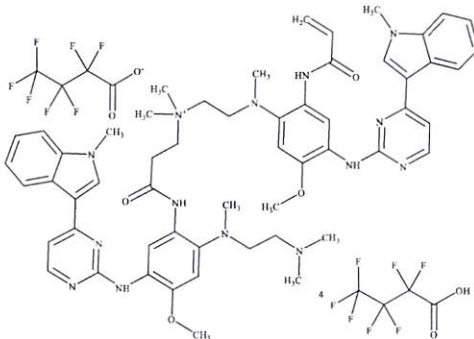


Certificate of Analysis


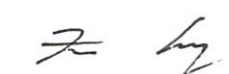
Certificate No.: **20250422002**

Date: April 22, 2025

Retest date: April 16, 2028

Compound Name:	Osimertinib Dimer Impurity 4 Pentaheptafluorobutyrate	
Synonyms:	<i>N</i> -(2-((2-acrylamido-5-methoxy-4-((4-(1-methyl-1 <i>H</i> -indol-3-yl)pyrimidin-2-yl)amino)phenyl)(methylamino)ethyl)-3-((2-((2-(dimethylamino)ethyl)(methylamino)-4-methoxy-5-((4-(1-methyl-1 <i>H</i> -indol-3-yl)pyrimidin-2-yl)amino)phenyl)amino)- <i>N,N</i> -dimethyl-3-oxopropan-1-aminium, 2,2,3,3,4,4,4-heptafluorobutanoate, 2,2,3,3,4,4,4-heptafluorobutanoic acid (1:1:4)	
TLC Catalogue Number:	A-194017	
CAS Number:	N/A	
Alternate CAS Number:	2564638-97-5 (free base)	
Molecular Weight:	1000.25 213.03 4*214.04	
Molecular Formula:	C ₅₆ H ₆₇ N ₁₄ O ₄ . C ₄ F ₇ O ₂ . 4 C ₄ HF ₇ O ₂	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	6746-042A12	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO	

Test Description	Specifications	Results
Visual Description	Yellow solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
¹⁹ F NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	97.1%
Impurity (HPLC)	RT 7.96, 0.37%; RT 14.39, 1.78%; RT 17.78, 0.59%	
Water Content (KF)	N/A	1.3%
Residual Solvents (qNMR)	0.9% heptafluorobutanoic acid	
Assay (%)	Not less than 90.0%	95.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		04/22/2025
Approved by:	Quality Assurance		04/22/2025

Attachments: Peak Attribution Table, HPLC, IR, MS and NMR spectra.