

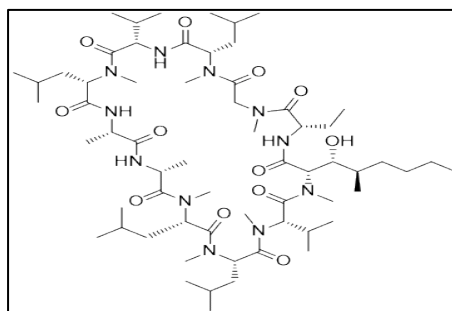
Analysis Date: 29-05-2025

Re-test Date: 04-02-2028

CYCLOSPORIN EP IMPURITY B

Identification

Chemical Name	: 1,11-anhydro[l-alanyl-d-alanyl-N-methyl-l-leucyl-N-methyl-l-leucyl-N-methyl-l-valyl-(2S,3R,4R)-3-hydroxy-4-methyl-2-(methylamino)octanoyl-(2S)-2-aminobutanoyl-N-methylglycyl-N-methyl-l-leucyl-l-valyl-N-methyl-l-leucine] (as per EP)
CAT No	: ALL-C04183
CAS No	: 59865-15-5
Molecular Formula	: C ₆₂ H ₁₁₃ N ₁₁ O ₁₂
Molecular Weight	: 1204.63



Analytical Information

Batch No.	: ALL-C04183	HPLC Purity	: 96.45%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 96.30%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.035 %	¹ HNMR	: Confirm
Residue On Ignition	: 0.115 %		

Additional Information

$$\% \text{Potency} = [100 \% - (\text{Weight Loss By TGA \%} + \text{Residue On Ignition \%}) \times \text{Chromatographic Purity\%}] / 100 = [100 - (0.035 + 0.115) \times 96.45] / 100 = 96.30\%$$

Recommendation : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul Khadse Jr. Executive	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

Attachment : HPLC, Mass, ¹H NMR, IR, TGA

Shipping Condition : All Product are stable to be shipped at room temperature, unless otherwise specified

Corporate Office

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