Spectrophotometric estimation of loratidine in bulk drug and dosage forms

ANVESHA G. VYAS AND SADHANA J. RAJPUT*

Dept. Pharmacy, Faculty of Tech. & Engg.

Kalabhavan, M.S. University of Baroda, Vadodara 390 010

A simple and rapid spectrophotometric method has been described for the assay of Loratidine in bulk drug and dosage forms. The method is based upon the reaction of loratidine with potassium iodide in the presence of hydrochloric acid to yield a chromogen having absorption at 370 nm.

LORATIDINE, 11 - [(N-ethoxy carbonyl)-4-piperidylene]-8-chloro- 6,11-dihydro-5H benzo [5,6] cyclohepta [1-2b-] pyridine[1] is a long acting well tolerated antihistamine (Fig. 1) having high selectivity for peripheral histamine H receptors and devoid of the central nervous system represent effects often associated with some of the older antihistamines. A few chromatographic methods[2-5] have been reported for the determination of loratidine and its metabolities in biological fluids but no spectrophotometric method is available for the analysis of loratidine in its pharmaceutical dosage forms. We report here a simple, sensitive and inexpensive spectrophotometric method for the analysis of loratidine in pure form and in tablets. The method reported here is based upon the reaction of loratidine with potassium iodide in presence of hydrochloric acid. The chromogen obtained was extracted in benzene as a pale yellow product which could be measured at λmax 370 nm.

A Hitachi model V-2000 UV-vis spectrophotometer with 1 cm matched quartz cuvetts was used. All reagents used were of analytical grade. Loratidine was obtained as a gift sample from Cadila Pharma Ltd. Ahmedabad and was used as such as working standard.

Fifty mg of Loratidine was accurately weighed, transferred to a 50 ml. volumetric flask, dissolved

in methanol and the volume made upto 50 ml with the same solvent. From this a series of dilutions were prepared to obtain a range of 30 to 110 µg of loratidine per ml.

Twenty lorfast tablets [Cadila Pharma Ltd. Ahmedabad] containing 10 mg, of loratidine per tablet were ground to a fine powder. The powder equivalent to 25 mg of loratidine was weighed and dissolved in 25 ml, methanol. The solution was filtered. As lorfast was the only formulation available in Indian market at the time of study, a mixture was prepared by taking 20 mg, loratidine, 68 mg lactose 40 mg dried starch and 16 mg talc. A portion of the mixture
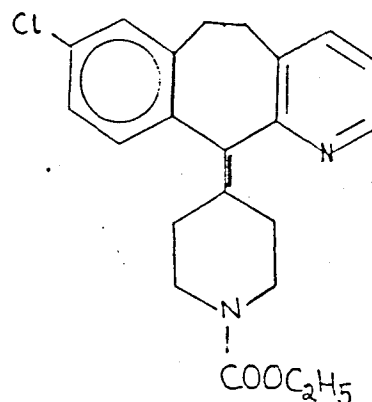

Fig. 1: Loratidine

* For correspondence

Table 1
Comparative Study of Proposed Method and Reported Methods

Methods		Limit	Correlation Coefficient
1.	HPLC (using RP-18 column and fluroscent detector)	upto 0.5 ng/ml	--
2.	HPLC (using shandon ODS column and UV detector at 249 nm)	10-70 μg/ml	0.995
3.	GLC	0.1-0.3 ng/ml	> 0.998
4.	Proposed method	30-110 μg/ml	0.825

equivalent to 5 mg loratidine was accurately weighed and dissolved in 50 ml of methanol. The solution was filtered and analysed by proposed method.

An aliquot of the standard loratidine solution was transferred into a test tube. Two ml, 10% w/v solution of potassium iodide was added followed by 1 ml, of 6 N HCL. The mixture was heated on a water bath for 30 min. at 80°. After cooling the yellow coloured product was extracted with 10 ml benzene in three lots of 5, 3 and 2 ml, dried over 'anhydrous, sodium sulphate. The solution was diluted to 25 ml with benzene and scanned for λmax which was found to be at 370 nm against a similarly treated reagent blank. A graph was drawn using standard solution in the concentration range of 30-110 μg of loratidine per ml. An aliquot of sample solution was taken in a test tube and treated in the same manner as the standard solution. The absorbance was measured at 370 nm against a reagent blank.

In this study, loratidine, forms a chromogen with potassium iodide in the presence of acid. The yellow coloured product is soluble in benzene and can be measured at 370 nm. A number of other solvents were also tested to check the efficiency of extraction and benzene was found to be most efficient. Effect of concentration of potassium iodide, volume of hydrochloric acid and effect of heating was studied to optimize the reaction conditions. It was found that 2 ml of 10% w/v potassium iodide solution and 1 ml 6N HCL give the best results.

The method was applied successfully for the estimation of loratidine in bulk drug, its solid dosage formulation and in a synthetic mixture. Average recoveries range from 96.14 - 99.77 % indicating efficiency, accuracy and reproducibility of the method, absence of interference from common excipients and additives. Table - 1 shows a comparison of the present method with the already reported methods.

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