ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE IN COMBINED DOSAGE FORM

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ABSTRACT

A Simple, accurate and precise UV Spectroscopic (First order derivative method) and RP-HPLC method were developed and validated for simultaneous estimation of Clindamycin phosphate and Benzoyl peroxide in combined dosage form. First order derivative method based on the measurement of absorbance at two wavelength 211 nm and 243 nm ZCP of BENZ and CLINDA respectively. The calibration curve was linear in a concentration range of 1.2-6 µg/ml for CLINDA and 3-15 µg/ml for BENZ. The RP-HPLC method has shown adequate separation of CLINDA and BENZ in combined dosage form. The separation was achieved on column Thermo BDS C18 (250 mm x 4.6 mm, i.d. 5 µm particle size) with mobile phase of Phosphate buffer (pH 4.5): Acetonitrile in the ratio of (50:50 v/v). The flow rate was 1.0 ml/min and detection wavelength was 210 nm. The retention time for BENZ and CLINDA was obtained 3.550 min and 5.187 min respectively. The linearity of the proposed method was in the range of 1.2-6 µg/ml and 3-15 µg/ml for CLINDA and BENZ respectively.

Correlation coefficient was 0.9996 and 0.999 for CLINDA and BENZ respectively. The method was validated as per ICH Q2(R1) guidelines and acceptance criteria for linearity, recovery, precision, and robustness. The Forced degradation study was carried out as per ICH guideline under acidic, basic, oxidative, thermal and Photolytic conditions. All peaks of degraded product were resolved from the drug with different retention time effectively, as it employed as a stability indicating one.

Keywords: Clindamycin phosphate (CLINDA), Benzoyl peroxide (BENZ), First order derivative method, RP-HPLC method, Force degradation study, Validation.