

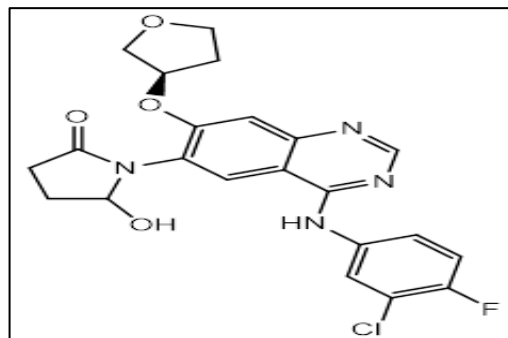
Analysis Date: 10-05-2025

Re-test Date: 10-05-2028

AFATINIB IMPURITY 13

Identification

Chemical Name	: 1-(4-((3-Chloro-4-fluorophenyl)amino)-7-(((R)-tetrahydrofuran-3-yl)oxy)quinazolin-6-yl)-5-hydroxypyrrolidin-2-one ; Des-(4-dimethylamino-2-en-1-oxo)butylamino 6-(5-Hydroxy-pyrrolidin-2-on-1-yl) Afatinib
CAT No	: ALL-A07954
CAS No	: 2413212-19-6
Molecular Formula	: C ₂₂ H ₂₀ ClFN ₄ O ₄
Molecular Weight	: 458.9



Analytical Information

Batch Code	: ALL-A07954	HPLC Purity	: 98.04%
Solubility	: MeOH: ACN	Potency	: 96.48%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: 2-8 °C	IR Analysis	: Confirm
Weight Content By TGA	: 0.821%	¹ HNMR	: Confirm
Residue Of Ignition	: 0.738%		

Additional Information

$$\% \text{Potency} = [100 - (\text{Inorganic Impurities \%} + \text{Water \%}) \times \text{Chromatographic Purity\%}] / 100 =$$

$$[100 - (0.821 + 0.738) \times 98.04] / 100 = 96.48\%$$

Recommendation : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul Khadse Jr. Executive	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

Attachment : HPLC, Mass, ¹H NMR, IR, TGA

Shipping Condition : All Product are stable to be shipped at room temperature, unless otherwise specified

Corporate Office

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