ISSN: 2634 - 8861

Journal of Infectious Diseases & Case Reports

SCIENTIFIC Research and Community

Research Article

Open Access

Estimation of Tolnaftate in Pharmaceutical Preparations Samples

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ABSTRACT

A simple, accurate, precise, rapid, economical and sensitive ultraviolet spectrophotometric method has been developed for the determination of Tolnaftate in pharmaceutical preparations which shows maximum absorbance at 260 nm in distilled water. Beer's law was obeyed in the range of 1 -14 µg/ ml ,with molar absorptivity of 2.183×10^4 $L.mol^{-1}.cm^{-1}$, relative standard deviation of the method was less than 1.8%, and accuracy (average recovery %) was 100 ± 1.0. No interference was observed from common excipients and additives often accompany with Tolnaftate in pharmaceutical preparations .The method was successfully applied to the determination of Tolnaftate in some pharmaceutical formulations (creams and topical solutions) samples. The proposed method was validated by sensitivity and precision which proves suitability for the routine analysis of Tolnaftate in true samples.

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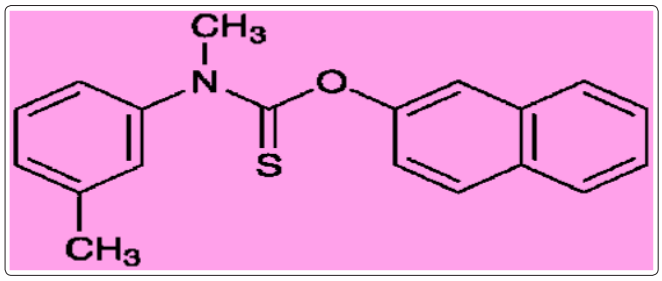
Received: August 14 2020; **Accepted:** August 20, 2020; **Published:** August 27, 2020

Keywords: Tolnaftate, Pharmaceutical Preparations, Ultraviolet Spectrophotometric.

Introduction

Tolnaftate: (O-Naphthalene -2-yl N-methyl-N- (3-methyl phenyl) thiocarbamate [I].



$C_{19}H_{17}NOS$ = 307.41 g/mol

Figure 1: Chemical structure of Tolnaftate

Tolnaftate, discovered in Japan in 1962 by Noguchi and colleagues , is a thiocarbamate antifungal and used topically in the treatment of cutaneous disease such as jock itch, athlete, s foot, the other skin infections due to, epidermophyton, Microsporum, Trichophyton species, and Malasseziafurfur [1-6]. A survey of literature revealed that only a few visible spectrophotometric methods were reported, spectrofluorimetry method [7-10]. High performance liquid chromatography (HPLC) and (HPTLC), however these methods lack sensitivity, and simplicity needed for routine analysis [3,11,12]. The present method described a simple, economical, accurate, sensitive and reproducible ultraviolet spectrophotometric method for the determination of Tolnaftate in pharmaceutical preparations (creams and topical solutions) samples.

Experimental

Apparatus

Shimadzu UV- 1700 pharmaspec (double beam) spectrophotometer with 1.0 cm quartz cells was used for absorption measurement.

Reagents

All chemicals used were of analytical or pharmaceutical grade and the Tolnaftate standard material was provided from state company for drug industries and medical appliance (HPI) Mosul-Iraq.

Tolnaftate Stock Solution (100 ppm)

This solution was prepared by dissolving 0.01gm of Tolnaftate in 50 ml methanol and diluting to 100 ml with distilled water.

Tolnaftate Standard Solution 20ppm

This solution was prepared by diluting 20 ml of stock solution into 100ml by (1:1 methanol: distilled water) in a volumetric flask.

Recommended Procedure

From the absorption maxima, calibration curve was prepared in the concentration range of 1-14µg/ml. The absorbance was measured at 260 nm against methanol-water 1:1 as a blank .The concentration of the sample solution can be determined by using the calibration curve.

Procedure for Pharmaceutical Preparations

Cream

1gm of cream, equivalent to about 10mg of Tolnaftate was transferred to a 250ml separator containing about 75ml of chloroform. The chloroform solution successively washed with two 25ml portions of 0.1N NaOH, two 25ml portions of 0.1N HCl and 25ml of water. The chloroform layer was filtered through a chloroform-washed cotton pledged into a 100ml volumetric flask. Chloroform was added to volume, and mix. 1ml of chloroform

solution was evaporated on a steam bath just to dryness and the residue was dissolved in 50 ml of methanol and diluted up to 100 ml with distilled water [13]. 1 ml of this solution was treated as mentioned under recommended procedure.

Topical Solution

0.1 ml of solution containing 1mg of Tolnaftate was transferred into 100ml volumetricflask and diluted up to mark with (1:1 methanol: distilled water), a 1 ml of this Solution was treated as mentioned under the recommended procedure

Result and Discussion

UV visible spectrophotometry is still considered to be a convenient and low cost method for the determination of pharmaceuticals and has been increased considerably in recent years because of their importance in pharmaceutical analysis [14-16]. A new method has been developed for the spectrophotometric determination of tolnaftate in pharmaceutical preparations (creams and topical solutions) samples.

Determination of Absorption Maxima

The standard solution of Tolnaftate (10µg/ml) was scanned in the range of 250-400 nm which shows maxima located at 260 nm Figure 2. Therefore, 260 nm wavelength was selected for the construction of calibration curve.

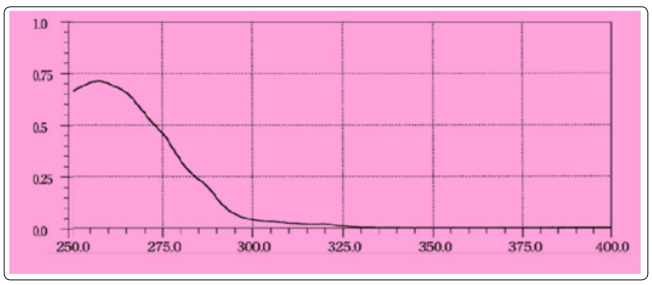


Figure 2: Absorption spectra of 10µg/ml Tolnaftate against blank

The method used for the determination of Tolnaftate in pharmaceutical preparations samples was found to be sensitive, simple, accurate, and reproducible .Beer s law was obeyed in the concentration range of 1-14 µg/ml .Figure 3, with correlation coefficient of 0.997, intercept of 0.0027 and slope of 0.071 .The conditional molar absorptivity was found to be 2.183×10^4 l/mol. cm.

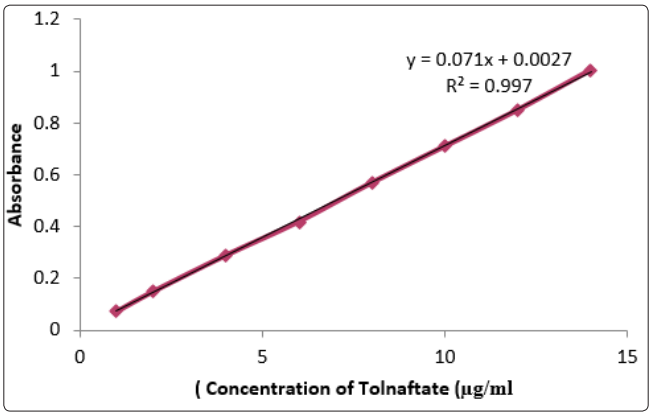


Figure 3: Calibration graph of Tolnaftate

The accuracy and precision of the method, a pure drug solution was analyzed at three different concentrations, each determination being repeated six times. The relative error (%) and relative standard deviation values are summarized in Table 1. From table 1 the values of standard deviation were satisfactory and the recovery studies were close to 100%.The RSD% value is less than 1.8 indicative of accuracy of the method.

Table I: Accuracy and precision of the proposed meth

Tolnaftate taken µg/ml))	Er (%)a	RSD (%)
2	2.04	1.3
10	9.95	1.1
14	13.98	1.3

A: Mean of six determinations.

Effect of Interferences

The interfering effect of foreign species often accompanied with Tolnaftate in the pharmaceutical preparations were studied by adding different amounts of foreign species to 7µg\ 10 ml of Tolnaftate in solution and the recommended procedure for the determination of Tolnaftate was followed. The species are considered to interfere seriously if they cause a change of more than 2% in the absorbance obtained for Tolnaftate a lone [17, 18]. It was observed that the Betamethazone 17-valerate, gentamycine sulphate and clioquinol don't interfere with determination method at levels found in the dosage form cited in table 2, so that the selectivity of method is very good.

Table 2: Determination of Tolnaftate in Presence of Excipients

Excipients	Amount taken, µg	Average recovery* , %
Betamethazon 17-valerate	30	100.05
Gentamycine sulphate	60	100.0
Clioquinol	50	100.08

*Average of seven replicate analyses.

Analytical Applications

The proposed method was satisfactorily applied to the determination of Tolnaftate in its pharmaceutical formulations. The results of the assay of the pharmaceutical formulations revels that there was closed agreement between the results obtained by the proposed method and the label claim. The results were also compared statistically by student t-test and by the variance ratio F-test with those obtained by official method [13] at 95% confidence level. The calculated t- and F- values did not exceed the theoretical values indicating that there was no significant differences between the precision of the proposed and official method as cited in Table 3.

Table 3: Determination of Tolnaftate in Pharmaceutical Formulations

Pharmaceutical formulations(NDI)	Label amount, mg	Official method [15]	Proposed method *	F-value	t- value
Quadreem cream	10mg/gm	9.95	9.94	1.04	1.17
Topical solution	10mg/ml	9.96	9.97	1.08	1.97

*Mean value of ten determinations

T values (n=10, at 95% confidence level tabulated value 2.101).

F values (n1-1 and n2-1 =9, at 95% confidence tabulated value 3.18).

Conclusion

The developed method is found to be high sensitive, accurate, simple, precise and economical, and can be used for routine quality control analysis of Tolnaftate in pure form, pharmaceutical formulations samples.

Acknowledgments

The author [Dr. Nief Rahman Ahmad] wishes to express gratitude to AL-hokamaa Company for pharmaceutical industries (HPI) Mosul-Iraq, for providing gift samples of Tolnaftate standard materials and pharmaceutical preparations.

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