IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.301
Volume 3, Issue 1, June 2023

RP-HPLC Method Development and Validation for the Simultaneous Determination of Clindamycin and Miconazole in Pharmaceutical Dosage Forms

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Abstract: *A simple, precise, reliable, rapid and reproducible reversed phase–high-performance liquid chromatography method was developed and validated for the simultaneous estimation of Clindamycin (CDM) and Miconazole (MCZ) present in tablet dosage forms... Method: Chromatographic separation achieved isocratically on Inertsil ODS C18 (250x4.6 mm, 5 mm) column and buffer (pH 3.5) and acetonitrile (65:35 v/v) as mobile phase, at a flow rate of 1 ml/min. Detection was carried out at 220 nm. Parameters such as linearity, precision, accuracy, recovery, specificity and ruggedness are studied as reported in the ICH guidelines. The retention times for CDM and MCZ was found to be 2.2 and 3.2 min, respectively. Linearity for CDM and MCZ was in the range of 5-30 µg/ml and 10-60 µg/ml, respectively. The mean recoveries obtained for CDM and MCZ were 99.73 ± 0.8 and 100.2 ± 0.58%, respectively, and Relative standard deviation (RSD) was less than 2. The correlation coefficients for all components are close to 1. The RSDs for three replicate measurements in three concentrations of samples in tablets are always less than 2%.: Developed method was found to be accurate, precise, selective and rapid for simultaneous estimation of CDM and MCZ in tablets.*

Keywords: Clindamycin, Miconazole, RP-HPLC, Simultaneous estimation, Tablets.

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