

Analysis Date: 18-09-2025

Re-test Date: 18-09-2028

## SALBUTAMOL IMPURITY 13

### Identification

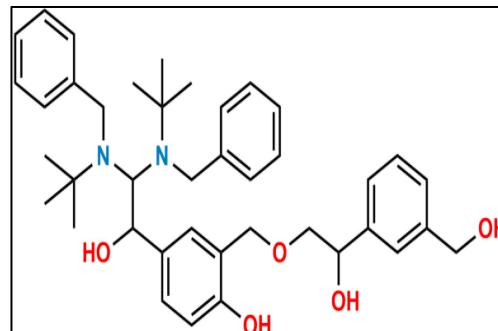
**Chemical Name** : 4-((S)-2-(Tert-butylamino)-1-hydroxyethyl)-2-(5-((R)-2-(tert-butylamino)-1-hydroxyethyl)-2-hydroxybenzyl)-6-(hydroxymethyl)phenol

**CAT No** : ALL-SALB-29

**CAS No** : N.A.

**Molecular Formula** : C<sub>40</sub>H<sub>52</sub>N<sub>2</sub>O<sub>5</sub>

**Molecular Weight** : 640.9



### Analytical Information

<b>Batch Code</b>	: ALL-SALB-29	<b>HPLC Purity</b>	: 98.00%
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 97.02%
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20°C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 0.248%	<b><sup>1</sup>HNMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 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, <sup>1</sup>H NMR, IR, TGA

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

#### Corporate Office