

CERTIFICATE OF ANALYSIS

(Certificate No. KMP004098-01)

Release Date: 09/02/2026

Re-test Date: 08/02/2029

Pregabalin Impurity Mixture of PD0312236 & PD0312237

Identification

Chemical Name :

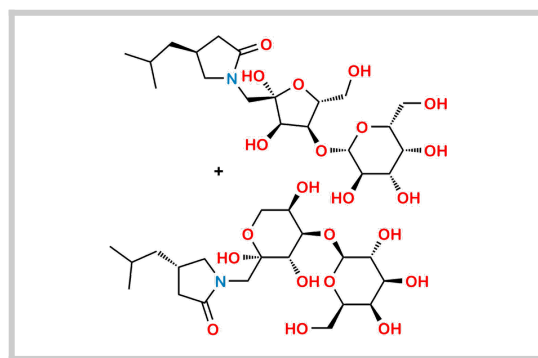
(S)-1-(((2R,3R,4S,5R)-2,3-dihydroxy-5-(hydroxymethyl)-4-(((2S,3R,4S,5R,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydro-2H-pyran-2-yl)oxy)tetrahydrofuran-2-yl)methyl)-4-isobutylpyrrolidin-2-one compound with (S)-4-isobutyl-1-(((2R,3S,4R,5R)-2,3,5-trihydroxy-4-(((2S,3R,4S,5R,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydro-2H-pyran-2-yl)oxy)tetrahydro-2H-pyran-2-yl)methyl)pyrrolidin-2-one (1:1)

CAT No. : KMP004098

CAS No. : Not Available

Molecular Formula : C₂₀H₃₅NO₁₁

Molecular Weight : 465.5



Analytical Information

Batch No. : P004098-114-159

Description : Off White Solid

HPLC Purity : 97.04 %

Weight Loss By TGA : 4.05 %

% Potency : 93.11 %

Solubility : Water

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 - 4.05(Weight Loss By TGA)] x [97.04(HPLC Purity)]/100 = 93.11 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		09/02/2026
Reviewed & Approved By	Quality Control	Jatin Patel		09/02/2026

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