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A Validated UV Spectroscopic Method for determination of Levamisole HCl

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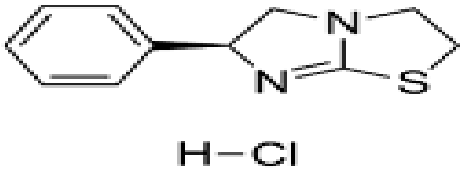
ABSTRACT:

A UV spectroscopic approach that is appropriate for Levamisole hydrochloride was developed and confirmed in this work. Accuracy, precision, LOD, LOQ, recovery study, and range were examined as validation parameters throughout the method's development using 0.1N HCl as the solvent at 216 nm. With a regression correlation of 0.998, the established technique was determined to be accurate and precise, making it suitable for routine analysis of Levamisole hydrochloride in any dose form.

INTRODUCTION:

Levamisole hydrochloride chemically known as 2, 3, 5, 6–tetra hydro –6 – phenylimidazo [2,1b], thiazole hydrochloride is used to treat parasitic worm infection. The drug appears to restore depressed immune function rather than to stimulate response to above-normal levels. Levamisole can stimulate formation of antibodies to various antigens, enhance T-cell responses by stimulating T-cell activation and proliferation, potentiate monocyte and macrophage functions including phagocytosis and chemotaxis, and increase neutrophil mobility, adherence, and chemotaxis.[1]



The UV spectrophotometric method is one of the commonest and economical method for determination of any drug substance. The aim of this work was the development and fully validation of a new UV spectrophotometric method, which can be more economical and simpler than the official methods and with other methods published. The UV spectrophotometric method is simpler than the others studied because it does not need derivative and chemometric assistance. Moreover, this method can be used in dissolution studies because it uses its own dissolution medium as diluent [2-3].

Determination of drug substance is that the most vital facet of any drug development whether or not in bulk or together, an acceptable technique should be developed therefore on make sure that any drug either in dose type orbulk type is identified. Thetactic dev elopmentensures thatquantity of specific drug is si mply determined. The validation parameters ensure that the developed technique is precise, correct and reproducible and might be used for routine analysis of Levamisole in bulk and combined dose type.[4]

I. MATERIALS & METHODS:

Instrumentation:

The spectrophotometric approach was carried out using a UV-Visible Spectrophotometer (UV- 1600 SHIMADZU). The weights were all performed using a digital ledger (Shimadzu AUW-220 model)

Chemicals and reagents:

I got a complimentary sample of Levamisole HCl with the batch number "LEV 1110002" from Encore Pharmaceuticals in Paithan, Aurangabad. Dewormis, a local market, sold GSK-manufactured tablets with 50 mg of Levamisole HCl each.

Get the typical stock solution ready:

To make a stock solution of 100 µg/ml of

Figure 01: Structure of Levamisole HCl

Levamisole HCl, a standard drug solution was generated by precisely weighing 10 mg of the medication and dissolving it in 0.1N HCl. The volume was then increased to 100 ml [5-6].

Analytical Wavelength Determination:

A 10 ml volumetric flask was used to transfer 0.8 ml of the standard stock solution. 0.1N HCl was added till the volume reached 10 ml. The solution with 8µg/ml was then scanned from 200 to 400 nm, as described in references 5 and 6.

Getting the Calibration Curve Ready:

Volumes of0.2,0.4,0.6,0.8,1.2, and 1.4 in aliquots

10 millilitre volumetric flasks were filled to the top with 0.1N HCl after transferring millilitre portions of stock solutions. A range of 2, 4, 6, 8, 10, 12, and 14µg/ml were used to construct the serial dilution series. The maximum absorption was recorded at 216 nm [5-9].

Validation of the UV Method: Linearity and Range

At doses ranging from 2 to 14µg/ml, the drug's linear response was confirmed. To get the calibration curve, we plotted the analyse the relationship between absorbance and concentration using linear regression. We were able to derive the Levamisole HCl calibration curve equation from the literature [5-9].

Precision:

Recovery studies were conducted to evaluate the method's accuracy. The % recovery was determined after each solution was repeated

three times. Studies of intra- and inter-day fluctuation [5–9] proved the method's accuracy.

Critical Detection and Quantification Limits:

The values of LOD and LOQ were determined using the following equations: LOD = 3.3σ/S and LOQ = 10σ/S.

S represents the calibration curve's slope and Ϲ stands for the residual standard deviation.

Investigation into Recovery:

Recovery experiments were used to study the method's accuracy. Three concentrations of Levamisole HCl standard were used for the recovery: 80, 100, and 120 percent. Each recovery level's recovery samples were prepared according to the aforementioned process. We then used the calibration curve to determine the % recoveries after analysing the solutions [7–12].

II. RESULTS & DISCUSSION:

Analytical Wavelength:

The maximum absorption was found to be at the wavelength of 216nm hence the wavelength for levamisole HCL was found to be 216nm as shown in figure: 02

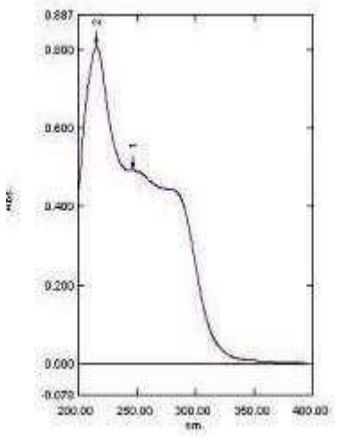


Figure 02: A typical UV Spectrum of Levamisole HCl at 216nm

Calibration Curve:

The results of absorbance for all the prepared concentrations were plotted i.e. Concentration vs. Absorbance the method was found to be linear over the prepared concentration range with the standard equation y=0.1013x+0.0201 and Regression value was found to be 0.9987, as shown in figure: 03. From the calibration data obtained it was found that the regression coefficient was less than 1 which is within the limits of Beer lamberts' law.

Table 01: Calibration Curve Data of Levamisole HCl

Sr. No.	Concentration (µg/ml)	Absorbance ± SD
1	2	0.219 ±0.26
2	4	0.425 ±0.15
3	6	0.623 +0.95
4	8	0.831 ±0.54
5	10	1.038 ±0.3
6	12	1.263 ±0.1
7	14	1.412 ±0.4

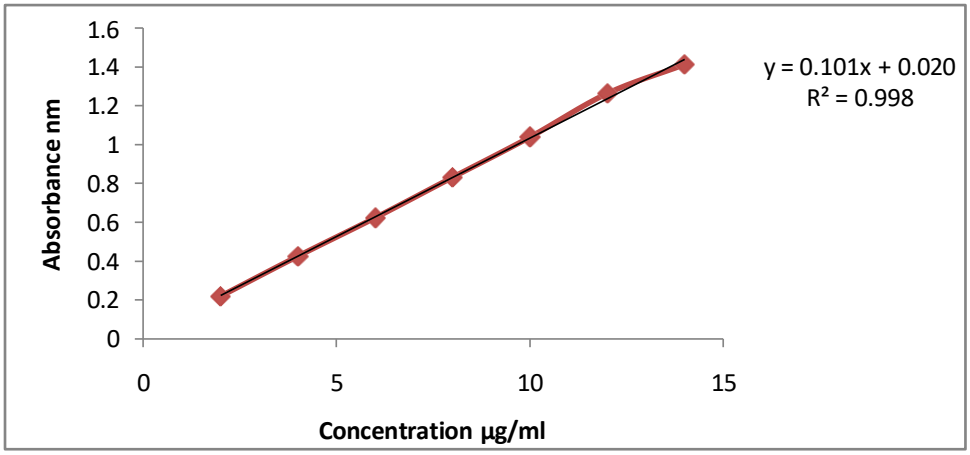


Figure 03: Calibration graph of Levamisole HCl at 216 nm

Precision:

Precision of the method was evaluated for Levamisole. The reproducibility (inter-day precision) of the method and repeatability (intra- day precision) was evaluated in the same laboratory. The values obtained were as pr Table 02 and table 03. From the data obtained in the method was found to be precise in respect of reproducibility as well as repeatability.

Table 02: Precision Determination Intra – day Precision by UV

	Absorbance		
Analyte	**0 Hr.**	**3 Hr.**	**6 Hr.**
Mean	0.4134	0.4116	0.4025
SD	0.0015	0.0006	0.0005
%RSD	0.3857	0.5117	0.1368

Table 03: Inter – day Precision by UV

	Absorbance		
Analyte	**0 Hr.**	**24 Hr.**	**48 Hr.**
Mean	0.4134	0.388	0.382
SD	0.0015	0.001	0.0060
%RSD	0.3857	0.2577	1.5923

Accuracy (Recovery Study):

Accuracy of the method was studied by recovery experiments. The recovery was performed at three levels 80, 100 and 120% of Levamisole standard concentration. Three samples were prepared for each recovery level. The solutions were then analyzed and the percentage recoveries were calculated from the calibration curve. The recovery value for Levamisole HCL was 99.30±0.616 and RSD was 0.6409 which is less than 2, which shows that the method has good reproducibility.

Table 04: Recovery Study

	Level of Recovery		
Statistics	**80%**	**100%**	**120%**
Amount present (µg/ml)	2	2	2
Amount of standard added (µg/ml)	1.6	2	2.4
Total amount recover	3.58	4.00	4.38
%recovery	98.75	100	99.16
Mean	99.30		
SD	0.6364		
%RSD	0.6409		

Limit of detection (LOD) and limit of quantification (LOQ):

Limit of detection is the lowest amount of analyte which can be detected but not necessarily quantified, and limit of quantification is the lowest possible concentration that can be quantified LOD and LOQ were found to be 0.39675 µg/ml & 0.95523 µg/ml respectively.

Specificity:

Specificity is the ability of the method to accurately measure the analyte response in the presence of all potential sample components (excipients). The results were compared with the

analysis of a standard Levamisole and tablet formulations. Excipients of the solid dosage form did not interfere with the analyte, which shows that the method has good specificity.

Validation parameters:

All the validation parameters as reported in table 05 were found to be within the desired range which depicts that the method was found to be reproducible with respect to all the validation parameters and can be a useful tool for routine evaluation of eletriptan in bulk and combined dosage form.

Table 05: Validation Parameters

Parameter	Results
Linearity range	2-14 µg/ml
Regression eq.	y=0.1013x+0.0201
Correlation coefficient	0.9987
Slope (m)	0.1013
Y-Intercept(c)	0.0201
Λmax	216 nm
LOD	0.39675 µg/ml
LOQ	0.95523 µg/ml
Interday precision	0.2675
Intraday precision	0.3447
Accuracy (%mean recovery)	99.30

III. CONCLUSION:

In the present study a suitable UV Spectroscopic method was developed for Levamisole hydrochloride in 0.1 N HCl as dissolution medium for drug and method was validated for different parameters as accuracy, precision, specificity, LOD, LOQ and recovery. It can be concluded that the developed method has good reproducibility and can be routinely used for estimation of Levamisole hydrochloride in bulk and combined formulation

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Wagh S discuss the development and testing of fluconazole microsponge gels. The article is located on page 231-239. The DOI for this article is http://dx.doi.org/10.22270/ajprd.v8i4.753.
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