

Analysis Date: 24-05-2025

Re-test Date: 24-05-2028

## SALBUTAMOL EP IMPURITY N (ALBUTEROL DIMER)

### Identification

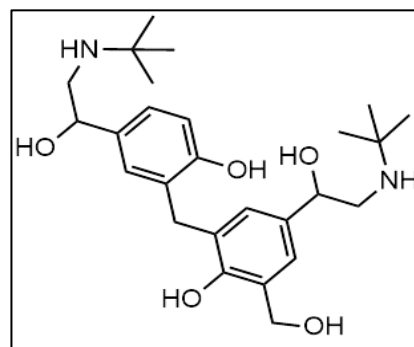
**Chemical Name** : 4-[(1E)-2-(tert-butylamino)-1-hydroxyethyl]-2-[[5-[(1E)-2-(tert-butylamino)-1-hydroxyethyl]-2-hydroxyphenyl]methyl]-6-(hydroxymethyl)phenol (as per EP)

**CAT No** : ALL-A08171

**CAS No** : 149222-15-1

**Molecular Formula** : C<sub>26</sub>H<sub>40</sub>N<sub>2</sub>O<sub>5</sub>

**Molecular Weight** : 460.6



### Analytical Information

|                              |                   |                          |           |
|------------------------------|-------------------|--------------------------|-----------|
| <b>Batch Code</b>            | : ALL-A08171      | <b>HPLC Purity</b>       | : 98.01%  |
| <b>Solubility</b>            | : MeOH: ACN       | <b>Potency</b>           | : 96.44%  |
| <b>Appearance of Product</b> | : Off White Solid | <b>Mass</b>              | : Confirm |
| <b>Long Term Storage</b>     | : 2-8 °C          | <b>IR Analysis</b>       | : Confirm |
| <b>Weight Content By TGA</b> | : 0.742%          | <b><sup>1</sup>H NMR</b> | : Confirm |
| <b>Residue Of Ignition</b>   | : 0.851%          |                          |           |

### Additional Information

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

[100 - (0.742+0.851× 98.01)]/100 = 96.44%

**Recommendation** : Released

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