

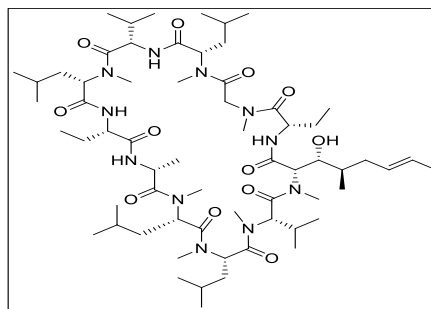
Analysis Date: 19-12-2024

Re-test Date: 19-12-2027

CYCLOSPORINE IMPURITY E

Identification

| | |
|--------------------------|--|
| Chemical Name | : 1,11-Anhydro[acide D-alanyl-N-méthyl-L-leucyl-N-méthyl-L-leucyl-N-méthyl-L-valyl-(2S,3R,4R,6E)-3-hydroxy-4-méthyl-2-(méthylamino)oct-6-énoyl-(2S)-2-aminobutanoyl-N-méthylglycyl-N-méthyl-L-leucyl-L-valyl-N-méthyl-L-leucyl-(2S)-2-aminobutanoïque] (as per EP) |
| CAT No | : ALL-C08293 |
| CAS No | : 108027-46-9 |
| Molecular Formula | : C ₆₃ H ₁₁₃ N ₁₁ O ₁₂ |
| Molecular Weight | : 1216.7 |



Analytical Information

| | | | |
|------------------------------|-----------------------------------|--------------------|-----------|
| Batch No. | : ALL-C08293 | HPLC Purity | : 97.50 % |
| Solubility | : USP Diluent / EP Diluent (MEOH) | Potency | : 96.70 % |
| Appearance of Product | : Off White Solid | Mass | : Confirm |
| Long Term Storage | : -20°C | IR Analysis | : Confirm |
| Weight Loss By TGA | : 0.788 % | 1HNMR | : Confirm |
| Residue Of Ignition | : 0.029 % | | |

Additional Information

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

$$[100 - (0.788 + 0.029) \times 97.50] / 100 = 96.70 \%$$

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, UV Report

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

Corporate Office