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Visible Spectroscopic Estimation and Validation of Ornidazole in Bulk and Pharmaceutical Dosage Forms

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A simple, sensitive, accurate visible spectroscopic method has been developed for the quantitative estimation of ornidazole in bulk and pharmaceutical dosage forms. The method was mainly based on the formation of green colour chromogen with potassium dichromate in acidic condition or medium. The produced colour was measured at wavelength maximum of 570 nm against reagent blank. The proposed method was showing linearity in the concentration range of 1 -5 µg/mL.The developed method was validated statically for its linearity, accuracy and precision as per FDA guidelines.

Key Words: Visible spectroscopy, Ornidazole.

INTRODUCTION

Ornidazole[1] is an antihelmenthitic drug for oral administration, chemically it is 1-(3-chloro-2-hydroxypropyl)-2-methyl-5-nitroimidazole is used as an antiinfective agent. Its empirical formula is $C_7H_{10}N_3O_3Cl$ having molecular weight 219.63. Ornidazole is used in combination with other fluoroquinolone in the treatment of protozoal infectious diseases (PID) and intra-abdominal infection. It is nitro imidazole anti-protozoal agent used in amoeba and trichomonas infections, partially plasma bound and has radiation, sensitizing action. In present investigation an attempt was made to develop a simple and economical, validated spectrophotometric method with greater precision, accuracy and sensitivity for the estimation of ornidazole in bulk as well as in pharmaceutical formulations. Literature survey[2-9] reveals that there is no visible spectrophotometric method has been reported for the estimation ornidazole in bulk and pharmaceutical dosage forms.

EXPERIMENTAL

The pure standard of ornidazole was obtained as a gift sample from A TO Z Pharmaceuticals, Chennai. The purity of the standard was found to be 99.67 %. A Shimadzu-UV-Visible double beam spectrophotometer-1601,

with matched cells was used for spectral measurements. All the chemicals used for performing the work were of AR grade from S.D. Fine Chemicals, Mumbai. The 0.03 potassium dichromate solution, methanol, concentrated sulphuric acid and ornidazole tablets was employed for this study.

Preparation of working standard solution of standard drug: Accurately weighed quantity of drug, equivalent to 100 mg was dissolved in few mL of methanol and the volume was made up to 100 mL with methanol to get the concentration about 1000 µg/mL (stock-1).From the above stock solution 1 mL was taken and made up to the volume to 100 with methanol to get the concentration about 100 µg/mL (stock-2).

Preparation of solution of marketed formulation: 20 Tablets of ornidazole were weighed and the average weight of tablets was determined. The tablets were powdered and the powder equivalent to 100 mg of drug was dissolved in the 100 mL of methanol to get the concentration about 1000 µg/mL (stock-1). From the above stock solution 1 mL was taken made up to the volume to 100 with methanol to get the concentration about 100 µg/mL (stock-2).

Assay of marketed formulation: From above stock solutions of both standard and sample were taken as a series of aliquots of drug solution ranging from 0.1-0.5 mL and transferred into a five cleaned test tubes. To this added 4 mL of 0.03 M potassium dichromate solution and 2 mL of concentrated sulphuric acid, finally made up the volume with distilled water to 10 mL to get the concentrations about 1-5 µg/mL. The produced green colour was measured for absorbance at the wavelength maximum of 570 nm against reagent blank. The calibration curve was constructed that showed good linearity in range of 1-5 µg/mL.

RESULTS AND DISCUSSION

The optimum conditions were established by varying each parameter at a time and keeping the other constant by observing the effect produced on absorbance of the coloured species. Various parameters was optimized before starting the development of the method like concentration of reagent, volume of reagent added, the time required for absorbance of prepared solutions (stability of colour),volume of sulphuric acid added and linearity range were optimized. The optical characteristics and precision of method was given in Table-1. The regression equation was calculated by method of least squares for calibration curve. A good linear relationship (r = 0.9989) was observed between drug concentration and absorbance. The regression equation found to be Y = 0.0289X - 0.0265 (where Y = absorbance of the drug, X = concentration of drug).The accuracy of the method was found by analyzing the five replicate sample of the known concentration of the drug.

TABLE-1
OPTICAL CHARACTERISTICS OF THE METHOD

λ_{max}	570
Beer's law limit (μg/mL)	1-5
Molar absorptivity constant (L mol^{-1} cm^{-1})	1.345×10^5
Sandell's sensitivity (μg/mL 0.001-absobance unit)	0.0185
Regression equation (Y)	
Slope (b)	0.0289
Intercept (a)	0.0265
Correlation coefficient (r)	0.9989
RSD (%)	0.3140
Range of errors*	
Confidence limits with 0.05 level	0.00365
Confidence limits with 0.01 level	0.00245

*Y = a + bc where c = concentration of analyte.

To ensure the reliability and accuracy of the method recovery studies were carried out by mixing a known quantity of drug with pre-analyzed sample and contents were reanalyzed by the proposed method. About 99.99 % of ornidazole could be recovered from the pre-analyzed sample indicating the high accuracy of the proposed spectroscopic method. Recovery studies were given in the Table-2.

TABLE-2
RECOVERY STUDIES

Drug	Amount added (mg)	Amount present (mg)	Mean amount found* (mg)	Mean recovery (%)
Ornidazole	100	200	199.95	99.97
	200	300	299.97	99.99
	300	400	396.97	99.14

*Mean of five replicates.

The drug content in the tablets was quantified using the proposed analytical method. The values were given in the Table-3.

TABLE-3
ASSAY

Brand name	Label claim (mg)	Amount estimated (mg)	Mean (± SD) mean (mg) found by proposed method*	Mean (± SD) % labelled amount*
Orizole	500	501.76	501.15 ± 0.0271	100.23 ± 0.023
Ornizen	500	500.85	500.17 ± 0.0173	100.03 ± 0.054

*Mean of five replicates.

It can be concluded that the proposed visible spectrophotometric method is simple, sensitive, rapid and reproducible for analysis of ornidazole in bulk and pharmaceutical dosage forms.

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REFERENCES

1. The Merk Index, edn. 13, p. 1937, 6240 (2001).
2. G.L. Liu, R.G. Sha, S.A. Gao, Y.X. Shen and S.X. Wang, *Yaoxue Xuebao*, **28**, 216 (1993).
3. S. Liu, Q. Dai, W. Ma, C. Ling and X. Tang, *Yaowu Fenxizazhi*, **18**, 33 (1998).
4. H. Liang, M.B. Kays and K.M. Sowinski, *J. Chromatogr. B*, **53**, 772 (2002).
5. M. Bakshi, B. Singh, A. Singh and S. Singh, *J. Pharm. Biomed. Anal.*, **26**, 891 (2001).
6. L. Mishra, Drugs Today, Lorina Publications, New Delhi, India, Issue 11, p. 375 (2003).
7. K. Vishwanathan, M.G. Bartlett and J.T. Stewart, *Rapid Commun. Mass Spectrom.*, **15**, 915 (2001).
8. C.M. Perry, D. Ormrod, M. Hurst and S.V. Onrust, *Drugs*, **62**, 169 (2002).
9. M. Somasekhar, J.V. Sagar, N. Narsaiah, R.A. Kumar and D.R. Krishna, *Indian J. Pharm. Sci.*, **67**, 302 (2005).

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