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New RP-HPLC method for the determination of Afatinib dimaleate in bulk and pharmaceutical dosage forms

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A novel stability indicating liquid chromatographic assay method was developed and validated as per ICH guidelines for the quantitative estimation of afatinib in tablet formulation. A gradient reverse phase LC-method was developed using X-Terra RP-8, 250x4.6 mm, 5 µm column and a mobile phase were aqueous potassium dihydrogen orthophosphate buffer adjusted pH at 3.0 with o-phosphoric acid (mobile phase solvent-A) and acetonitrile:methanol (70:30 v/v) (mobile phase solvent-B) in a gradient mode. The detector set at 258 nm with flow rate of 1.0 mL.min-1. The method is linear between 0.12 to 0.36 mg/mL with a good linear relationship (r2=0.998) was observed and the limit of detection (LOD) is 0.06 µg/mL 0.02% and limit of quantification (LOQ) is 0.06 mg/mL 0.06%. The accuracy of the method was found to be in the range of 99.70% to 100.26%. The mean inter and intraday precision has Relative Standard Deviation (%RSD) were less than 0.147. Robustness was done by change in column, variation in change of flow rate of +/-0.2 mL/min., the values were found to be within the limits. The proposed method was found to be linear, precise and accurate for the quantitative estimation of afatinib in tablet formulations and can be used for commercial purposes.

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Notes: