CERTIFICATE OF ANALYSIS

(Certificate No. KME003004-01)

Release Date: 22/08/2023 **Re-test Date:** 21/08/2026

Erlotinib Impurity B

Identification

Chemical Name :
4-chloro-6,7-bis(2-methoxyethoxy)quinazoline

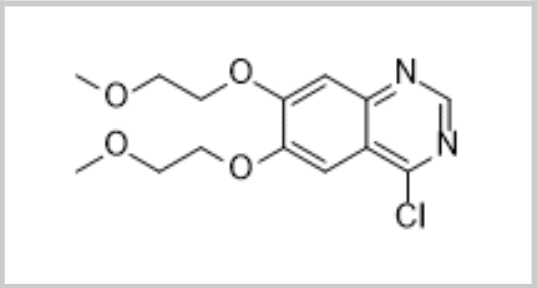
Alt. Name : Erlotinib Chloro Impurity

CAT No. : KME003004

CAS No. : 183322-18-1

Molecular Formula : C14H17ClN2O4

Molecular Weight : 312.75



Analytical Information

Batch No.	: ERL-IMP-D-045-256	**Solubility**	: ACN
Description	: Light Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 97.11 %	**IR**	: Confirm
Weight Loss By TGA	: 0.02 %	**1H NMR**	: Confirm
% Potency	: 97.09 %		

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be shipped at room temperature

% Potency = [100 - 0.02(Weight Loss By TGA)] x [97.11(HPLC Purity)]/100 = 97.09 %
Remarks : COA Re-generated on 15.03.2023

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		15/03/2024
Reviewed & Approved By	Quality Control	Jatin Patel		15/03/2024

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA