %	Conc. of solution µg/mL	Intraday % RSD	Inter day %RSD
1	80	8	0.065	0.069
2	100	10	0.052	0.04
3	120	12	0.046	0.043

Table 3 Amounts of Levoceterizine present in the linear solutions

Sl.No.	Level of the solution%	Amount of the Drug µ g/mL	Absorbance
1	25	5	0.146
2	50	7.5	0.218
3	75	10.0	0.294
4	100	12.5	0.368
5	125	15.6	0.44
6	150	17.5	0.514

Table 4 Results of ruggedness

Sl.No.	Amount taken	Analyst – I	%RSD	Analyst – II	% RSD
1	10 µg	9.94 µg	0.052	9.93µg	0.048

Table 5 Results of Repeatability

Sl.No.	Amount of the drug taken µg	Amount found µg	% Recovery	% RSD
1	10	9.94	99.4	0.082

Tables 6 Results analysis of Pharmaceutical Dosage form VOZET

Sl.No.	Amount of Toradol taken	Amount found	% of Assay
1	10 mg	9.92 mg	99.2

Table 7 Results of analysis of tablets by the present method and the reference spectrophotometric method – statistical comparison of the results (t and F tests):

S.no	Amount of drug in each tablet (mg)	% of the drug found by the present method	% of the drug found by the reference method[8]	t_{cal}	t_{table}	F_{cal}	F_{table}
1	10	99.2±0.61	98.48±0.9	1.794	3.25	2.177	6.39

Table 8 Optical characteristics of Levoceterizine

Sl.No	Parameter	Value
1.	Wave length of absorbance measurements	230 nm
2.	Regression Equation	Y=0.029X
3.	Slope (S)	0.029
4.	Correlation coefficient (r)	0.9998
5.	Beer's law limits	5-17.5/ μg/mL
6.	Standard deviation (σ)	0.1772
7.	LOD (3.3 σ/S) μg/ML	20.164
8.	LOQ (10 σ/S) μg/ML	61.103

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