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NOTE

Spectrophotometric Determination of Mizolastine in Pharmaceutical Formulations

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A simple and precise UV spectrophotometric method was developed for the estimation of mizolastine in pharmaceutical dosage forms. The λ_{max} of mizolastine was found to be 289 nm. Linearity for this method lies in the range of 5-15 µg/mL. The proposed method is sensitive, accurate, reproducible and useful for the routine determination of mizolastine in tablet dosage forms. No interference was observed from the excipients.

Key Words: Mizolastine, UV Spectrophotometer.

Mizolastine is a new benzimidazole derivative drug, which is a potent and selective antagonist of histamine H_1 receptors. It is described chemically as (2[[[1-[(4-fluorophenyl)methyl]-1*H*-benzimidazol-2-yl]-4-piperidinyl]-methylamino]-4(3*H*)-pyrimidinone[1]. Literature survey reveals that reverse phase liquid chromatographic method in plasma[2] and stability study in formulation[3]. The aim of present study is to develop a simple, rapid, efficient, reliable and economic spectrophotometric method for the assay of mizolastine in pure form and in tablet formulations. The method is based on the measurement of light absorption in UV region in methanol.

All spectral measurements were made on Shimadzu UV/Vis spectrophotometer 1601 with 1 cm matched quartz cells. Mizolastine was supplied by Dr. Reddy's Pharmaceutical Pvt. Ltd., Hyderabad. The tablets were obtained commercially. All other chemicals were of analytical grade. Quartz processed high purity water was used through out.

The stock solution of mizolastine was prepared by dissolving 25 mg of pure drug in methanol in a 100 mL volumetric flask. It was diluted as and when required. The absorbance of 10 µg/mL was measured against a solvent blank between 200-400 nm. A graph was plotted and the absorption maximum was determined as 289 nm. A calibration curve was obtained at 289 nm for a series of concentrations in the range of 5-15 µg/mL. It was found to be

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linear and hence, suitable for the estimation of the drug. The slope, intercepts, correlation coefficient[4] and optical characteristics have been summarized in Table-1.

TABLE-1
OPTIMUM CONDITIONS, OPTICAL CHARACTERISTICS AND STATISTICAL DATA OF THE REGRESSION EQUATION

Parameters	UV Method value
Absorption maximum (nm)	289
Beer's law limit (mcg/mL)	5-15
Correlation coefficient (r)	0.9998
Molar extinction coefficient (L $mol^{-1} cm^{-1}$)	165536.43
Regression equation	0.0054 + 0.0376x
Slope (m)	0.0376
Intercept (c)	0.0054

*For five replicate analysis with in Beer's law limits.

Market sample analysis: 20 Tablets were weighed and finely powered. A quantity equivalent to 25 mg of mizolastine was transferred in the 100 mL volumetric flask and dissolved about 50 mL methonal. The solution was sonicated for 0.5 h and filtered through Whatmann filter paper no: 41 and the final volume were made up to the same solvent. Appropriate aliquots were subjected to the above methods and the amount of mizolastine was determined. The results are shown in Table-2.

TABLE-2
RESULTS OF ASSAY

Sample	Label claim (mg)	UV Method	
		Amount found (mg)	RSD (%)
Tablet A	10	9.83	0.3954
Tablet B	10	9.86	0.3892

Recovery studies: To study the accuracy and reproducibility of the proposed method, adding a known amount of drug to preanalyzed sample at three levels and the percentage of recovery was calculated. The results are summarized in Table-3,which was found to be satisfactory.

TABLE-3
RECOVERY STUDIES OF MIZOLASTINE

Method	Sample concentration	Fortified concentration	Percentage recovery	
			Tablet A	Tablet B
UV Method	10	80	98.7	98.9
		100	99.1	98.7
		120	99.9	99.5

The λ_{max} of mizolastine in methanol was found to be 289 nm. The amount of drug determined by the proposed method was in good agreement with label claimed providing the accuracy of the proposed method. The low percentage RSD value indicates the reproducibility of the method. The method is useful for tablet formulations where there is no interference of excipients in the absorbance of mizolastine.

Conclusion

The proposed method is simple, rapid and more economically as compared to the reported methods. Hence, the proposed method could be used as a better alternative for the assay of mizolastine in pharmaceutical solid dosage forms such as tablets.

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