

COMPARATIVE ANALYSIS AND APPLICATION OF NOVEL SPECTROPHOTOMETRIC APPROACHES AND BIOASSAY FOR FAST MACROLIDE QUANTIFICATION IN TABLETS

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Abstract. Novel spectrophotometric and microbiological methods have been developed and validated for the quantitation of clarithromycin in tablets. Spectrophotometric methods were based on charge transfer complexation through naphthoquinone derivatives. Reactions were carried out by using 1,2-naphthoquinone-4-sulphonate and phylloquinone in alkaline medium, which showed an absorption maximum at 452 and 455 nm, respectively. While microbiological assay was based on the inhibitory effect of this macrolide upon the strain of *Bacillus subtilis* ATCC 9372 by applying the cylinder-plate. Linear calibration curves with correlation coefficients of 0.9980-0.9998 were obtained over the selected concentration ranges. The validation of the developed methods was performed for specificity, linearity, precision, accuracy, robustness, limit of detection, limit of quantitation. The % recovery was in the range of 97.5–101.9%, with the % relative standard deviation being less than 3.5%. A comparative study was established and the methods were successfully applied for the quantification of clarithromycin in solid dosage forms.

Keywords: spectrophotometric method, 1,2-naphthoquinone-4-sulphonate, phylloquinone, clarithromycin, bioassay.