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ASSAY OF CISAPRIDE IN TABLETS BY VISIBLE SPECTROPHOTOMETRY

K. PRABHAVATHI, N. RAMI REDDY* and M. RAMESH KUMAR[a]

Department of Chemistry, S. B. S. Y. M. Degree College, KURNOOL – 518004 (A. P.) INDIA
[a]The Adoni Arts and Science College, Adoni, KURNOOL – 518004 (A. P.) INDIA

ABSTRACT

A simple spectrophotometric method for the estimation of cisapride either in pure form or in tables has been developed. The developed spectrophotometric procedure was based on the reaction of cisapride with vanillin under acidic conditions to produce yellow coloured Schiff's base. The absorbance of yellow coloured solution was measured after 15 min at 405 nm against reagent blank. Beer's law was obeyed in the concentration of 80-200 μg/mL of drug. The method was successfully employed for the assay of cisapride in tablets.

Key words : Spectrophotometry, Cisapride, p-Hydroxy acetanilide

INTRODUCTION

Cisapride is chemically cis-4-amino-5-chloro-N-{1-[3-(4-fluoro phenoxy)-propyly]-3-methoxy-4-piperidyl}-2-methoxy benzamide monohydrates. Cisapride stimulates gastro- intestinal motility and is used in the treatment of gastro-oesophagical reflux disease. Some analytical methods have been reported for assay of cisapride in pure as well as in pharmaceutical dosage forms. These methods include colorimetric[1,2], HPLC[3,4] and spectrophotometric methods[5,6].

In the present work, the amino group in cisapride was reacted with vanillin and hydrochloric acid to produced yellow coloured Schiff's base. The yellow coloured species formed in the method is stable for more than 6 hours. The yellow coloured species was measured at 405 nm against reagent blank prepared in a similar manner omitting drug solution. The aim of this study was to develop a simple spectrophotomeric procedure for the determination of cisapride in pharmaceutical formulations.

* Author for correspondence

EXPERIMENTAL

Instrumental

A Milton Roy 1001 plus spectrophotometer with 1 cm quartz cells was used for all measurements.

Chemicals and regents

All the chemicals and reagents used were of AR grade. Double distilled water was used throughout the investigation. Hydrochloric acid (4 N) was prepared and standardized with standard procedure. Vanillin (1%) solution was prepared.

Preparation of standard cisapride solution

Pure cisapride (50 mg) was dissolving in 50 mL methanol. This stock solution was further diluted with methanol to get desired concentrations.

Preparation of calibration curve

Different aliquots (0.4, 0.6, 0.8, 1.0 mL) of cisapride were transferred into a series of 10 mL volumetric flasus. To each flask, 0.1 mL of 1% vanillin solution and 1.0 mL of 4 N hydrochloric acid solutions were added. The flasks were shaken for 1 min and the volume in each flask is made up to the mark with methanol. The absorbance of yellow coloured solution was measured after 15 min at 405 nm against reagent blank prepared in a similar manner omitting drug solution. The amount of cisapride was determined from calibration graph.

Estimation of cisapride in tables

Twenty tables of cisapride were weighed and powdered. The powder equivalent to 50 mg of cisapride was transferred into 50 mL volumetric flask, shaken thoroughly with 30 mL methanol and filtered. The filtrate was diluted to 50 mL with methanol. This stock solution is further diluted to obtain the working concentration of 200 μg/mL. Different aliquots of solutions were taken and analyzed by using the procedure described earlier and the amount of cisapride present in sample was read from calibration graph. The results are tabulated in Table 1.

RESULTS AND DISCUSSION

The proposed method involves the condensation of cisapride with vanillin in acidic

medium to produce yellow coloured Schiff's base. The absorbance of the coloured species was measured at 405 nm against reagent blank. Beer's law obeyed in the concentration range of 8-200 mg/mL of cisapride. The results shown in Table 1 are in good agreement with those obtained with the reported method. The optimum conditions were established by varying one paramenter and keeping other fixed and observing the effect on the absorbance of the solution. The effect of hydrochloric acid concentration and reagent concentration were studied through controlled experiments and optimum conditions were incorporated in the procedure. Recovery experiments were performed and the results are tabulated in Table 1.

Table 1. Assay of cisapride in tablets

Sample	Labelled amount (mg)	Amount found (mg)		% Recovery	*t_{cal}
		Proposed method ± S. D.*	Official method*		
Tablet 1	10	10.02 ± 0.03	9.99	99.40	0.1474
Tablet 2	10	9.96 ± 0.33	9.94	99.80	0.3334
Tablet 3	10	9.88 ± 0.46	9.86	99.50	0.5763
Tablet 4	10	10.06 ± 0.28	10.01	100.1	0.2840
Tablet 5	10	9.98 ± 0.32	9.99	100.4	0.1399

* Average of five determinations based on label claim. Tabulated value or theoretical value 2.78.

The recovery values ranged between 99.4 and 100.4 %. This provides an indication of the reliability of the proposed method during its routine application. The common excipients employed do not interfere in the estimation of cisapride. The statistical analysis was studied by proposed method. The standard deviation values were satisfactorily low, which indicates the accuracy and reproducibility of the proposed method. The calculated t-values did not exceed the theoretical value; thus, indicating that there is no significant difference between proposed method and official method.

The proposed method has the advantages of being simple, sensitive and suitable for routine analysis in control laboratories. It can be applied to the analysis of cisapride in different pharmaceutical dosage forms.

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