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SPECTROPHOTOMETRIC METHODS FOR THE DETERMINATION OF AMOROLFINE

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ABSTRACT

Two simple and sensitive spectrophotometric methods have been developed for the estimation of amorolfine (AMF) in pure and pharmaceutical dosage forms. Method A is based on the formation of ion-pair complex of the drug with acidic dye methyl orange (λmax 420 nm). The absorbance of the chloroform extracts was measured against the corresponding reagent blank. Method B is based on charge transfer, when the drug reacts with chloranil (λmax 640 nm). These methods have been statistically evaluated and found to be precise and accurate.

Key words: Amorolfine, Spectrophotometric.

INTRODUCTION

Amorolfine (AMF), which is chemically, cis- 4-[3-[4-(1,1-dimethylpropyl)phenyl]-2-methylpropyl]-2,6-dimethylmorpholine, is an antifungal agent. A number of methods such as HPTLC and LCMS were reported for the estimation of AMF. Literature survey reveals that visible spectrophotometric methods have not been reported for its quantitative determination in its pure form and pharmaceutical formulations. In the present investigation, two simple and sensitive spectrophotometric methods have been developed for the determination of AMF. The developed methods involve the formation of colored chromogens with methyl orange and chloranil. The colored chromogens showed absorption maximum at 420 and 640 nm, respectively. Beer's law is obeyed in the concentration ranges of 5-15 μg/mL and 50-250 μg/mL, respectively. The results of analysis for the two methods have been validated statistically and by recovery studies[1-6].

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EXPERIMENTAL

Preparation of reagents

(i) Methyl orange solution: 0.1%w/v in distilled water.

(ii) Hydrochloric acid: 0.1N HCl.

(iii) Chloranil : 0.1% w/v of chloranil in 1,4-dioxane.

(iv) Standard drug solution (Method A) : About 100 mg of amorolfine was accurately weighed and dissolved in 100 mL of methanol to obtain a stock solution of 1 mg/mL. This solution was further diluted to get working standard solution of 100 µg/mL.

(v) Standard drug stock Solution (Method B): About 25 mg of amorolfine was accurately weighed and taken in a 125 mL separating funnel containing 10 mL of 10% sodium carbonate. Then it was extracted with 25 mL of chloroform. The extract was collected and made upto 25 mL with chloroform.

Assay procedures

Method A: Aliquots of working standard solution of AMF ranging from 0.5-1.5 mL were transferred into a series of 125 mL separating funnels. To these, 1 mL of methyl orange dye was added. The total volume of aqueous phase was adjusted to 10 mL with distilled water and 10 mL of chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the yellow colored chromogen was measured at 420 nm against reagent blank and the amount of AMF present in the sample solution was computed from its calibration curve.

Method B: Aliquots of working standard solution of AMF ranging from 0.5-2.5 mL were transferred into a series of 5 mL volumetric flasks and kept in water bath until the solution evaporates. To these, 1.5 mL of dimethylformamide, 0.2 mL of acetaldehyde and 2 mL of chloranil reagent was added. It was boiled for 30 min and made upto volume with 1,4-dioxane.The absorbance of the green colored chromogen was measured at 640 nm against reagent blank and the amount of AMF present in the sample solution was computed from its calibration curve.

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation and percent range of error (0.05 and 0.01 confidence limits) were calculated for both the methods and results are summarized in Table 1. The values obtained for the determination of AMF in pharmaceutical formulations (solution) by the proposed methods are presented in Table 2. Studies reveal that the common excipients and other additives usually present in the solution did not interfere in the proposed methods.

Table 1: Optical characteristics, precision and accuracy of the proposed method

Parameters	Method A	Method B
λ_{max} (nm)	420	640
Beer's law limit (μg/mL)	5-15	50-250
Sandell's sensitivity (μg/cm^2/0.001 abs. unit)	0.0304	0.427
Molar absorptivity (litre.mole^{-1}. cm^{-1})	1.1646×10^5	0.828×10^4
Regression equation (Y*) :		
Slope (b)	0.403	0.133
Intercept (a)	-0.067	0.151
Correlation coefficient (r)	0.9986	0.9992
% Relative standard deviation**	1.979	1.10
% Range of error :		
0.05 significance level	1.655	0.92
0.01 significance level	2.448	1.361

*Y = a + bx, where 'Y' is the absorbance and x is the concentration of amorolfine in μg/mL

**For six replicates

Table 2: Estimation of amorolfine in pharmaceutical formulations

Formulations (Solution)	Labelled amount (5% w/v)	Amount found* by proposed method (in %)		% Recovery** by proposed method	
		Method A	Method B	Method A	Method B
Sample 1	5	4.68	4.88	99.34	99.42
Sample 2	5	4.84	4.90	99.27	99.53
Sample 3	5	4.50	4.85	98.88	99.39
Sample 4	5	4.80	4.92	99.16	99.44

*****Average of six determinations

******Recovery of amount added to the pharmaceutical formulation (Average of three determinations)

CONCLUSION

The proposed methods are applicable for the assay of drug AMF and have an advantage of wider range under Beer's law limits. The proposed methods are simple, selective and reproducible and can be used in the routine determination of AMF in pure form and formulations with reasonable precision and accuracy.

REFERENCES

1. The Merck Index, 13th Ed., Merck Research Laboratories, Merck and Co. Inc., Whitehouse Station, NJ (2001) p. 1061.
2. Martindale The Extra Pharmacopoeia, 31st Ed., J. E. F. Reynolds (Ed.), Royal Pharmaceutical Society, London, UK (1996) p. 1298.
3. Sunil K. Dubey and Anil Patni, E-J. Chem., **6(4)**, 1043 (2009).
4. G. Devala Rao and S. Vijaya Saradhi, Acta Ciencia Indica, **25C**, 154 (2009).

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