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Analytical Validation of a Quantification Method by UV-Vis Spectrometry of Naltrexone Hydrochloride in Capsules

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***SUMMARY*. Naltrexone hydrochloride is an opioid antagonist prescribed in the treatment of opioid addiction, alcoholism and recently has been employed in association with bupropion for adjuvant therapy of obesity. Pharmacopeias have not yet provided an official monograph for determination of naltrexone hydrochloride (NAL) in pharmaceutical preparations. The aim of this paper is to develop and validate an analytical method by UV-Vis spectrometry for the drug quantification in capsules. Method validation was performed according to international guidelines. Linearity was determined for the analytical range of 60 to 250 μg/mL, with a correlation coefficient of 0.99955, limit of detection 1.63 μg/mL and limit of quantification 5.45 μg/mL. Accuracy presented the following results of recovery: 107.33 ± 3.89% (60 μg/mL), 94.9 ± 1.73% (100 μg/mL) and 96.5 ± 1.2% (250 μg/mL). Repeatability and intermediate precision showed mean values of relative standard deviation of 0.95% and 1.23%, respectively. The influence of temperature and measurement time was evaluated in robustness. All data were analyzed by ANOVA that revealed no statistical variation among the groups. The presented method was specific in the quantification of NAL in commercial capsules in face of the excipients.**

KEY WORDS: Analytical validation, Naltrexone hydrochloride, UV-Vis spectrometry.

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