

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

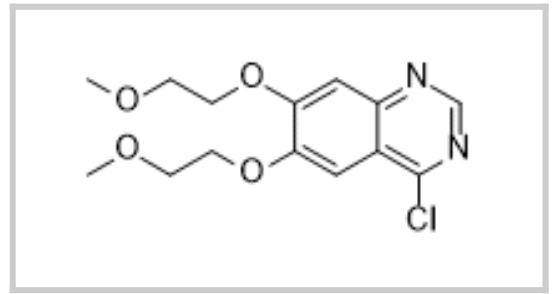
Alt. Name : Erlotinib Chloro Impurity

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, ¹H NMR, IR and TGA