

Analysis Date: 20-09-2025

Re-test Date: 20-09-2028

SALBUTAMOL EP IMPURITY O

Identification

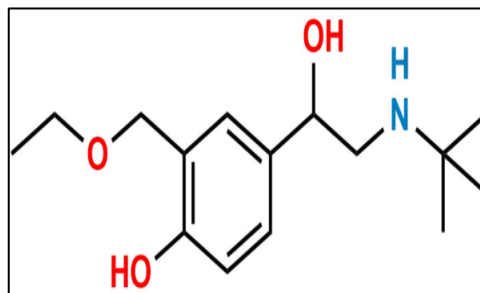
Chemical Name : 4-(2-(Tert-butylamino)-1-hydroxyethyl)-2-(ethoxymethyl)phenol

CAT No : ALL-SALB-62

CAS No : 754926-25-5

Molecular Formula : C₁₅H₂₅NO₃

Molecular Weight : 267.4



Analytical Information

Batch Code	: ALL-SALB-62	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 96.82%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.620%	¹H NMR	: Confirm
Residue Of Ignition	: 0.578%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.620+0.578) × 98.00]/100 = 96.82%

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