## **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)-

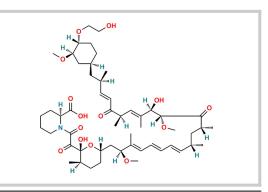
seco-[4-O-(2-Hydroxyethyl)] Rapamycin

**CAT No.** : KME014005

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

Molecular Formula : C53H83NO14

**Molecular Weight** : 958.2



### **Analytical Information**

: EVE-EPB-045-053 **Solubility** Batch No. : Acetonitrile **Description** : Off White Solid : Confirm **Mass HPLC Purity** : 91.99 % IR : Confirm Weight Loss By TGA : 0.88 % 1H NMR : Confirm % Potency : 91.18 % **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(Weight Loss By TGA)] x [91.99(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