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Original Article

Development and Validation of UV Spectrophotometric Method for Estimation of Metronidazole in Tablet Dosage Form

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A R T I C L E   I N F O

A B S T R A C T

A simple, rapid and accurate spectrophotometric method has been developed for estimation of metronidazole. The method involved measurement of absorbance at wavelength 320 nm using water as the solvent. The method was validated according to ICH guidelines with respect to different analytical parameters such as linearity, precision, accuracy, Limit of Detection (LOD) and Limit of Quantification (LOQ). Beer's law obeyed in concentration range of 2-20 µg/ml. Limit of detection and quantification values were determined to be 0.763µg/ml and 2.312µg/ml respectively. The recovery values were found to be in the range of 98-102%. The proposed method was also found to be precise since %RSD value was less than 2 and can be used for routine quality control analysis.
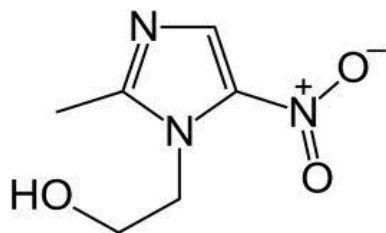
Keywords: Metronidazole, UV Spectrophotometric, method development, method validation

1. INTRODUCTION

Metronidazole is antibiotic and antiprotozoal drug. Chemically, it is 2-(2-methyl-5-nitro-1*H*-imidazol-1-yl) ethanol (Figure 1). Clinically used in the treatment of bacterial vaginosis, pelvic inflammatory disease, intra abdominal infections and amoebiasis.

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Fig 1: Structure of Metronidazole

Literature survey revealed that there are only few methods reported for the estimation of metronidazole, individually or with other drugs using UV-spectrophotometry [1-4] and RP-HPLC [5-6]. Hence present study aim to develope a precise, linear, simple, rapid, validated and cost effective UV-spectrophotometry method for the estimation of metronidazole in tablet dosage forms.

2. MATERIALS AND METHODS

2.1 Instruments used

SHIMADZU double beam UV/Visible Spectrophotometer model UV 1800s was employed with a spectral band width of 1nm and a wavelength accuracy of 0.3 nm (with automatic wavelength correction with a pair of 1cm matched quartz cells). SHIMADZU Electronic balance model AX 200 and Ultra Sonicator (Fast clean) model 2k811056 were also used during the analysis.

2.2 Materials

Analytically pure sample of Metronidazole was obtained as gift sample from Dr. Reddy's Laboratories (Hyderabad). Tablets of brand "Metrogyl 500" manufactured by JB chemicals were purchased from local pharmacy.

2.3 Method

Selection of solvent and wavelength

The UV spectra of Metronidazole in different solvents like water, acetonitrile, methanol and ethanol were recorded. The drug showed good absorbance when dissolved in water and also as water is economic it was selected as the solvent. In this the drug was showing good absorbance at wavelength of 320nm.

Preparation of standard solutions

Metronidazole of 100mg was accurately weighed and transferred to a 100 ml volumetric flask and dissolved in water to get a solution of concentration 1000µg/ml.

Preparation working standard solutions

Working standard solutions of 10 µg/ml were prepared by diluting 1ml of above standard solution to 100ml with water and scanned it in the range 200 nm-400 nm to obtain the absorbance spectra (figure 2).

Preparation of sample solutions

Twenty Metrogyl 500 tablets each containing 500mg of Metronidazole were weighed, average weight was calculated and powdered. A quantity equivalent to 50mg of Metronidazole was weighed and transferred to 100ml volumetric flask and dissolved in water. The solution was made up to the volume with water to obtain concentration of 500 µg/ml and filtered. 5µg/ml standard solution was prepared by diluting 1ml of standard solution to 100ml with water.

3. RESULTS AND DISCUSSION

The analytical method developed was validated according to ICH guidelines [7] with respect to parameters such as linearity, precision, accuracy, limit of detection (LOD), limit of quantification (LOQ).

3.1 Linearity and Range

Linearity was established by least squares linear regression analysis of the calibration curve. The calibration curve was linear over the concentration range of 2-20 µg/ml. Correlation coefficient was found to be 0.998 (Fig.3).

3.2 Precision

The precision of the analytical method was studied by multiple sampling of the homogenous sample. The precision was done by measuring the absorbance for six times. The %RSD value was found to be 0.69 indicating that the method is precise. The results are given in Table.1.

3.3 Accuracy

Recovery studies were carried out by applying the method to drug sample to which known amount of Metronidazole at three concentration levels of 80, 100 and 120 % were added. At each level %recovery was determined, which are in the range of 98-102%. The results are given in Table 2.

3.4 Sensitivity

LOD and LOQ decide about the sensitivity of the method. LOD is the lowest detectable concentration of the analyte by the method while LOQ is the minimum quantifiable concentration. LOD and LOQ were calculated by standard calibration curves. LOD and LOQ were found to be 0.763μg/ml and 2.312μg/ml respectively.

3.5 Analysis of marketed formulation

The developed and validated method was applied for the assay of marketed formulation. The results are shown in Table 3.
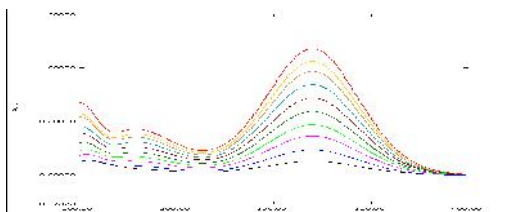

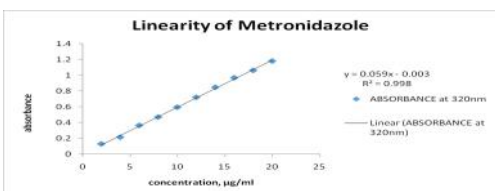**Fig 2: Overlain spectra of Metronidazole**

Fig 3: Calibration curve of Metronidazole

4. CONCLUSION

The evaluation of obtained values suggests that the proposed UV Spectrophotometry methods provide simple, precise, rapid and accurate analytical method for determination of Metronidazole in tablet dosage form. Correlating the obtained results with the standard values, the method is found to be valid and hence the method can be easily and conveniently adopted for routine estimation Metronidazole in tablet dosage form.

Table 1: Precision studies of Metronidazole

S.No	Absorbance at 320nm	%RSD
1	0.33398	0.69
2	0.32991	
3	0.33569	
4	0.33265	
5	0.33361	
6	0.32998	

Table 2: Accuracy studies of Metronidazole

Amount of Metronidazole taken(μg/ml)	% recovery	Amount added (μg/ml)	Total amount recovered (μg/ml)	% Recovered
5	50	2.5	7.4	98.66
	100	5	10.9	99
	150	7.5	12.7	101.6

Table 3: Analysis of marketed formulation

Drug	Labeled amount, mg/ tablet	Amount found, mg/ tablet	% Label claim
Metronidazole	500	500.4	100.08

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