


RESEARCH ARTICLE

# New validated liquid chromatography-tandem mass spectrometry method for the determination of Dacomitinib in human plasma and its application to a pharmacokinetic study

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## Abstract

Dacomitinib, a quinazoline compound, exhibits antineoplastic activity against brain metastasis activities in non-small cell lung cancer and the central nervous system. In this study, the liquid-liquid extraction method with high-performance liquid chromatography and tandem mass spectrometry detection method was established and validated for the determination of Dacomitinib in human plasma. Plasma samples were prepared and chromatographic separation was achieved on analytical column Discovery C<sub>18</sub> (10 cm × 4.6 mm, 5 μm) with gradient elutes at a flow rate of 0.8 mL/min, using a mobile phase consisting of acetonitrile and ammonium formate. Dacomitinib and dacomitinib D<sub>10</sub> (internal standard) were detected by multiple reactions. The method was fully validated according to the United States Food and Drug Administration guidelines. The calibration curve was linear with an excellent correlation coefficient ( $r^2 < 0.99$ ). The method validation steps such as carry-over, matrix effect, extraction recovery, dilution effect, intra-inter accuracy, and precision were found

**Article related abbreviations:** AUC, area under the concentration-time curve; CC, calibration curve; HEGFR, human epidermal growth factor receptor; HPLC, high-performance liquid chromatography; LC-MS/MS, liquid chromatography-tandem mass spectrometry; LLOQ, lower limit of quantitation; NSCLC, non-small cell lung cancer; QC, quality control; T<sub>1/2</sub>, elimination half-life; UPLC, ultra-performance liquid chromatography; ULOQ, upper limit of quantitation.