

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA078015-01)

Release Date: 25/01/2025

Re-test Date: 24/01/2028

## Albuterol Impurity E

### Identification

**Chemical Name :**

(1RS)-2-[Benzyl(1,1-dimethylethyl)amino]-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanol (as per EP)

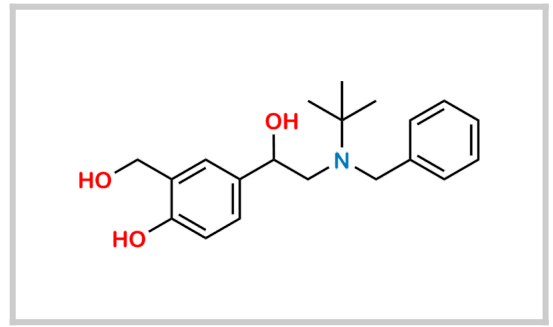
**Alt. Name** : Salbutamol BP Impurity E ; N-Benzyl Albuterol

**CAT No.** : KMA078015

**CAS No.** : 24085-03-8

**Molecular Formula** : C<sub>20</sub>H<sub>27</sub>NO<sub>3</sub>

**Molecular Weight** : 329.4



### Analytical Information

**Batch No.** : A078015-091-178

**Solubility** : Acetonitrile

**Description** : Off White Solid

**Mass** : Confirm

**HPLC Purity** : 98.89 %

**IR** : Confirm

**Weight Loss By TGA** : 0.70 %

**<sup>1</sup>H NMR** : Confirm

**% Potency** : 98.2 %

### 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 - 0.70(Weight Loss By TGA)] x [98.89(HPLC Purity)]/100 = 98.2 %

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		27/01/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA