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Research Article

UV Spectrophotometric Method Development and Validation for Quantitative Estimation of Mebendazole

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ABSTRACT

Aim: UV Spectrophotometric Method Development and Validation for quantitative estimation of Mebendazole. **Objective:** U.V Spectrophotometric method have been widely employed for determination of analyte in a mixture. Our aim is to develop spectroscopic method for estimation of the Mebendazolein ternary mixture by using U.V spectrophotometry. **Methodology:** The method was validated as per ICH guidelines. The recovery studies confirmed the accuracy and precision of the method. **Conclusion:** It was successfully applied for the analysis of the drug in bulk and could be effectively used for the routine analysis.

Key words: Mebendazole, UV spectrophotometric method, Validation.

Introduction

Mebendazole, chemically Methyl-5-benzoyl-2-benzimidazole carbamate, is used as an anthelmintic agent. The drug is known to act through irreversible inhibition of glucose uptake in the parasite, leading to depletion of glycogen store. This in turn decrease adenosine tri phosphate activity. Only 5-10% of the ingested drug, gets absorbed from the human gastrointestinal tract. The drug is known to be dysmorphonegic in experimental animals. The aim of current work is to develop and validate a simple, rapid, reliable and precise U.V spectrophotometric methods for analysis of Mebendazole in bulk and tablet formulation (Swamy et al., 2013).

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Material and Method

Material

Mebendazolesupplied as a gift sample fromCipla Pvt. Ltd (Mumbai, India) used as working standard.

Instrumentation

A double beam UV-VIS spectrophotometer (UV-1700, Shimadzu, Japan) connected to a computer loaded with spectra manager software UV Probe was used. The spectra were obtained with the instrumental parameters as follows: Wavelength range: 200–400 nm. All weights were taken on an electronic balance (Model Shimadzu AUX 120).

Preparation of standard stock solution

According to European pharmacopoeia, 10 mg of Mebendazolewas dissolve in 100 ml of methanol (100 µg/mL). Out of this stock 0.2-1.0 ml was pipetted and diluted up to 10 ml by methanol (2-10 µg/mL) and examined between 200-400 nm. The maximum absorbance was determined using UV-Vis Specrophotometer (UV-1700, Shimadzu, Japan) to confirm the λmax of the drugs (Savale et al., 2017).

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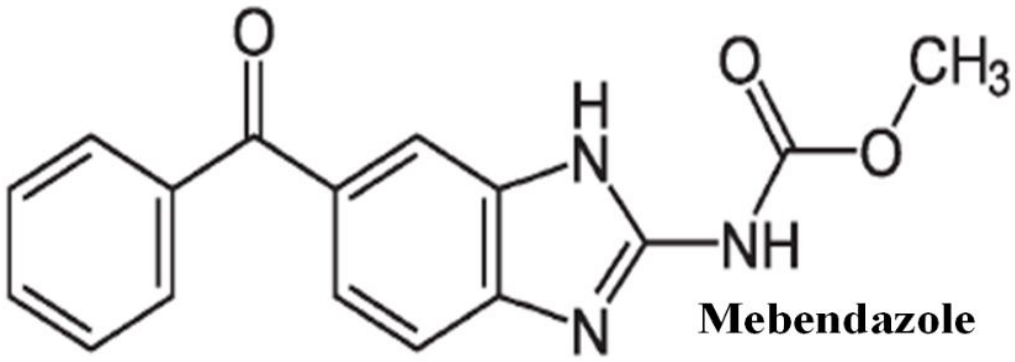

Validation of analytical method

The analytical performance characteristics which may be tested during methods validation: % Recovery, Precision, Ruggedness and sensitivity (Savale et al., 2017).

Results and Discussion

Method Development

The solution of Mebendazole in methanol was found to exhibit maximum absorption at 246.6 nm after scanning on the UV-Vis spectrophotometer which was reported as λmax in the literature and the procured drug sample of Mebendazole complies with the reference spectra (Figure 1) (Savale et al., 2017).

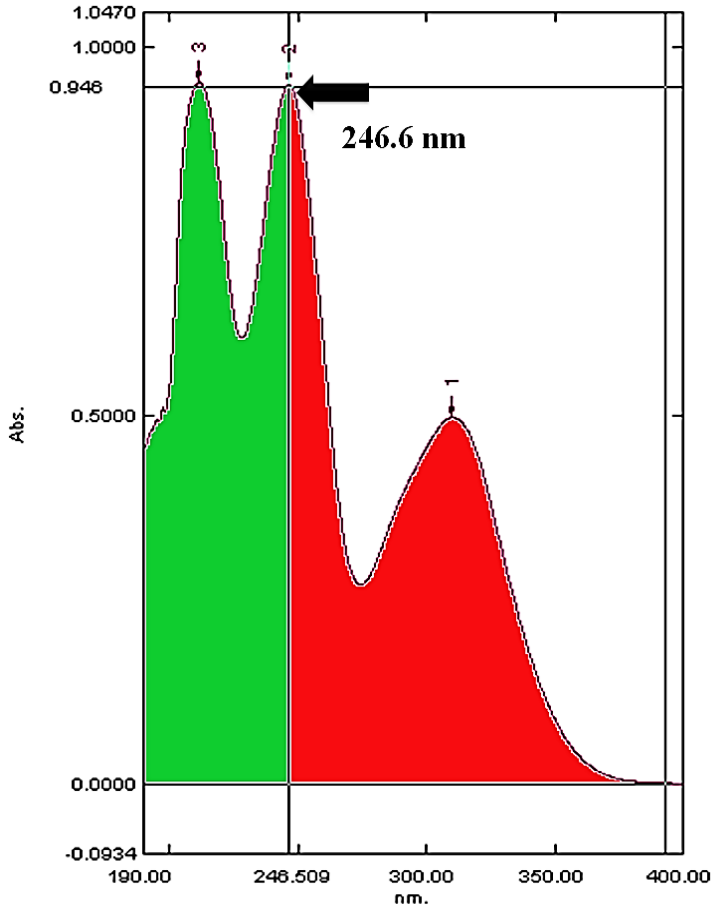

Figure 1. UV spectra of Mebendazole

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Validation of analytical method

Linearity

Accurately weighted Mebendazole(10 mg) was dissolved in 100 ml of methanol to obtain working standard of 100 µg/ml. Aliquots were pipetted from the stock solution of drug and were transferred to 10 ml volumetric flask, the final volume was adjusted with methanol so that concentration of 2-10 µg/ml could be made. Absorbance of the above solution were taken at 246.6 nm by using UV-Vis spectrophotometer (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 2) and R^2 was found to be 0.9992.

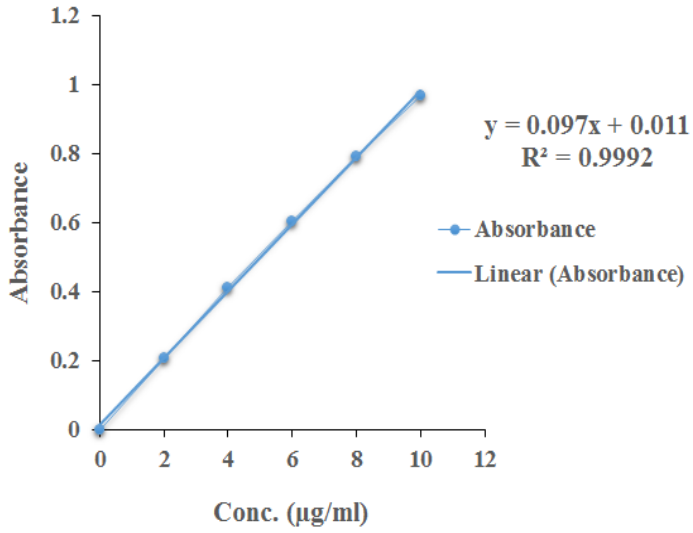

Figure 2. Calibration curve of Mebendazole

Recovery

Recovery study is performed by standard addition method by adding the known amount of Mebendazole (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 1.

Table 1. Recovery study

Drug	Initial amount (µg/ml)	Added Amount (µg/ml)	% Recovery	% RSD (n = 3)
Mebendazole	2	1.8	100.09	0.05
	2	2	99.77	0.02

Precision

Intra-day precision was determined by analysing, the two different concentrations 2 µg/ml, 4µg/ml containing Mebendazole, for three times in the same day (n = 3) Table 2. Inter-day variability was assessed using above mentioned three concentrations analysed on three different days, over a period of one week (n = 3) Table 2 (Savale et al., 2017).

Table 2. Presion study

		Intra - Day		Inter - Day	
Drug	**Con. (µg/ml)**	**Mean ± SD**	**% RSD**	**Mean ± SD**	**% RSD**
Mebendazole	2	2.0 ± 0.0055	0.06	2.0 ± 0.0048	0.01
	4	4.0 ± 0.0087	0.01	4.0 ± 0.0049	0.03

Ruggedness

From stock solution, sample solution containing Mebendazole (2 µg/ml) was prepared and analyzed by two different analysts using similar operational and environmental conditions (Table 3) (n = 3).

Table 3. Ruggedness study

	% Amount Found		% RSD	
Drug	**Analyst I**	**Analyst II**	**Analyst I**	**Analyst II**
Mebendazole	100.12	100.78	0.09	0.07

Sensitivity

Sensitivity of the proposed method were estimated in terms of Limit of Detection (LOD) and Limit of Quantitation (LOQ) (Table 4) (Savale et al., 2017).

Table 4. Sensitivity study

Drug	LOD	LOQ
Mebendazole	0.46 ± 0.001	0.98 ± 0.016

Conclusion

The proposed UV spectrophotometric method was found very simple, rapid and economical. The method is validated in compliance with ICH guidelines is suitable for estimation of Mebendazolewith excellent recovery, precision and linearity.

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