

Analysis Date: 10-11-2025

Re-test Date: 10-11-2028

SPIRAMYCIN EP IMPURITY C

Identification

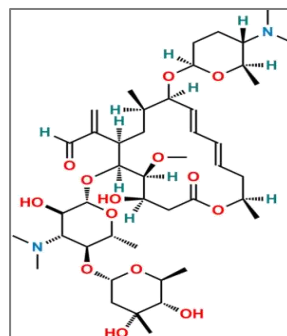
Chemical Name : (4R,5S,6S,7S,9R,10R,11E,13E,16R)-6-[[[3,6-dideoxy-4-O-(2,6-dideoxy-3-C-methyl- α -l-ribo-hexopyranosyl)-3-(dimethylamino)- β -d-glucopyranosyl]oxy]-7-(1-formylethenyl)-4-hydroxy-5-methoxy-9,16-dimethyl-10-[[[2,3,4,6-tetradeoxy-4-(dimethylamino)- β -d-erythro-hexopyranosyl]oxy]oxacyclohexadeca-11,13-dien-2-one (as per EP)

CAT No : ALL-S09300

CAS No : 177584-13-3

Molecular Formula : C₄₄H₇₄N₂O₁₄

Molecular Weight : 855.1



Analytical Information

| | | | |
|------------------------------|-----------------------------------|--------------------------|-----------|
| Batch No. | : ALL-S09300 | HPLC Purity | : 98.00 % |
| Solubility | : USP Diluent / EP Diluent (MEOH) | Potency | : 96.25% |
| Appearance of Product | : Off White Solid | Mass | : Confirm |
| Long Term Storage | : -20°C | IR Analysis | : Confirm |
| Weight Loss By TGA | : 1.104 % | ¹H NMR | : Confirm |
| Residue Of Ignition | : 0.672% | | |

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.104 + 0.672) × 98.00]/100 = 96.25%

Recommendation : Released

| | Department | Name | Signature |
|--------------------------|------------|------------------------------------|-----------|
| Prepared and Reviewed by | Analytical | Mr. Vipul khadase 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