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UV SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION FOR QUANTITATIVE ESTIMATION OF MICONAZOLE NITRATE (MIC)

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ABSTRACT

UV Spectrophotometric Method Development and Validation for quantitative estimation of Miconazole nitrate (MIC). U.V Spectrophotometric method have been widely employed in determination of individual components in a mixture or fixed dose combination. Our aim is to develop spectroscopic method for estimation of the Miconazole nitrate (MIC) in ternary mixture by using U.V spectrophotometry. The method was validated as per ICH guidelines. The recovery studies confirmed the accuracy and precision of the method. It was successfully applied for the analysis of the drug in bulk and could be effectively used for the routine analysis.

KEYWORDS

Miconazole Nitrate, UV spectrophotometric method, MIC and Validation.

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INTRODUCTION

Miconazole nitrate (MIC) was belongs to class of imidazole and it is an antifungal agent commonly applied topically to the skin or to mucous membranes to cure fungal infections. Miconazole nitrate (MIC) was approved by FDA in 1974. MIC used in treatment of superficial candidiasis. It may also be given orally as a gel for the treatment of oropharyngeal and intestinal candidiasis. Several analytical methods have been reported for the determination of MIC in pharmaceuticals and biological samples includes spectrophotometric, HPLC either alone or in combination with other drugs, Gas Chromatography, HPTLC and voltammetry determinations. The aim of the study

was to develop a simple, precise and accurate spectrophotometric method for the estimation of Miconazole nitrate (MIC) in pure and in its pharmaceutical dosage forms[1-3].

MATERIAL AND METHODS

Material

Miconazole nitrate (MIC) were kindly supplied by Sigma, Egypt.

Apparatus

A Shimadzu UV/Visible double beam spectrophotometer (Model 1700) with 1 cm matched quartz cells were used in present study for spectral and absorbance measurements.

Method

Selection of solvent

After the solubility study of Miconazole nitrate (MIC) in different solvents, methanol was confirmed as a common solvent for developing spectral characteristic.

Preparation of standard stock solution

According to European pharmacopoeia, 10 mg of MIC was dissolve in 100 ml of methanol (100µg/mL). Out of this stock 0.5-3.0 mL was pipetted and diluted up to 10 ml by methanol (5-30µg/mL) and examined between 200-400 nm. The maximum absorbance was determined using UV-Vis Spectrophotometer (UV-1700, Shimadzu, Japan) to confirm the λmax of the drugs.

Validation of analytical method

The analytical performance characteristics which may be tested during methods validation: % Recovery, Precision, Ruggedness and sensitivity[3-6].

RESULTS AND DISCUSSION

Method Development

The solution of MIC in methanol was found to exhibit maximum absorption at 272 nm after scanning on the UV-Vis spectrophotometer which was reported as λ max in the literature and the procured drug sample of MIC complies with the reference spectra (Figure No.1).

Linearity

Accurately weighted MIC(10 mg) was dissolved in 100 ml of methanol to obtain working standard of 100µg/mL. Aliquots were pipetted from the stock solution of drug and were transferred to 10mL volumetric flask, the final volume was adjusted with methanol so that concentration of 5-30µg/mL could be made. Absorbance of the above solution was done at 272 nm by using UV-Vis spectrophotometric method (UV-1700, Shimadzu, Japan) against the blank solution prepared in the same manner without adding the drug. A graph of absorbance vs concentration was plotted (Figure No.2) and R^2 was found to be 0.997.

VALIDATION OF ANALYTICAL METHOD

Recovery

Recovery study is performed by standard addition method by adding the known amount of MIC (Working standard) at two different concentration levels i.e 80%, 100% of assay concentration and % recovery for all these drug were calculated. Result was reported in Table No.1.

Precision

Intra-day precision was determined by analysing, the two different concentrations 5 mg/mL, 10mg/mL containing MIC, for three times in the same day (n = 3) Table No.2. Inter-day variability was determine two concentrations such as 5mg/mL, 10 mg/mL was analyzed on three different days, over a period of one week (n = 3) Table No.2.

Ruggedness

From stock solution, sample solution containing MIC (5µg/mL) was prepared and analyzed by two different analysts using similar operational and environmental conditions (Table No.3) (n = 3).

Sensitivity

Sensitivity of the proposed method were estimated in terms of Limit of Detection (LOD) and Limit of Quantitation (LOQ) (Table No.4).

Table No.1: Recovery study

S.No	Drug	Initial amount (µg/mL)	Added Amount (µg/mL)	% Recovery	% RSD (n = 3)
1	MIC	5	4.8	99.46	0.05
2		5	5.0	100.09	0.01

Table No.2: Presion study

S.No	Drug		Intra - Day		Inter - Day	
		Con. (µg/mL)	Mean ± SD	% RSD	Mean ± SD	% RSD
1	MIC	5	5.0 ± 0.0010	0.03	5.0 ± 0.0038	0.04
2		10	10.0 ± 0.0057	0.09	10.0 ± 0.0047	0.09

Table No.3: Ruggedness study

S.No	Drug	% Amount Found		% RSD	
		Analyst I	Analyst II	Analyst I	Analyst II
1	MIC	100.14	100.28	0.01	0.01

Table No.4: Sensitivity study

S.No	Drug	LOD	LOQ
1	MIC	0.28 ± 0.004	0.99 ± 0.001

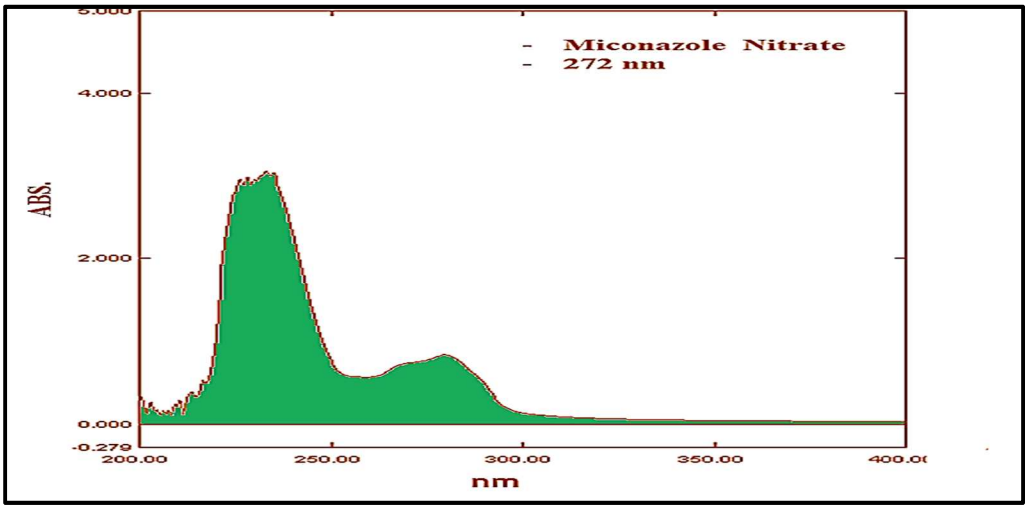

Figure No.1: UV spectra of Miconazole Nitrate (MIC)

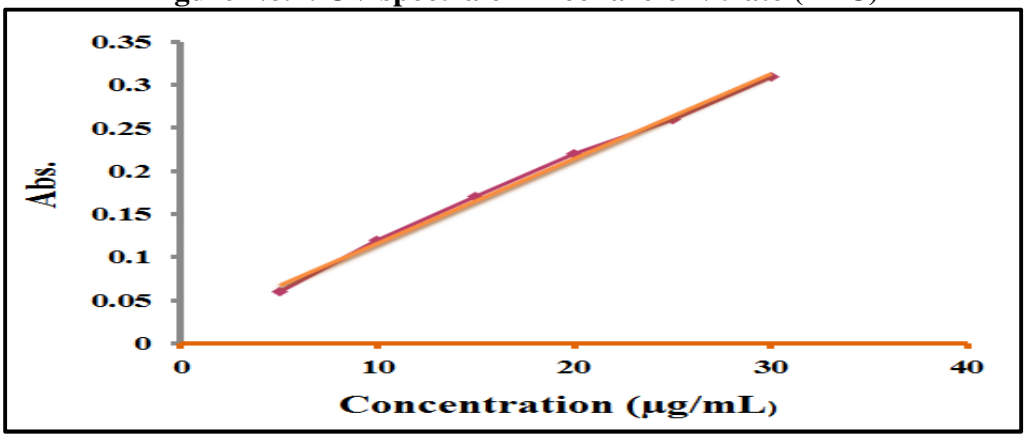

Figure No.2: Calibration curve of Miconazole Nitrate (MIC)

CONCLUSION

The method was validated in compliance with ICH guidelines is suitable for estimation of MIC with excellent recovery, precision and linearity.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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