# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMA078013-02)

**Release Date:** 24/09/2025 **Re-test Date:** 23/09/2028

## **Albuterol EP Impurity C**

#### **Identification**

#### **Chemical Name:**

4-[(1RS)-2-(tert-butylamino)-1-hydroxyethyl]-2-methylphenol (as per EP)

**Alt. Name** : Albuterol USP Related Compound A;

Levalbuterol USP Related Compound B

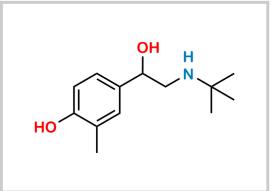
; Salbutamol Deshydroxy Impurity ; 3-

Dehydroxy Salbutamol

**CAT No.** : KMA078013 **CAS No.** : 18910-68-4

Molecular Formula : C13H21NO2

**Molecular Weight** : 223.3



### **Analytical Information**

(1:1)

**Description** : Off White Solid

**HPLC Purity** : 98.71 %

**Weight Loss By TGA** : 0.42 %

**% Potency** : 98.3 %

Mass : Confirm

IR : Confirm

**1H NMR** : Confirm

**13C 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 - 0.42(Weight Loss By TGA)] x [98.71(HPLC Purity)]/100 = 98.3 %

\*As per client request chemical name change as per EP monograph

-Re-tested in client method on 24.09.2025

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/10/2025

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA