

# **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

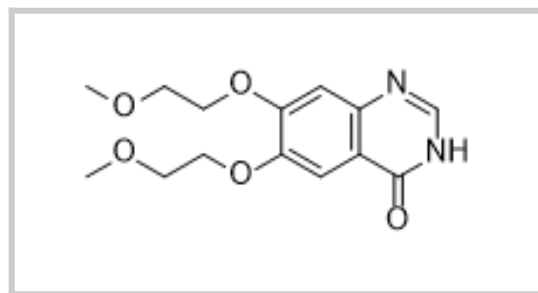
**Alt. Name** : Erlotinib Lactam Impurity

**CAT No.** : KME003002

**CAS No.** : 179688-29-0

**Molecular Formula** : C<sub>14</sub>H<sub>18</sub>N<sub>2</sub>O<sub>5</sub>

**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

**<sup>1</sup>H 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, <sup>1</sup>HNMR, IR and TGA