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Spectrophotometric Method Development and Determination of Ornidazole in Bulk and Tablet Dosage Form

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Abstract: Ornidazole is an antimicrobial agent. Here, to develop a simple, precise and accurate spectrophotometric method determination and validation for ornidazole in bulk and solid dosage form. Ornidazole shows a maximum absorbance at 310.5 nm in ethanol as a medium. Beer's law was observed in the concentration range of 5-25 µg/ml. The methods were validated statistically and by recovery studies and it were found to be accurate, precise and reproducible for determination of ornidazole in bulk and marketed dosage form. The methods were validated statistically and by recovery studies and it were found to be accurate, precise and reproducible for determination of ornidazole in bulk and solid dosage form.

Key words: Ornidazole, Ethanol, Spectrophotometric Method, Validation.

INTRODUCTION

Ornidazole is a 5-nitroimidazole derivative, chemically-chloromethyl-2-methyl-5nitro-1H-imidazole-1-ethanol with molecular formula C7H10N3O3Cl[1] used as antimicrobial agent. Ornidazole has antiprotozoal and antibacterial properties against anaerobic bacteria. The antimicrobial activity of this compound is due to reduction of the nitro group to a more reactive amine group that attacks microbial DNA, inhibiting further synthesis, and leading to degradation of existing DNA.[2] It is not official in any pharmacopoeia. Literature survey[3-8] reveals that ornidazole is estimated by voltametry 9 and HPLC10 methods for its determination in dosage forms and biological fluids.

Ornidazole, chemically α-chloromethyl-2-methyl-5-nitro-1H-imidazole-1-ethanol, with molecular formula $C_7H_{10}N_3O_3Cl$. It is not an official drug in any pharmacopoeia. Few methods are available for the determination of ornidazole in bulk and solid dosage form.

The present studies describe accurate, precise and reproducible spectrophotometric methods for estimation of ornidazole in bulk and solid dosage form.The method was validated by using various parameters as per ICH guidelines.[9]

MATERIALS AND METHODS

Materials

Ornidazole was obtained as a gift sample from Zydus Healthcare, Rangpo, East Sikkim. Ethanol and other reagents were of analytical grade. The U.V-Visible double beam spectrophotometer (Shimadzu-1700) with a fixed slit width (2 nm) and 10 millimeter quartz cell was used to obtain spectrum and absorbance measurement.

Methods

Procedure for Preparation of Calibration Curve

Ornidazole 10 mg was accurately weighed and diluted with 10 ml of ethanol. From this, 0.05ml, 0.1ml, 0.15ml, 0.2ml and0.25ml were taken and diluted each to 10 ml with ethanol to give solution of 5µg, 10µg, 15µg, 20µg and 25µg concentration of drug per ml respectively. The solutions were scanned in U.V/Visible double beam spectrophotometer (Shimadzu-1700) against ethanol as a blank.

Procedure for Drug Recovery

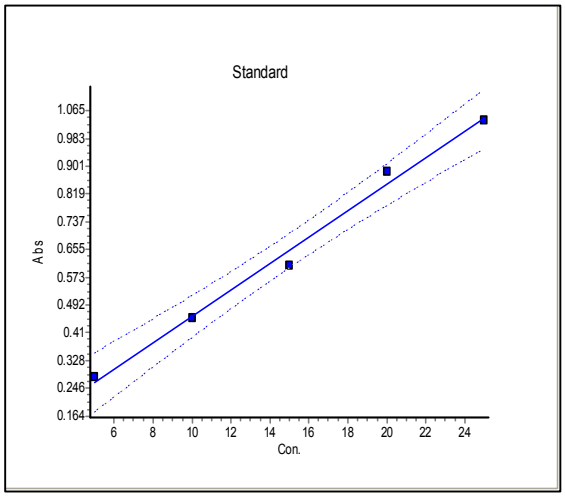
In order to assess the drug recovery 10 tablets each from two market products (a) Orni- 500mg (Zydus Healthcare) and (b) Ornida 500mg (Aristo Pharmaceutical Pvt.Ltd) were weighed and powdered. From this, powder equivalent to 10mg was weighed, diluted to 10 ml with ethanol. The solution was shaken well and filtered through whatman filter paper (No.41). After suitable dilution, absorbance of final sample corresponding to 10 µg/ml was recorded against blank.To examine the absence of either positive or negative interference of excipients used in formulation, recovery studies were carried out at five different labels.

Table 1: Statistical Analysis (ANOVA Table) for Standard (Bulk) and Test Sample

Best-fit 95% confidence interval						
STANDARD LINEAR REGRESSION	Number of points =5	Parameter	Value	Error	From	To
		Slope	0.03894	0.002250	0.03178	0.04610
		Y-intercept	0.06830	0.03731	-0.05042	0.1870
		X-intercept	-1.754			
		Correlation coefficient (r) = 0.9950, r-squared = 0.9901				
		Standard deviation of residuals from line (Sy.x) = 0.03557				
ANOVA TABLE FOR STANDARD		Source of Variation	Degrees of freedom	Sum of squares	Mean square	F = 299.57
		Linear regression (Model)	1	0.3791	0.3791	
		Deviations from linearity (Residual)	3	0.003796	0.001265	
		Total	4	0.3829		
		The P value is 0.0004, considered extremely significant.				
TESTLINEAR REGRESSION	Number of points =5	Parameter	Value	Error	From	To
		Slope	0.03806	0.002421	0.03036	0.04576
		Y-intercept	0.2671	0.04015	0.1393	0.3949
		X-intercept	-7.018			
		Correlation coefficient (r) = 0.9940, r-squared = 0.9880				
		Standard deviation of residuals from line (Sy.x) = 0.03828				
ANOVA TABLE FOR TEST		Source of Variation	Degrees of freedom	Sum of squares	Mean square	F = 247.08
		Linear regression (Model)	1	0.3621	0.3621	
		Deviations from linearity (Residual)	3	0.004397	0.001466	
		Total	4	0.3665		
		The P value is 0.0006, considered extremely significant.				

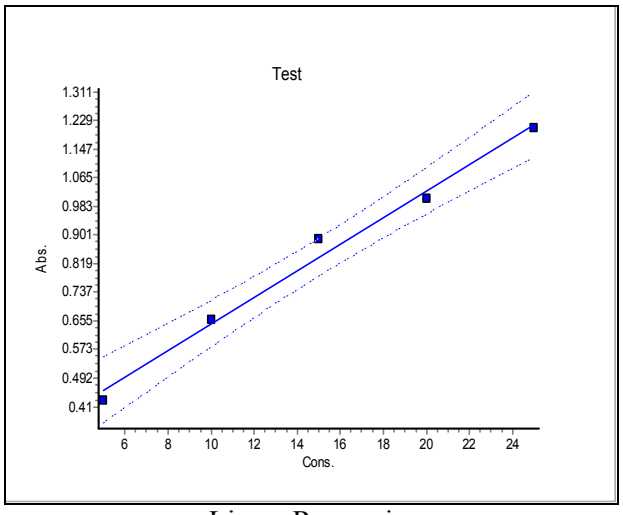
Table 2 :Ornidazole Bulk and Test Parameters Comparative Study

PARAMETERS	STANDARD	TEST
Absorption maximum(nm)	310.5nm	310.5nm
Beer's law limit (µg/ml)	5-25 µg/ml	5-25 µg/ml
Regression equation(y=mx+c)	y=0.038x+0.068	Y=0.038+0.267
Slope (m)	0.038	0.038
Intercept (c)	0.068	0.267
Regression coefficient(r^2)	0.990	0.988
Correlation coefficient(r)	0.9950	0.9940
Standard deviation	0.0374	0.0211
Molar absorptivity($mol^{-1}cm^{-1}$)	83457.5	---------
P value	0.0004	0.0006
Linear regression	0.0389	0.0380
Deviation from linearity	0.0355	0.0382
Percentage Recovery ± S.D	----------	96.30-98±0.021%



———— Linear Regression
---------- 95% Confidence interval

Figure 1: Linear Regression Curve for Standard Sample Ornidazole



———— Linear Regression
---------- 95% Confidence interval

Figure 2: Linear Regression Curve for Test Sample Ornidazole

RESULTS AND DISCUSSION

The Maximum absorption for pure ornidazole in ethanol using U.V spectrophotometer at 310.5nm was recorded. According to ICH guideline[9] the method was validated. Linear regression of standard with correlation coefficient r= 0.9950 indicates a good linearity between absorbance and concentration range of 5-25 mcg/ml and linear regression both for standard and test sample of ornidazole described by figure 1 and 2. The statistical analysis for both standard (bulk) and test sample described by table 1 and the optical characters such as Beer's law limit, molar absorptivity and other parameters are summarized in table 2.

CONCLUSION

The proposed method obeyed beer's law in the concentration range of 5-25 µg/ml with ethanol. The recovery studies were carried were found close to 100% indicating accuracy and precision of the proposed method. Hence this developed method could be used for routine estimation of ornidazole from tablet formulations.

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