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DEVELOPMENT AND VALIDATION OF AN ASSAY METHOD FOR CIPROFLOXACIN HYDROCHLORIDE DETERMINATION IN COMBINATION EAR DROPS

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Abstract. A simple, precise and accurate UV-Vis spectrophotometric method has been developed and validated for assaying ciprofloxacin hydrochloride in combination ear drops with basil oil (*Ocimum basilicum*). Ciprofloxacin hydrochloride presented an absorption maximum at 278 nm, while the placebo solution showed a very low absorption in the 220-400 nm range. The parameters of validation have been determined according to the International Conference of Harmonization guidelines „Q2R1: For Analytical Procedures and Validation". Linearity was obtained over the concentration range 2-10 µg/mL with a correlation coefficient of 0.999. The value of the limit of detection was of 0.786 µg/mL and of the limit of quantification was of 2.383 µg/mL. The percentages of recovery of ciprofloxacin hydrochloride in combination ear drops exceeded 99.0%. The relative standard deviation values of precision and robustness were less than 2%. Short-term stability results showed that the samples were stable at room temperature for 24 hours.

Keywords: ciprofloxacin hydrochloride, UV-Vis spectroscopy, validation, ear drop, *Ocimum basilicum*.

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