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A new UV-spectrophotometric method for the determination of Ornidazole in bulk and in formulations using sodium citrate as hydrotropic solubilizing agent

Dr.K.Rajeswar Dutt*, Rabha Hani, G.Yeshwanth, V.Bharani, Md.Rayees Ahmed, G. Koteswar Rao, I.Santhosh, Dr. K.N.V. Rao.

Department of Pharmaceutical Analysis and Quality Assurance, Nalanda College of Pharmacy, Charlapally, Nalgonda, Telangana-508001

***Corresponding Author: Dr.K.Rajeswar Dutt**
Email: pharmadutt@gmail.com

ABSTRACT

A thorough literature survey of the various analytical methods for the quantitative estimation of Ornidazole in both bulk drug and dosage forms has revealed that very few analytical methods are available utilizing the hydrotropic solubilisation technique to date. The present research paper is a description n of a new analytical method developed using the principle of Hydrotropy employing very easily available chemical namely 0.75M Sodium citrate solution. The method has been validated as per ICH guidelines and found to conform to ICH guidelines. In the present investigation the use of organic solvent has been avoided due to their high cost, volatility and toxicity, making the method environmental friendly. The findings revealed that the method is new, simple, safe, environmental friendly, accurate, precise, reproducible and cost-effective. It can be successfully employed as a routine analytical procedure for the analysis of Ornidazole tablets. Hence the authors suggest that this analytical method can be adopted in the Pharmaceutical industry for the analysis of Ornidazole in bulk and various dosage forms. Ornidazole shows its maximum absorbance at 303 nm and Beer's law was obeyed in concentration range of 1-5µg/ml in presence of 0.75M Sodium citrate and Molar absorptivity. The statistical analytical parameters namely Correlation coefficient were computed and found to be, 0.950

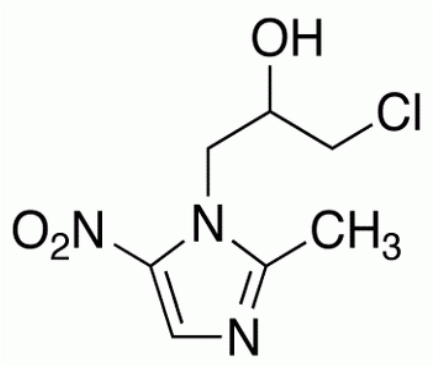
Keywords: Spectrophotometry, Hydrotropy, Ornidazole, Sodium citrate.

INTRODUCTION

The method of estimation of drugs are divided into physical, chemical, physico-chemical and biological. Physico-chemical and physical methods are used commonly. Physical methods of analysis involve the study of the physical properties of a substance, as determination of solubility, transparency or degree of turbidity, color density,

specific gravity, moisture content, melting point, freezing and boiling points. Physico-chemical methods are used to study the physical phenomenon that occurs as a result of chemical reactions. Among the physico-chemical methods, the most important are optical (refractometry, polarimetry, emission, fluorescence methods of analysis, photometry including photocolorimetry and spectrophotometry covering UV-Visible and IR regions and nephlometry or turbidimetry) and chromatographic methods [1-5].

Ornidazole Molecular structure



Compounds that cause increase in aqueous solubility are sometimes called hydrotropes. Concentrated aqueous hydrotropic solutions of urea, sodium citrate, nicotinamide, sodiumsalicylate, sodium acetate and sodium benzoate have been observed to enhance the aqueous solubility of many poorly water-soluble drugs. The primary objective of the present investigation was to employ a hydrotropic solution to extract the drug from the fine powder of Ornidazole tablets, precluding the use of costlier organic solvents for spectrophotometric analysis. Costlier organic solvents are more often employed to solubilize the poorly water-soluble drugs for spectrophotometric analysis. Volatility and pollution are drawbacks of such solvents. Various techniques are employed to enhance the aqueous solubility of poorly water-soluble drugs. Hydrotropic solubilization is one of them. In the present investigation, hydrotropic solubilizing agent, 0.75M Sodium citrate was employed to solubilize Ornidazole from the fine powder of its tablets to carryout spectrophotometric analysis. Ornidazole showed maximum absorbance at 303 nm and Beer's law was obeyed in the concentration range of 1-5µg/ml in presence of Sodium citrate [6-10].

EXPERIMENTAL SECTION

Standard drugs

Ornidazole was procured from the SURA labs.

Chemicals and reagents

Purified water, Sodium citrate.

Instruments

UV (SHIMADZU 1601), Sonicator (Analytical technologies).

Determination of absorption maxima by UV/Visible Spectrophotometry

Accurately weigh 50 mg of drug in to 100 ml volumetric flask. To this add 5 ml of diluent sodium citrate and sonicate it and further make up the volume with diluent. From this take 5ml and make up to100ml. The solutions were scanned in the range of 200-400 nm in 1cm cell against blank [11-15].

Figure: 2. Shows UV spectrum of Ornidazole

Preparation of mobile phase

Accurately measured 100 ml of sodium citrate, were degassed in an ultrasonic water bath for 10minutes and then filtered through 0.45 µ nylon filter under vacuum filtration [16-20].

Diluent

Mobile phase is used as diluents.

Standard preparation

Accurately weigh 50 mg of **Ornidazole** and transfer in to 100ml volumetric flask. Add 100 ml of hydrotropic solution, sonicate it to dissolve for 10 mins. Cool the solution to room temperature and dilute to volume with sodium citrate. Transfer 5ml of above solution in to a 100ml volumetric flask and make up the volume with hydrotropic solution [21-26].

Optimized conditions

Wavelength - 303nm
Solvent - **0.75M** sodium citrate

Method validation:

The following parameters were considered for the analytical method validation of **Ornidazole** in bulk form

Accuracy

For accuracy determination, three different concentrations were prepared separately 80%, 100% and 120%for the concentrations of absorbance values are recorded.

Precision

The standard solution was placed into cuvettes for six times and measured for all six concentrations absorbance values by using max in UV. The %RSD for the area of six replicate concentrations was found to be within the specified limits.

Robustness

As part of the Robustness, deliberate variations in method parameters and provides an indication of its reliability during normal usage. Wavelength was varied between plus or minus to. The solutions were made in triplicates and were analysed the %RSD is determined.

Linearity and range

Linearity of the analytical method for assay by placing the linearity solutions prepared in the range of 1µg to 5µg of test concentration, into the

curettes, covering minimum 5 different concentrations.

RESULTS AND DISCUSSION

Standard preparation

Accurately weigh 50 mg of **Ornidazole** and transfer in to 100ml volumetric flask. Add 100 ml of hydrotropic solution; sonicate it to dissolve for 10 mins. Cool the solution to room temperature and dilute to volume with sodium citrate. Transfer 5ml of above solution in to a 100ml volumetric flask and make up the volume with hydrotropic solution.

Figure: 3. Shows UV absorption spectrum of Ornidazole standard

Accuracy

Average recoveries of **Ornidazole** are 98.55%, 99.13%, 98.60%, at 80%, 100% & 120% concentrations level respectively. The percentage recoveries of the drug are within the limits 98-102%. So, the method is accurate, accuracy data for **Ornidazole** are presented in;

Table: 01 .Shows Accuracy results of Ornidazole

Concentration level	Amount added (mg)	%recovery	Average % recovery
	8mg		98.55%
	8mg	98.70%	
80%	8mg	98.56%	
		98.41%	
	10mg	99.42%	99.13%
	10mg	98.56%	
100%	10mg	99.42%	
	12mg		98.60%
	12mg	98.56%	
120%	12mg	98.56%	
		98.70%	

Result

The accuracy for the average of triplicate in each concentration samples are within the limit.

Table: 02. Shows % Recovery of Ornidazole

Amount added (mg)	Amount to be found(mg)	Average % recovery
10mg	9.91mg	99.13%

Precision

Precision are summarized in **Table No: 3**, respectively. The %RSD values for Precession was less than 2.0%, which indicates that the proposed method is precise.

Table: 03.Shows Precision Results of Ornidazole

Concentration (µg/ml)	Absorbance of Ornidazole
10	0.691
10	0.685
10	0.691
10	0.691
10	0.685
10	0.691
Mean	**0.689**
SD	**0.0013**
%RSD	**0.188**

Linearity

The response was found linear over a concentration range of 1-5µg/mL of Ornidazole. The correlation co-efficient were found to be 0.950 for Ornidazole**.** So the method is linear, data is presented in

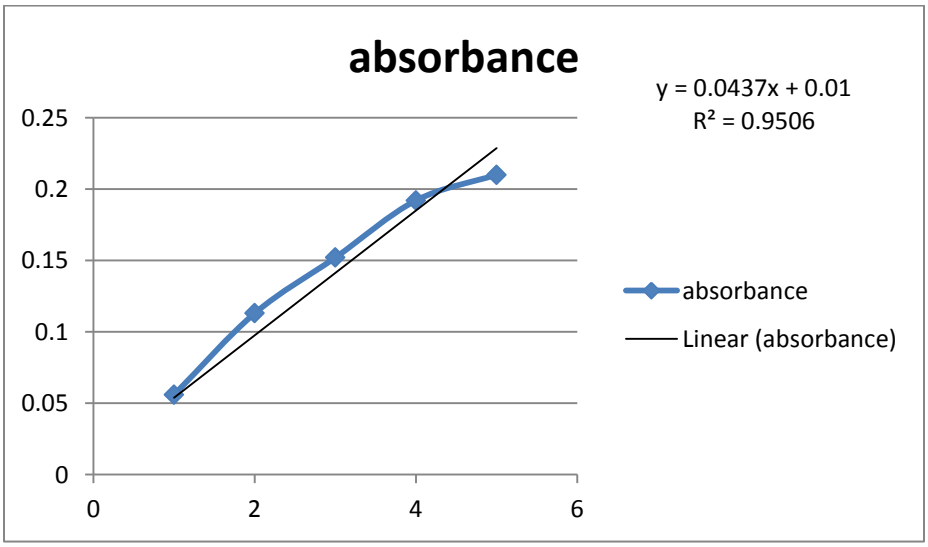


Table: 04 Shows linearity results of Ornidazole

S.no	Linerty level	Concentration	Absorbance
1	I	1µg	0.056
2	II	2 µg	0.132
3	III	3µg	0.152
4	IV	4 µg	0.192
5	V	5µg	0.210
Correlation Coefficient			0.950
Intercept			Y=0.043x+0.01
Slope			0.043

Robustness

The Robustness of the method was determined by making slight changes in the experimental conditions such as change in the wavelength.

Table: 05. Shows Results of Robustness

Analyst-1

S.no	Linerty level	Concentration	Absorbance
1	I	10µg	0.691
2	II	10 µg	0.685
3	III	10 µg	0.685
4	IV	10 µg	0.691
5	V	10 µg	0.691
6	VI	10 µg	0.691
Correlation Coefficient			0.950
Intercept			Y=0.043x+0.01
Slope			0.043

Analyst-2

S.no	Linerty level	Concentration	Absorbance
1	I	10µg	0.691
2	II	10 µg	0.685
3	III	10 µg	0.685
4	IV	10 µg	0.685
5	V	10 µg	0.691
6	VI	10 µg	0.685
Correlation Coefficient			0.950
Intercept			Y=0.043x+0.01
Slope			0.043

Limit of Detection (LOD) & LOQ

The detection limit is determined by the analysis of samples with known concentration of analyte and by establishing that minimum level at which the analyte can reliably detected **,** The LOD are calculated from the calibration curve by formula LOD = 3.3 x SD/ b The quantification limit is generally determined by the analysis of sample with known concentrations of analyte and by establishing the minimum levelat which the analyte can be quantified with acceptable accuracy and precision, The LOQ are calculated from the calibration curve by formula LOQ = 10 x SD/ b

Table: 13. Shows LOD & LOQ results of Ornidazole

Parameters	Ornidazole
LOD	0.099µg/ml
LOQ	0.299µg/ml

Validation parameter results

Table: 14. Shows summary of validation parameter Results

S.NO	Parameter	Acceptance criteria	UV
1	%recovery	92-103%	98.42%
2	Linearity range (µg/ml)	-	1-5(µg/ml)
3	Correlation Coefficient	NLT 0.999	0.950
4	Precision	%RSD (NMT 2%)	0.188
5	Intermediate Precision	%RSD (NMT 2%)	0.246
6	Robustness	%RSD (NMT 2%)	0.276
7	LOD	-	0.099(µg/ml)
8	LOQ	-	0.299(µg/ml)
9	**Sandell's sensitivity**		**0.0236** µg/cm^2/0.001/abs
10	**Molar absorptivity**		**3.89×10^3 mol^{-1} cm^{-1} ×10^3**

CONCLUSION

In the present investigation, we are find out a simple, sensitive, precise and accurate UV-Visible spectroscopy method is developed for the quantitative estimation of **Ornidazole** in bulk drug and pharmaceutical dosage forms from the literature review.

This method is simple, since diluted samples are directly used without any preliminary chemical divinization or purification steps. This method can be used for the routine determination of Ornidazole in bulk drug and other drugs.

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