

Analysis Date: 19-09-2025

Re-test Date: 19-09-2028

N-NITROSO SALBUTAMOL EP IMPURITY M

Identification

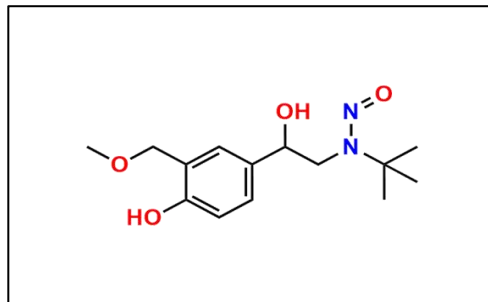
Chemical Name : N-(Tert-butyl)-N-(2-(3-chloro-4-hydroxy-5-(hydroxymethyl)phenyl)-2-hydroxyethyl)nitrous amide

CAT No : ALL-SALB-58

CAS No : N.A.

Molecular Formula : C₁₃H₁₉ClN₂O₄

Molecular Weight : 302.8



Analytical Information

Batch Code	: ALL-SALB-58	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 95.45%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.236%	¹HNMR	: Confirm
Residue Of Ignition	: 1.364%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.236+1.364) × 98.00]/100 = 95.45%

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