

CERTIFICATE OF ANALYSIS

(Certificate No. KME003002-01)

Release Date: 19/08/2023

Re-test Date: 18/08/2026

Erlotinib Impurity A

Identification

Chemical Name :

6,7-bis(2-methoxyethoxy)quinazolin-4(3H)-one

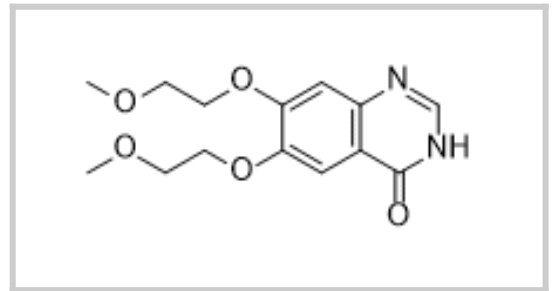
Alt. Name : Erlotinib Lactam Impurity

CAT No. : KME003002

CAS No. : 179688-29-0

Molecular Formula : C₁₄H₁₈N₂O₅

Molecular Weight : 294.30



Analytical Information

Batch No. : ERL-IMP-A-045-249

Description : White Solid

HPLC Purity : 99.88 %

Weight Loss By TGA : 1.75 %

% Potency : 98.13 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

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 - 1.75(Weight Loss By TGA)] x [99.88(HPLC Purity)]/100 = 98.13 %

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, ¹H NMR, IR and TGA