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A SIMPLE SPECTROPHOTOMETRIC DETERMINATION OF CISAPRIDE IN PHARMACEUTICAL PREPARATIONS

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ABSTRACT

A simple, sensitive, accurate and economic method has been developed for the quantitative estimation of cisapride in bulk drugs and its formulations. The method is based on the reaction of the drug in methanolic solution with vanillin in acidic condition producing Schiff's base having a absorption maximum at 410 nm. Beer's law is obeyed in concentrations ranging from 20-100 µg/mL. The results obtained with the proposed methods are in good agreement with labeled amounts when the marketed pharmaceutical formulations are analyzed. The results of analysis have been validated statistically and by recovery studies.

Key words: Cisapride, Vanillin, Spectrophotometric, Pharmaceutical.

INTRODUCTION

Cisapride is chemically, cis-4-amino-5-chloro-N-{1-[3-(4-fluorophenoxy)-propyl]-3-methoxy-4-piperidyl}-2-methoxybenzamide monohydrate and is used in the treatment of gastro-oesophagical reflux disease. Various analytical methods have been developed for its quantitative estimation in pharmaceutical formulations, which include colorimetric method[1,2], spectrophotometric method[3-8] and HPLC method.[9-16] The aim of the present work is to develop and validate new spectrophotometric method for the estimation of cisapride in bulk and pharmaceutical formulations.

EXPERIMENTAL

Instrumentation

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

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measurements. All the chemicals and reagents used were of AR grade. Double distilled water was used throughout the investigation.

Chemicals and reagents

Hydrochloric acid (4 N) was prepared and standardized with standard procedure. Vanillin (1% w/v) solution was prepared.

Preparation of standard drug solution

100 mg of the bulk drug was weighed accurately and dissolved in 25 mL methanol in a 100 mL volumetric flask. The solution was made up to 100 mL with methanol. This stock solution is further diluted with methanol to obtain the working concentration of 100 µg/mL.

Assay procedure

Aliquots of drug ranging from 0.2-1.0 mL (100 µg/mL) were transferred in a series of 10 mL volumetric flasks. To each of the flask, 1.0 mL of vanillin and 1.0 mL of 4N hydrochloric acid were added. It was warmed on a water bath for 2 min and kept aside for 15 min. at room temperature. A yellow color was developed. The volume was made up to mark with methanol. The absorbance of the yellow colored chromogen was measured at 410 nm against reagent blank. The amount of cisapride present in the sample was computed from calibration curve

Pharmaceutical preparations

For the sample solution, tablets of cisapride were accurately weighed and average weight per tablet was determined. The tablets were powdered and powder equivalent to 100 mg of drug was taken into 100 mL volumetric flask and dissolved in 25 mL methanol. It was shaken for 15 min., made up to 100 mL with methanol and filtered. This solution was brought to 100 µg/mL with methanol. Different aliquots of solutions were taken and analyzed by using the procedure described earlier and the amount of cisapride present in sample was computed from calibration curve. The results are tabulated in Table 1.

Table 1: Assay of cisapride in tablets

Sample	Labelled amount (mg)	*Amount found by proposed method ± S.D*	% Recovery	$^{*}t_{cal}$
Tablet 1	10	9.88 ± 0.46	99.8	0.5763

Cont…

Sample	Labelled amount (mg)	*Amount found by proposed method ± S.D*	% Recovery	*t_{cal}
Tablet 2	10	10.02 ± 0.30	100.1	0.1474
Tablet 3	10	10.06 ± 0.47	100.3	0.2840
Tablet 4	10	9.96 ± 0.38	99.9	0.3334
Tablet 5	10	9.98 ± 0.31	99.7	0.1399

*Average of five determinations based on label claim

RESULTS AND DISCUSSION

The proposed method involves the condensation of cisapride with vanillin in acidic medium to form yellow colour chromogen. The absorbance of yellow colour chromogen was measured at 410 nm against reagent blank. Beer's law was obeyed in the concentration range of 20-100 μg/mL of cisapride. The optimum conditions for proposed method have been established by varying the parameters one at a time, keeping the other parameters fixed and observing the effects of product on the absorbance the absorbance of the colored species and incorporated in the procedures. To evaluate the validity and accuracy of the method, known amount of pure drug were added to the previously analyzed pharmaceutical preparations and mixture was analyzed by the proposed method. The percent recoveries are given in Table 1. The statistical analysis was studied by proposed method. The standard deviation values were satisfactorily low, indicating the accuracy and reproducibility of the proposed method. The calculated t-values did not exceed the theoretical value indicates the precision of the proposed method. The common additives like antioxidants and preservatives were usually present in tablets, did not interfere at their regularly added levels.

The proposed method was found to be simple, accurate, sensitive, precise and economical and can be used in the estimation of cisapride in bulk drug and its pharmaceutical formulations.

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