

Analysis Date: 23-05-2025

Re-test Date: 23-05-2028

## SALBUTAMOL EP IMPURITY J (SALBUTAMONE HCL)

### Identification

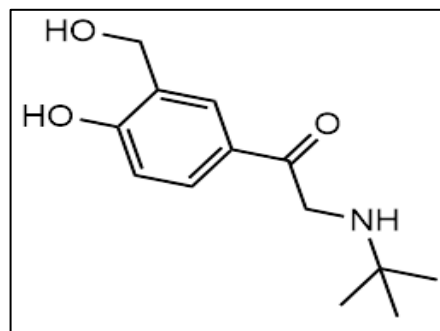
**Chemical Name** : 2-[(1,1-Dimethylethyl)amino]-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanone (as per EP)

**CAT No** : ALL-A08168

**CAS No** : 156547-62-5

**Molecular Formula** : C<sub>13</sub>H<sub>19</sub>NO<sub>3</sub>

**Molecular Weight** : 237.3



### Analytical Information

**Batch Code** : ALL-A08168

**HPLC Purity** : 98.09%

**Solubility** : MeOH: ACN

**Potency** : 97.01%

**Appearance of Product** : Off White Solid

**Mass** : Confirm

**Long Term Storage** : 2-8 °C

**IR Analysis** : Confirm

**Weight Content By TGA** : 0.452%

**<sup>1</sup>H NMR** : Confirm

**Residue Of Ignition** : 0.640%

### Additional Information

%Potency = [100 - (Inorganic Impurities % + Water %) × Chromatographic Purity%]/100 =

[100 - (0.452+0.640 × 98.09)]/100 = 97.01%

**Recommendation** : Released

|                          | Department | Name                                | Signature |
|--------------------------|------------|-------------------------------------|-----------|
| Prepared and Reviewed by | Analytical | Mr. Vipul Khadse<br>Jr. Executive   |           |
| Approved By              | QA&QC      | Dr. Ashish Kechhe<br>Director QA&QC |           |

**Attachment** : HPLC, Mass, <sup>1</sup>H NMR, IR, TGA

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

### Corporate Office

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