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# Spectrophotometric method for the determination of amorolfine

**A. APARNA*, B. ANUPAMA , G. VINDYA and G. DEVALA RAO**

K.V.S.R. Siddhartha College of Pharmaceutical Sciences,
Siddhartha Nagar, Vijayawada - 520 010 (India).

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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 oxidative coupling of the drug with 3-methyl 2-benzothiazolinone hydrazone(MBTH λmax 660 nm). The absorbance of the colored species is measured against the corresponding reagent blank. Method B is based on oxidation followed by complex formation when the drug reacts with ferric chloride and 1,10-phenanthroline (λmax 510nm) .These methods have been statistically evaluated and found to be precise and accurate.

**Key words:** Spectrophotometry, Amorolfine, pharmaceutical dosage form.

## 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, 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 complexes with MBTH & 1,10-Phenanthroline. The colored chromogens showed absorption maximum at 660 and 510nm respectively. Beers law is obeyed in the concentration ranges of 10-30µg/ml and 10-50µg/ml respectively. The results of analysis for the two methods have been validated statistically and by recovery studies[1-6].

## EXPERIMENTAL

### Preparation of reagents

1. An aqueous solution of MBTH(0.2%w/v) and solution of Ferric Chloride (0.7%w/v) in 0.5N HCl was prepared.
2. 1,10-Phenanthroline: 198mg in 100ml of 0.1N HCl.
3. Ferric chloride solution: 162mg in 100ml distilled water,From this 33.3ml was diluted to 100ml with distilled water.
4. O-Phosphoric acid: 1.3ml in 100ml distilled water.
5. Standard drug solution: About 100mg 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.

### Assay Procedures

### Method A

Aliquots of working standard solution of AMF ranging from 1-3 ml were transferred into a series of 10 ml volumetric flasks. To these 2 ml of Ferric Chloride was added. The contents were shaken and kept aside for 2 minutes.Then add 1.5ml of MBTH reagent and wait for 10min.Finally the volume was made upto 10ml with distilled water. The absorbance of the Green colored chromogen was measured at 660 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 1-5 ml were transferred into a series of 10ml volumetric flasks. To these 1 ml of Ferric chloride and 1ml of 1,10-Phenanthroline was added and made upto equal volume with distilled water. Then boil the flasks for about 45min at 70ºC.The flasks were cooled and add 2ml of O-Phosphoric acid.The total volume was made to 10ml with water.The absorbance of the red colored chromogen was measured at 510nm against reagent blank. The amount of AMF present in the sample solution was computed from its calibration curve.

## RESULTS AND DISCUSSION

The optical characteristics such as beers law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation, 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

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

| Parameters | Method A | Method B |
|---|---|---|
| $\lambda_{max}$ (nm) | 660 | 510 |
| Beer's law limit (µg/mL) | 10-30 | 10-50 |
| Sandell's sensitivity (µg/cm$^2$/0.001 abs. unit) | 0.033 | 0.102 |
| Molar absorptivity(litre.mole$^{-1}$.cm$^{-1}$) | $10.637\times10^4$ | |
| $3.457\times10^4$ | | |
| Regression equation(Y*) : | | |
| Slope(b) | 0.388 | 0.0959 |
| Intercept(a) | -0.176 | 0.0077 |
| Correlation coefficient(r) | 0.9994 | 0.9982 |
| %Relative standard deviation** | 1.047 | 1.68 |
| %Range of error : | | |
| 0.05 significance level | 0.875 | 1.405 |
| 0.01 significance level | 1.295 | 2.078 |

*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 | Amount found* by proposed method (in %) | | % recovery** by proposed method | |
|---|---|---|---|---|---|
| | (5%w/v) | Method A | Method B | Method A | Method B |
| Sample 1 | 5 | 4.66 | 4.76 | 99.78 | 99.90 |
| Sample 2 | 5 | 4.28 | 4.47 | 99.65 | 99.97 |
| Sample 3 | 5 | 4.38 | 4.16 | 99.56 | 99.88 |
| Sample 4 | 5 | 4.98 | 4.87 | 99.45 | 99.67 |

* Average of six determinations

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

Pharmaceutical formulations (Solution) by the proposed methods are presented in Table 2. Studies reveal that the common recipients and other additives usually present in the Solution did not interfere in the proposed methods.

## CONCLUSION

The proposed methods are applicable for the assay of drug AMF and have an advantage of wider range under Beers 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.

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