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Isolation, Identification and Characterization of Erlotinib Novel Degradation Products by NMR and Mass Spectrometry: RP-UPLC Method Development and Validation

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ABSTRACT

To assess the stability of Erlotinib under stress conditions, it was subjected to Acid, Base, peroxide, photolytic and thermal degradation according to the ICH guideline Q1A (R2). The drug showed degradation only in Acid and Peroxide mediate hydrolysis, it was stable in Basic, thermal and photolytic conditions. Four degradation products were formed, which were separated on an X-Bridge Prep C18 5µm, 19 mm × 250 mm Column employing GILSON Prep HPLC using gradient elution. The structures were established by extensive 1D and 2D NMR spectroscopic studies and mass spectrometry. The products were identified as 6,7-bis(2-methoxyethoxy)quinazolin-4(3H)-one(ERL-DP-1), 1-(3-((6,7-bis(2-methoxyethoxy)quinazolin-4-yl)amino)phenyl)ethan-1-one(ERL-DP-2), N-(3-(1-chlorovinyl)phenyl)-6,7-bis(2-methoxyethoxy)quinazolin-4-amine(ERL-DP-3), 4-((3-ethynyl phenyl) amino)-6,7-bis(2-methoxyethoxy) quinazoline 1-oxide (ERL-DP-4). DP-4, the N-oxide derivative of Erlotinib was novel degradation products. A stability indicating RP-UPLC method was developed was validated with respect to specificity, linearity, accuracy, precision, limit of detection and limit of quantitation.

Graphical Abstract

Erlotinib Degradation
- Isolation and characterization
- UPLC Method validation

Keywords: Erlotinib, Method validation, Degradation products, UPLC-MS, Nuclear magnetic Resonance Spectroscopy.