Certificate Of Analysis

Analysis Date: 23-05-2025 **Re-test Date:** 23-05-2028

SALBUTAMOL EP IMPURITY H (SALBUTAMOL DIDESHYDROXY IMPURITY)

Identification

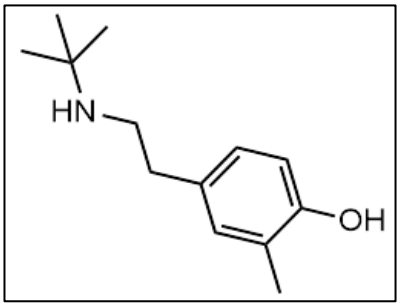
Chemical Name : 4-[2-[(1,1-Dimethylethyl)amino]ethyl]-2-methylphenol (as per EP)

CAT No : ALL-A08166

CAS No : 132183-64-3

Molecular Formula : C13H21NO

Molecular Weight : 207.3



Analytical Information

Batch Code	: ALL-A08166	**HPLC Purity**	: 98.02%
Solubility	: MeOH: ACN	**Potency**	: 97.09%
Appearance of Product	: Off White Solid	**Mass**	: Confirm
Long Term Storage	: 2-8 ^{0}C	**IR Analysis**	: Confirm
Weight Content By TGA	: 0.378%	**1HNMR**	: Confirm
Residue Of Ignition	: 0.561%		

Additional Information

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

[100 – (0.378+0.561× 98.02]/100 = 97.09%

Recommendation : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul Khadse 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

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