

# CERTIFICATE OF ANALYSIS

(Certificate No. KME014005-01)

Release Date: 09/01/2025

Re-test Date: 08/01/2028

## Everolimus Impurity B

### Identification

**Chemical Name :**

(2S)-1-[[[(2R,3R,6S)-2-hydroxy-6-[(2S,3E,5E,7E,9S,11R,13R,14R,15E,17R,19E,21R)-14-hydroxy-22-[[[(1S,3R,4R)-4-(2-hydroxyethoxy)-3-methoxycyclohexyl]-2,13-dimethoxy-3,9,11,15,17,21-hexamethyl-12,18-dioxodocosa-3,5,7,15,19-pentaen-1-yl]-3-methyloxan-2-yl](oxo)acetyl]piperidine-2-carboxylic acid (as per EP)

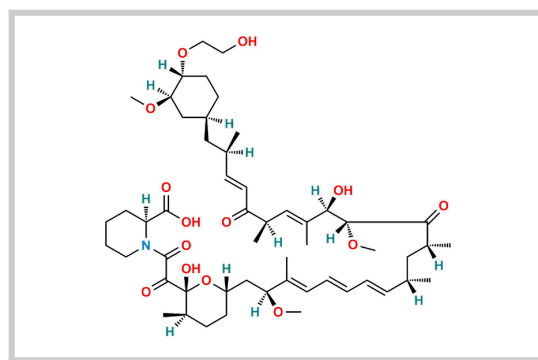
**Alt. Name** : Everolimus 19-Ene Open-Ring Impurity ; seco Everolimus ; (19E/Z)-seco-[4-O-(2-Hydroxyethyl)] Rapamycin

**CAT No.** : KME014005

**CAS No.** : 1062122-63-7

**Molecular Formula** : C53H83NO14

**Molecular Weight** : 958.2



### Analytical Information

**Batch No.** : EVE-EPB-045-053

**Description** : Off White Solid

**HPLC Purity** : 91.99 %

**Weight Loss By TGA** : 0.88 %

**% Potency** : 91.18 %

**Solubility** : Acetonitrile

**Mass** : Confirm

**IR** : Confirm

**1H NMR** : Confirm

**13C 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** =  $[100 - 0.88(\text{Weight Loss By TGA})] \times [91.99(\text{HPLC Purity})]/100 = 91.18 \%$   
-Re-tested on 09.01.2025

**Recommendation** : Released

|                        | Department      | Name         | Signature | Date       |
|------------------------|-----------------|--------------|-----------|------------|
| Prepared By            | Analytical      | Ravi Sakhiya |           | 16/01/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel  |           | 16/01/2025 |

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