

NOVEL INDIRECT SPECTROPHOTOMETRIC APPROACHES FOR SPIRAMYCIN QUANTIFICATION IN DOSAGE FORMS USING NAPHTHOQUINONE DERIVATIVE REAGENTS

Abdelghani Mahmoudi ^{a,b,*}, Silvia De Francia ^c, Yamina Boudinar ^a, Hela Mahmoudi ^d, Peixi Zhu ^e

^aChemistry Department, Faculty of Sciences, University of 20 August 1955 - Skikda, P.O. Box 26, El-Hadaiek Road, 21000, Skikda, Algeria

^bPharmaceutical Analysis, Research Laboratory on Bioactive Products and Biomass Valorization (LRPBVB), Ecole Normale Supérieure-Kouba, PB 92, 16038 Algiers, Algeria

^c Clinical Pharmacology, Department of Clinical and Biological Sciences, Faculty of Medicine, University of Turin, S. Luigi Gonzaga Hospital, Regione Gonzole 10, 10043, Orbassano, TO, Italy

^dLaboratory of Natural Substances, National Institute for Physicochemical Research and Analysis, Sidi Thabet, Ariana-Tunis - 2020 Tunisia

^eCollege of Pharmaceutical Sciences, Zhejiang University of Technology, Hangzhou 310014, Zhejiang, China

*e-mail: mahmoudi_a2003@yahoo.fr; phone: +213 38 72 31 52; fax: +213 38 72 31 52

Abstract. Development and validation of new spectrophotometric methods have been described for spiramycin determination in pure and dosage forms. Indirect analysis was performed via charge transfer reaction between spiramycin and naphthoquinone derivative agents of 1,2-naphthoquinone-4-sulphonate and phylloquinone in alkaline medium, to form a colored-complex of maximum absorption at 453 and 456 nm, respectively. Formation conditions of solvent, reagent concentration and reaction time were optimized. Linear calibration graphs were examined for either drug in the concentration range of 0.85 - 15.0 µg/mL and showed correlation coefficients of 0.9998, with a detection limit of 0.25 µg/mL and quantification limits about 0.75 µg/mL. Molar absorptivity and Sandell's sensitivity were 7.42-9.14 L/mole/cm and 0.0092-0.0095 µg/cm, respectively. Both methods demonstrated good precision, accuracy and robustness with % RSD below 3.1%. The methods were successfully applied for spiramycin quantification in tablets forms. The suggested approaches are simple, effective, and trustworthy enough to be employed as alternative quality-control methods.

Keywords: Spectrophotometry, spiramycin, 1,2-naphthoquinone-4-sulphonate, phylloquinone, pharmaceutical analysis, validation.