INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACY AND CHEMISTRY

Available online at www.ijrpc.com

Research Article

NEW VISIBLE SPECTROPHOTOMETRIC METHODS FOR THE ESTIMATION OF SILODOSIN IN PHARMACEUTICAL FORMULATIONS

CH. Mounika*, N. Umadevi and I. Sudheerbabu

Sir C. R. Reddy College of Pharmaceutical Sciences, Eluru, Andhra Pradesh, India.

ABSTRACT

Three simple spectrophotometric methods (A, B, C) have been described for the assay of silodosin, in bulk and pharmaceutical formulations. Method A is based on the oxidation of silodosin with iron (III) and subsequent chelation of iron (II) with 1, 10-phenanthroline (PTL) to form a red colour complex with λ max at 479nm. Method B is based of the oxidation or reduction between the silodosin and folin ciocalteu (FC) reagent to form a blue coloured chromogen with λmax 732nm.Method c is based on the oxidation of silodosin with iron (III) and chelation of iron with 3-methyl- 2-benzothiozoline hydrazone hydrochloride (MBTH), to form a green coloured complex with λ620 nm.

Keywords: Visible spectroscopy, Reagents, Silodosin.

INTRODUCTION

1-(3-hydroxy propyl)-5[(2R)-({2-[2-[2-(2,2,2-triflouroethoxy) ethyl] amino} propyl] indoline- 7 carboxamide, is widely used for the treatment of symptomatic benign prostatic hyperplasia(BPH). A survey of literature revealed that there is no report on visible spectrophotometry. Therefore, the need for a fast, low cost and selective method is obvious. Especially for the routine quality control analysis of pharmaceutical formulations containing silodosin.This paper describes three visible spectrophotometric methods for the determination of silodosin by making use of the reported procedures. 1,10 - phenanthroline is commonly used for the determination of metal ions like iron, cobalt, and cadmium. It is used for the determination of some phenolic compounds and drugs.Method A is based on the formation of a red coloured species (λ max: 479nm) on treating with silodosin with ferric chloride and 1,10 - phenanthroline in the presence of Ortho-phosphoric acid. Method B is based on the reaction of silodosin with FC reagent in the presence of sodium carbonate to form a blue coloured solution (λmax: 732nm). Reduction of hetero poly acid complexes by organic reagents was utilized as the basis for the determination of several organic compounds, particularly phenols, amines, enols. Among the various hetero poly acids, phosphomolybdo tungstic acid, the well known folin ciocalteu (FC) reagent was preferred by a number of workers for the determination of drugs containing not only phenolic or amino group but also certain other drugs which contain neither these groups. Method c is based on the formation of green coloured species on treating with ferric chloride and MBTH and 0.1N HCL (λ max 620nm).

EXPERIMENTAL

INSTRUMENT

A systronics UV- Visible double beam spectrophotometer (model:2202) with 1cm matched quartz cells was used for all spectral measurements.

REAGENTS

All chemicals used were of analytical grade and all the solutions were prepared with double distilled water. Aqueous solutions of ferric chloride (0.03M) , 1,10-phenanthroline(0.01M) and Ortho-phosphoric acid (0.02M) were prepared for method A. aqueous solution of sodium carbonate (10% w/v) and commercially procured FC reagent (2N) were used for method B. Aqueous solution of ferric chloride (0.2M), MBTH (0.2M), 0.1N HCl, were used for method C.

STANDARD DRUG SOLUTIONS

Stock solution of silodosin (1mg/ml) was prepared by dissolving 10mg of silodosin in 10ml of methanol. The working standard was prepared by dilution to 100ml with distilled water.

SAMPLE SOLUTIONS

Capsules of one brand was used for the purpose of analysis. One capsule was taken and the powder taken according to the labeled claim. The solution was prepared as under standard solution preparation and filter if insoluble portion present.

ASSAY PROCEDURES

METHOD A

Aliquots of standard drug solution representing 10-50µg/ml of silodosin, 1.5 ml of ferric chloride solution and 2.5 ml of 1,10-phenanthroline solution were successively added to a series of 15 ml graduated tubes. The contents of each tube were mixed well and heated on a boiling water bath for 15min. the tubes were cooled to room temperature and 2ml of Ortho-phosphoric acid was added to each tube and the volume was brought to 12ml with distilled water. The absorbance was measured against a reagent blank at 479nm. The amount of drug present in sample solution was deduced from calibration curve.

METHOD B

Aliquots of stock solution representing 300-500µg/ml were transferred to 10ml graduated tubes. 1.25 ml of FC reagent and 4.5 ml of sodium carbonate solution were added simultaneously and kept aside for 10min a room temperature. The solution was made upto volume with distilled water. The absorbance was measured at 732nm against a reagent blank. The amount of drug in the sample solution was deduced from calibration curve.

METHOD C

Aliquots of standard drug solution 10-50µg/ml were transferred to a series of 10ml with graduated tubes. 1ml of ferric chloride solution and 1ml of MBTH solution were added mixed well then 1ml of 0.1N HCL solution was added and made upto volume with distilled water. The absorbance was measured at 620nm against a reagent blank. The amount of drug in the sample solution was calculated from calibration graph.

Table 1

Serial no.	Optical character	Method A	Method B	Method C
1	λmax	479nm	732nm	620nm
2	Beer's law limits(µg/ml)	10-50	300-500	10-50
3	Molar Absorptivity	19.63×10^3	7.333×10^3	24.77×10^3
4	Sandell's Sensitivity	0.30	0.67	0.20
5	Regression Equation(Y) Slope(b) Intercept(a)	 0.054 -0.015	 1.517 -0.017	 0.069 -0.017
6	% RSD	0.60	0.87	3.76
7	% Range of Error	±0.50	±0.72	±3.14

Table 2

Sample	Labelled Amount (mg/cap)	Amount obtained(mg) Method A	Method B	Method C	% Recovery Method A	B	C
1	8 mg	8.67mg	10.2mg	8.23mg	102.37%	128%	102.9%

RESULTS AND DISCUSSION

All the three methods are simple sensitive and reproducible and can be used for the routine estimation of silodosin in bulk form and in pharmaceutical formulations.

ACKNOWLEDGMENT

The authors are thankful to Sir c.r. reddy college of pharmaceutical sciences, Eluru, for providing necessary facilities.

REFERENCES

1. Available from URL http:/ / www.nlm.nih.gov / medlineplus /druginfo / meds /a609002.html (accessed on 28/04/12).
2. Available from URL http://www.rxlist.com/rapaflo-capsulesdrug.htm (accessed on 01/05/12).
3. ICH Harmonized Tripartite Guidelines, Validation of analyticalprocedures: text & methodology, Q2 (R), Nov 2005.
4. Green, J.M.: A practical guide to analytical method validation, Analytical Chemistry,68, 305A-309A (1996).
5. Spectroscopic methods in organic chemisty by Dudley HWiliams and Iam Fleming, 5th edition page no 1-27.
6. M Yoshida, Y Homma, K Kawabe. Silodosin,a novelselective alpha 1A-adrenoceptor selective antagonist for the treatment of benign prostatic hyperplasia.Expert Opin Investing Drugs 16 (2007) 1955–1965.
7. NI Osman, CR Chapple, F Cruz , F Desgrandchamps, C Llorente , F Montorsi .Silodosin : a new subtype selective alpha-1 antagonist for the treatment of lower urinary tract symptoms in patients with benign prostatic hyperplasia Expert Opin Pharmacother 13(2012) 2085-2096.
8. T Goseki, H Ishikaw, S Ogasawar, K Mashimo, NNemoto, Y Taguchi, K Yago, K Shimizu. Effects oftamsulosin and silodosin on isolated albino and Pigmented rabbit iris dilators: possible mechanism of intraoperative floppy-iris syndrome .J Cataract RefractSurg.38 (2012) 1643-1649.
9. MP Curran. Silodosin: Treatment of the Signs and Symptoms of Benign Prostatic Hyperplasia Drugs.71 (2011) 897-907.
10. CR Sharma, J Akhtar , NM Jagani , YR Shankharva,JS Shah Pharm Analysis & Quality Assurance uv spectrophotometric method for estimation of silodosin From its solid dosage form. http://www.inventi.in/Article/ ppaqa/310 /12. Aspx.
11. Shaik Jafer vali, santhi kumar saladi, shakil s sait, lovleen kumar garg) Development and Validation of LC Method for Determination of the Enantiomeric Purity of Silodosin in Bulk Drug Substances. Am. J.PharmTech Res 22012) 751-758.
12. TP Aneesh and A Rajasekaran. Development and validation of HPLC method for the estimation of silodosin in bulk and pharmaceutical dosage form IJPBR 3(2012) 693-696.
13. X Zhao, Liu Y, J Xu, D Zhang, Y Zhou, J Gu , Y Cui .Determination of silodosin in human plasma by liquid chromatography-tandem mass spectrometry. JChromatogr B 877(2009) 3724-3728.
14. Stability testing of New Drug substances and Products (Q1AR2), ICH Harmonized Tripartite Guideline.
15. Validation of Analytical Procedures: Methodology (Q2B), ICH Harmonized Tripartite Guideline.