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DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF LEVOCETIRIZINE DIHYDROCHLORIDE

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Spectrophotometry, Validation, Levocetirizine Dihydrochloride, Antihistamine

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ABSTRACT: Levocetirizine Dihydrochloride is an orally active, non-sedative antihistamine drug. To determine the assay content of Levocetirizine Dihydrochloride drug substance, a very simple, accurate, specific, and precise UV-Spectrophotometric method has been built up as well as evaluated. The suggested method comprises dissolving Levocetirizine Dihydrochloride in distilled water and subjecting the consequential solution to UV Spectroscopic measurement. An absorption maximum was found to lie at about 230 nm and the measurements were carried out at this wavelength. Beer's law was followed in the concentration range of 4 to 32 µg/ml. The linearity showed on the calibration curve between concentration and absorbance by the line equation of y = 0.0304x + 0.0002 (R^2 = 0.9997). Reproducibility by repeating methods as %RSD was found to be less than 2%. The results of the accuracy and precision were found very satisfactory and here the suggested method was statistically validated as per the ICH guidelines in terms of specificity, linearity, accuracy, precision and robustness. Validation studies have discovered that the method is simple, specific, rapid, reproducible, precise, accurate and economical which is useful for the routine analysis of Levocetirizine Dihydrochloride.

INTRODUCTION: Levocetirizine Dihydrochloride is the third-generation antihistamine that is non-sedative, and it is derived from cetirizine that is a second-generation antihistamine [1, 2, 3]. This is a racemic mixture and R-enantiomer of the Cetirizine hydrochloride which has antihistaminic properties. Its chemical name is Acetic acid, [2 - [4 - [(R) - (4 - chlorophenyl) phenylmethyl] - 1 - piperazinyl] ethoxy]-, dihydrochloride; (2-{4-[(R)-(4-Chlorophenyl) phenylmethyl] piperazin-1-yl} ethoxy) acetic acid dihydrochloride and the chemical formula is $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$. Its molecular weight is about 461.82 [4, 5, 6, 7].

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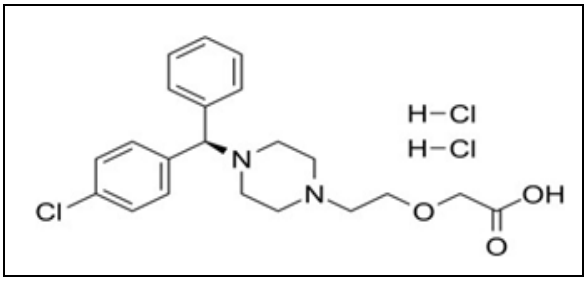

FIG. 1: LEVOCETIRIZINE DIHYDROCHLORIDE

Levocetirizine Dihydrochloride is usually prescribed to treat a runny nose, sneezing and watering eyes, itching as well as rashes [8, 9]. This antihistamine can also help to treat allergy by inhibiting the activity of the histamine in the human body and it has a quick onset of action. Levocetirizine Dihydrochloride helps to inhibit the histamine to bind with its receptors but doesn't prevent the release of histamine [10, 11]. Literature survey reveals that very few methods have been developed for analysis of Levocetirizine

Dihydrochloride drug substance. The present investigation was aimed to develop an accurate, rapid and reproducible method [12, 13].

MATERIALS AND METHODS: The instruments used were UV/Visible Spectrophotometer and PG UV 1600 analytical balance. Levocetirizine dihydrochloride pure drug was obtained from Almelo Pharmaceuticals Pvt. Limited, Hyderabad as gift sample with 99.99% w/w assay value and was used without further purification. All chemicals and reagents used were of analytical grade.

Preparation of Standard Stock Solution: Standard drug solution of levocetirizine Dihydrochloride was prepared by dissolving 100 mg levocetirizine dihydrochloride using distilled water in 100 ml volumetric flask and volume was made up to mark with distilled water to obtain stock-I solution of 1000 µg/ml concentration. From that taken 4 ml solution and volume was made up to 100 ml with distilled water to obtain 40 µg/ml concentration (Stock-II). For obtaining clear solution, solution was ultra - sonicated.

Preparation of Calibration Curve: Calibration curve was prepared in distilled water at λ_{max} 230 nm using UV/Visible Spectrophotometer. Suitable dilutions were made using this stock solution of 40 µg/ml (Stock-II) to get the solutions in the range of 4 µg/ml to 32 µg/ml. The calibration curve was plotted.

Preparation of Sample Solution: Ten tablets were weighed and powdered. The amount of tablet powder equivalent to 25 mg of levocetirizine dihydrochloride was weighed accurately and transferred to 100 ml volumetric flask containing distilled water and the volume was made up to the mark. The solution was filtered through Whatman filter paper. Adequate quantity of solution was suitably diluted to get a concentration of 30 µg/ml of levocetirizine dihydrochloride. The absorbance was measured against blank. The drug content of the preparation was calculated using a standard calibration curve. Amount of drug estimated by this method.

RESULTS AND DISCUSSION:

Linearity: From the graph it was found that levocetirizine dihydrochloride obeys beers law and the linearity concentration lies between 4- 32 µg/ml. The linearity data and calibration curve were shown in **Table 1** and **Fig. 2.**

TABLE 1: CALIBRATION CURVE OF LEVOCETIRIZINE

Concentration (µg/ml)	Absorbance
0	0
4	0.128
8	0.246
12	0.362
16	0.475
24	0.727
32	0.978

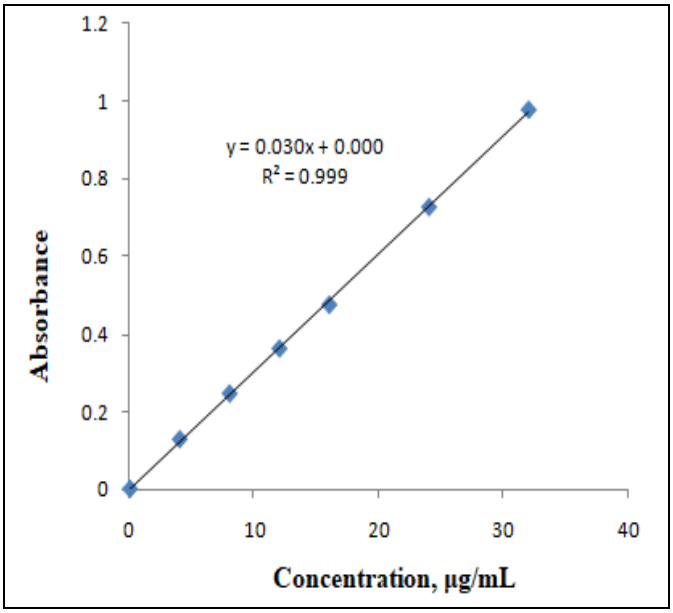

FIG. 2: CALIBRATION CURVE OF LEVOCETIRIZINE DIHYDROCHLORIDE

Discussion: Calibration curve was plotted, and correlation coefficient was found to be 0.9997. So, there was a good correlation between absorbance and concentration.

Precision: Intraday and Interday precision data were shown in **Table 2** and **3** respectively.

TABLE 2: INTRADAY PRECISION DATA OF LEVOCETIRIZINE DIHYDROCHLORIDE

Concentration (µg/mL)	Absorbance
16.0	0.475
16.0	0.478
16.0	0.472
16.0	0.478
16.0	0.477
16.0	0.473
MEAN	0.4755
Std. deviation	0.0025
% RSD	0.544

TABLE 3: INTERDAY PRECISION DATA OF LEVOCETIRIZINE DIHYDROCHLORIDE

S. no.	Concentration (µg/mL)	Intraday Absorbance Day-1	Interday Absorbance Day-2
1	16.0	0.475	0.473
2	16.0	0.477	0.479
3	16.0	0.478	0.475
4	16.0	0.473	0.477
5	16.0	0.471	0.473
6	16.0	0.471	0.478
MEAN		0.473	0.4758
STD. DEV		0.0027	0.0025
% RSD		0.573	0.538

Discussion: The % RSD for Intraday and Interday precision was found to be < 2%. It indicates that the method was precise.

Limit of Detection and Limit of Quantification: The LOD and LOQ data was shown in **Table 4.**

TABLE 4: LOD AND LOQ DATA

Parameters	Levocetirizine dihydrochloride (µg/mL)
LOD	0.19
LOQ	0.58

Discussion: LOD and LOQ values for levocetirizine dihydrochloride was found to be 0.19 µg/mL and 0.59 µg/mL. It indicates that the method was sensitive.

Accuracy:

Recovery Studies: Recovery studies were carried out by spiking the samples solution with standard solution at 50%, 100%, and 150% at 3 replicates and data was shown in **Table 5.**

TABLE 5: ACCURACY DATA OF LEVOCETIRIZINE DIHYDROCHLORIDE

Sample (% level)	Amount Taken (µg/mL)	Amount Added (µg/mL)	Amount Recovered (µg/mL)	% Recovery	Average
50	6	3	8.95	99.4	99.2
50	6	3	8.93	99.2	
50	6	3	8.91	99.1	
100	6	6	12.14	101.1	101.1
100	6	6	12.12	101.0	
100	6	6	12.16	101.3	
150	6	9	15.12	100.8	100.8
150	6	9	15.10	100.6	
150	6	9	15.18	101.2	

Discussion: The average % recovery of levocetirizine dihydrochloride was found to be in between 98-102%.

Robustness: Robustness data of method was shown in **Table 6.**

TABLE 6: ROBUSTNESS DATA OF METHOD

S. no.	Wavelength (λ_{max})	Absorbance
1	228	0.469
2	230	0.474
3	232	0.470

Discussion: There was no much variation in the absorbance with change in wavelength.

Stability: Sample solution of levocetirizine containing 6 µg/ml was taken to test the solution stability. The data of stability was shown in **Table 7.**

TABLE 7: STABILITY DATA OF LEVOCETIRIZINE DIHYDROCHLORIDE

Time	% Assay
Initial	99.5%
24 Hours	99.2%

Discussion: It was observed that the difference in the result was NMT 2% for formulation, indicating stability of levocetirizine dihydrochloride.

CONCLUSION: The developed method was found to be simple, sensitive, accurate, precise, reproducible, and can be used for routine quality control analysis of Levocetirizine dihydrochloride in bulk and pharmaceutical formulation.

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CONFLICT OF INTEREST: Authors declare no conflict of interest.

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