

CERTIFICATE OF ANALYSIS

(Certificate No. KMA078014-02)

Release Date: 14/02/2025

Re-test Date: 13/02/2028

Salbutamol EP Impurity D

Identification

Chemical Name :

5-[(1RS)-2-[(1,1-Dimethylethyl)amino]-1-hydroxyethyl]-2-hydroxybenzaldehyde (as per EP)

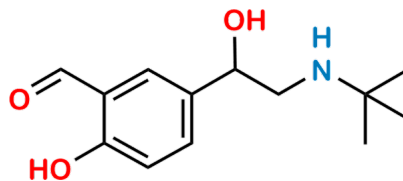
Alt. Name : Salbutamol BP Impurity D ;
Levalbuterol USP RC D ; Salbutamol
Aldehyde Impurity

CAT No. : KMA078014

CAS No. : 156339-88-7

Molecular Formula : C₁₃H₁₉NO₃

Molecular Weight : 237.3



Analytical Information

Batch No. : A078014-091-201

Description : Yellow Solid

HPLC Purity : 98.04 %

Weight Loss By TGA : 1.41 %

% Potency : 96.66 %

Solubility : Water

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 1.41(Weight Loss By TGA)] x [98.04(HPLC Purity)]/100 = 96.66 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		14/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		14/02/2025

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA