

Development and validation of a new HPLC analytical method for the quality control of clindamycin capsules

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Background and Aims: A simple and rapid isocratic reversed-phase high performance liquid chromatography (HPLC) method was developed, validated and applied for quantitation of clindamycin hydrochloride in capsules. The chromatographic method employed on a Nucleodur® CN-RP column (250mm×4.6mm i.d., 5mm particle size) at ambient temperature. The mobile phases were comprised of a mixture of water and acetonitrile containing tetramethyl ammonium(pH 4.2) (60:40 v/v) at a flow rate of 1 ml/min. The UV detection was made at 204 nm. Propyl paraben was used as the internal standard. The average retention times for internal standard and clindamycin were 5.1 and 7.8 min respectively. The calibration curve was linear ($r \geq 0.998$) over the concentration ranges of 2-9 µg/ml of clindamycin with detection limit of 0.3 µg/ml. Intra- and inter-day relative standard deviations were less than 2%. No chromatographic interferences from the capsule excipients were found. Results showed, the reported HPLC method for clindamycin provides several advantages of simplicity, high specificity, accuracy and short run-cycle time. This proposed method was successfully used in analyzing the drug in dissolution media and capsule formulations. The method may be used for the routine quality control analysis of clindamycin pure drug and its pharmaceutical preparations and even under certain circumstances for the drug bio- analysis.

Keywords: HPLC; Clindamycin; Capsule formulations; Quality control