

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

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Abstract. Novel spectrophotometric methods and bioassays have been developed and validated for clarithromycin quantitation in tablets. Spectrophotometric techniques were based on charge transfer complexation through naphthoquinone derivatives. Reactions were carried out in alkaline medium using 1,2-naphthoquinone-4-sulphonate and phylloquinone, which showed an absorption maximum at 452 and 455 nm, respectively. While bioassay was conducted dependent on the inhibitory effect upon the strain of *Bacillus subtilis* ATCC 9372, by applying cylinder-plate. Linear calibration curves with correlation coefficients of 0.9980–0.9998 were obtained. Molar absorptivity and Sandell's sensitivity were less than 10.73 L/mole/cm and 0.0099 µg/cm, respectively, with a detection limit down to 0.27 µg/mL and quantification limits of 0.68–0.78 µg/mL. The validation of the developed methods was performed for selectivity, precision, accuracy and robustness. Recoveries were found between 97.5–101.9% with % RSD being below to 3.5%. A comparative analysis was established and the methods were successfully applied for clarithromycin quantification in dosage forms.

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

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