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Development and Validation of Stability Indicating RP-HPLC Method for the Determination of Ezetimibe in Pharmaceutical Dosage Forms

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***SUMMARY*. In the present study, a simple, rapid and precise liquid chromatographic method was developed and validated for the determination of ezetimibe in its dosage form. Ezetimibe was separated in a 100 x 4.6 mm i.d., C18 column, 3 μm particle size, Luna phenomenex, using a mobile phase composition of water and acetonitrile (60:40 v/v). Column oven temperature was kept at 25 °C. The flow rate was 1.5 mL/min and the analyte monitored at 225 nm. The retention time of Ezetimibe was 8.47 min. The specificity of the method was determined by assessing interference from the placebo and by stress testing of the drug (forced degradation).The developed method was validated in terms of linearity, accuracy, precision, system suitability, limit of detection, limit of quantitation and solution stability. The proposed method was also applied successfully to the pharmaceutical dosage form self emulsified drug delivery without any interference by excipients.**

KEY WORDS: Ezetimibe, RP-HPLC, Self emulsifying drug delivery.

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