

Analysis Date: 18-09-2025

Re-test Date: 18-09-2028

SALBUTAMOL IMPURITY 9

Identification

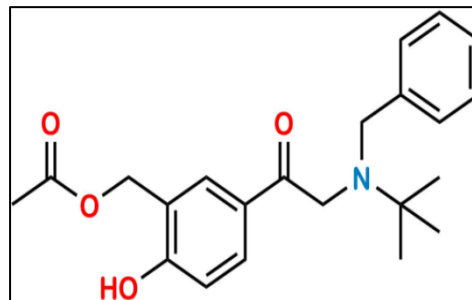
Chemical Name : 5-(N-Benzyl-N-(tert-butyl)glycyl)-2-hydroxybenzyl acetate

CAT No : ALL-SALB-43

CAS No : N.A.

Molecular Formula : C₂₂H₂₇NO₄

Molecular Weight : 369.5



Analytical Information

| | | | |
|------------------------------|-----------------------------------|--------------------------|-----------|
| Batch Code | : ALL-SALB-43 | HPLC Purity | : 98.00% |
| Solubility | : USP Diluent / EP Diluent (MEOH) | Potency | : 97.02% |
| Appearance of Product | : Off White Solid | Mass | : Confirm |
| Long Term Storage | : -20°C | IR Analysis | : Confirm |
| Weight Loss By TGA | : 0.248% | ¹H NMR | : Confirm |
| Residue Of Ignition | : 0.743% | | |

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.248+0.743) × 98.00]/100 = 97.02%

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