

QUANTITATIVE ESTIMATION OF MUPIROCIN CALCIUM FROM PHARMACEUTICAL OINTMENT FORMULATION BY UV SPECTROPHOTOMETRY**DEEPAK V. BAGESHWAR, AVINASH S. PAWAR, VINEETA V. KHANVILKAR*, VILASRAO J. KADAM**

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ABSTRACT

Assay procedure based on UV Spectrophotometry has been developed for the quantitative estimation of Mupirocin calcium from ointment formulation. The solvent system and wavelength of detection were optimized in order to maximize the sensitivity of the proposed method. Mupirocin calcium shows the maximum absorbance at 220 nm and the linearity was observed in the concentration range of 2-16 µg/ml. The developed UV Spectrophotometric method was found to be accurate, sensitive, precise, and reproducible and was successfully applied to a pharmaceutical ointment formulation for quantitative estimation of Mupirocin calcium.

Keywords: Mupirocin Calcium, UV Spectrophotometry.**INTRODUCTION**

Mupirocin calcium or calcium pseudomonate dihydrate (monocalcium bis [9-((2E)-4-[[[2S,3R,4R,5S)-5-[(2S,3S,4S,5S)-2,3-epoxy-5-hydroxy-4-methylhexyl]-3,4-dihydroxy-3,4,5,6-tetrahydro-2H-pyran-2-yl]-3-methylbut-2-enoyloxy]nonanoate]dihydrate) is a calcium salt of a substance having antibacterial activity produced by the growth of *Pseudomonas fluorescens*¹. The drug acts by inhibiting bacterial isoleucyl-tRNA synthetase^{2,3}, thereby blocking protein synthesis and indirectly inhibiting RNA synthesis⁴. It has in vitro activity against a range of gram-positive and some gram-negative bacteria⁵. Mupirocin has excellent activity against staphylococci, and gram-negative organisms such as *Haemophilus influenzae*, *Neisseria gonorrhoeae* and *Moraxella catarrhalis*⁶.

Mupirocin calcium is available in market in the form of ointment and cream. HPLC method for the measurement of mupirocin concentrations in both skin layers and percutaneous samples has been reported⁷. Another HPLC method for estimation of Mupirocin calcium in PEG bases is also reported⁸. A simple UV-spectrophotometric method for the estimation of mupirocin calcium from ointment is not yet reported.

The objective of present work is to develop a simple, sensitive, rapid and economic spectrophotometric method for the quantitative estimation of mupirocin calcium in bulk and pharmaceutical ointment formulation.

MATERIALS AND METHODS**Instrumentation**

A SHIMADZU 1601 UV-VISIBLE spectrophotometer with 1.0 cm matching quartz cells were used for absorbance measurements in the visible and ultraviolet regions, respectively. The UV spectra were recorded over the wavelength 200-300 nm. A CYBERLAB PHS-3D pH meter was used for pH measurement of solvent system.

Reagents

Mupirocin calcium was procured as a gift sample from Glenmark Pharmaceuticals. All other reagents and solvents were of analytical-reagent (AR) grade.

Method development**Preparation of stock solution**

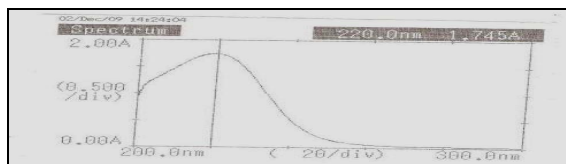
A standard stock solution of mupirocin calcium was prepared by dissolving 100 mg of drug in 100 ml of 50:50 v/v acetonitrile-sodium phosphate buffer (pH 6.4). Selection of solvent system was based on the solubility and stability of drug in solvent system as well as extraction of drug from its formulations. 10 ml of this solution was further diluted with same solvent to get the final concentrations of 100 µg/ml and this was used as the standard stock solution.

Preparation of calibration curve

From the stock solution various dilutions were made to obtain solutions of 2, 4, 6, 8, 10, 12, 14 and 16 µg/ml. Absorbance values of these solutions were measured at λ_{max} 220 nm. The calibration curve was plotted between concentration of Mupirocin calcium and respective measured absorbances. The stability of the drug in the solvent system and during actual analysis was also investigated.

Analysis of ointment formulation

Commercially available ointments of mupirocin calcium T-BACT (GSK) and SUPIROCIN (GLENMARK) were selected for estimation of total drug content by the proposed method. An amount of ointment equivalent to 0.2g of mupirocin calcium was weighed accurately and transferred to a 100 ml volumetric flask. 25 ml of 50:50 v/v acetonitrile-sodium phosphate buffer (pH 6.4) was added and vortexed for 5 minutes. Volume was adjusted to 100 ml with the same solvent and then filtered through whatman filter paper (#41). 20 ml of this solution was further diluted to 100 ml with the same solvent to get final concentration within the limits of linearity for the respective proposed method. The drug content of mupirocin calcium ointment was calculated using calibration curve equation. The results are tabulated in Table 3.

**Fig. 1: UV spectrum of Mupirocin calcium in 50:50 v/v acetonitrile- sodium phosphate buffer (pH 6.4) at λ_{max} 220 nm**

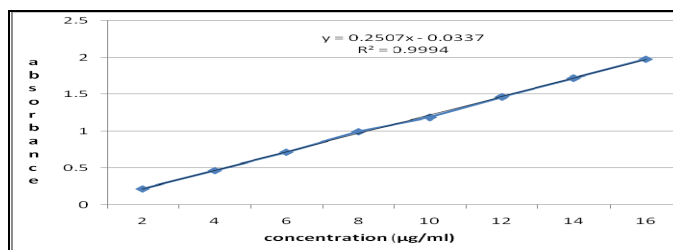


Fig. 2: Calibration curve for mupirocin calcium

Table 1: Regression characteristics of the proposed method

Statistical parameters	Results
Wavelength	220nm
Slope	0.12
Intercept	0.029
S.E of slope	0.0011
S.E of intercept	-0.0023
Regression equation	Y=0.2507 X - 0.0337
Correlation coefficient (r)	0.9994

Y = absorbance and X = concentration of the drug in µg/ml. *Based on six calibration values

Table 2: Validation report for the estimation of Mupirocin calcium

Analytical parameters	Results
Accuracy (%)	99.96 ± 0.2263
Precision (%)	99.76 ± 0.1041
Linearity	2-16 µg/ml
Specificity (at 220 nm for 10 µg/ml)	1.991 ± 0.0073
Limit of detection*	0.45 µg/ml
Limit of quantitation*	2 µg/ml
Ruggedness (%)	99.87 ± 0.45

*Based on S.D. of the response and the slope of the regression curve

Recovery studies

The accuracy of the developed assay method and interference of formulation additives were checked by performing analytical

recovery experiments. Here a known amount of pure drug was added to the pre-analysed sample of commercial formulation and the total drug quantity was estimated. The percent analytical recovery values are listed in Table 3.

Table 3: Results of the assay of pure Mupirocin calcium and its commercial formulations by the proposed method

Sample	Label claim (% w/w)	Recovery			Analytical recovery (%)
		Mean	R.S.D	S.E.	
Pure drug	-	2.045 ± 0.032	0.35	0.2079	100.13 ± 0.23
T-BACT	2	1.988 ± 0.012	1.06	0.9719	99.65 ± 0.17
Supirocin	2	1.979 ± 0.009	0.86	0.3309	99.92 ± 0.23

RESULTS AND DISCUSSION

Mupirocin calcium showed a good linear relationship in the concentration range of 2-16 µg/ml in 50:50 v/v acetonitrile-sodium phosphate buffer (pH 6.4) solvent system. The calibration curve yielded the linear regression equation as $Y = 0.2507 X - 0.0337$, where Y is the absorbance and X is the concentration (µg/ml) of pure mupirocin calcium solution having high correlation coefficient $r^2 = 0.9994$. The results of analysis of marketed formulations are shown in Table 3. High level of precision for the proposed method has been evidenced by the low values of standard deviation (S.D), standard error (S.E.) and relative standard deviation (R.S.D.). The percentage recoveries values indicate no interference from excipients used in the formulation.

CONCLUSION

The developed UV spectrophotometric method for the quantitative estimation of Mupirocin calcium is simple, sensitive and economic. The sample recoveries in both ointment formulations were in good agreement with their respective label claims and thus suggested the validity of the methods and non-interference of formulation

excipients present in the formulations. So this method can be applied for routine analysis of Mupirocin calcium in pure form and in its formulations without interference.

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