Received: 1 August 2023 | Revised: 13 November 2023 | Accepted: 24 November 2023

DOI: 10.1002/sscp.202300131

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

Tinku Gupta[1] | NaliniKanta Sahoo[2] | Maddela Rambabu[3] | M. Praveen[3] | Shrikant Charde[3] | Madhusmita Sahu[4] | Prasun Chakrabarti[5] | Bui Thanh Hung[6] | Martin Margala[7] | Bhuvan Unhelkar[8] | Arunaksharan Narayanankutty[9]

[1]Pharmacy Council of India, India Ministry of Health and Family Welfare, New Delhi, India

[2]MIT College of Pharmacy, MIT Campus, (Affiliated to Dr. A.P.J. Abdul Kalam Technical University), Moradabad, India

[3]ClinSync Clinical Research Pvt. Ltd., Hyderabad, India

[4]MET Faculty of Pharmacy, MIT Campus, (Affiliated to Dr. A.P.J. Abdul Kalam Technical University), Moradabad, India

[5]ITM (SLS) Baroda University, Vadodara, India

[6]Data Science Laboratory, Faculty of Information Technology, Industrial University of Ho Chi Minh City, Ho Chi Minh City, Vietnam

[7]University of Louisiana at Lafayette Bookstore, Lafayette, Louisiana, USA

[8]University of South Florida Tampa Bookstore, Tampa, Florida, USA

[9]PG and Research Department of Zoology, Division of Cell and Molecular Biology, St. Joseph's College, Calicut, India

Correspondence
Nalini Kanta Sahoo, MIT College of Pharmacy, MIT Campus (Affiliated to Dr. A.P.J. Abdul Kalam Technical University), Ram Ganga Vihar, Phase-II, Moradabad, 244001, UP, India.
Email: sahoo.nalini@gmail.com

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_{18} (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_{10} (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; $T_{1/2}$, elimination half-life; UPLC, ultra-performance liquid chromatography; ULOQ, upper limit of quantitation.

https://doi.org/10.1002/sscp.202300131