

CERTIFICATE OF ANALYSIS

(Certificate No. KMA078016-01)

Release Date: 21/02/2025

Re-test Date: 20/02/2028

Albuterol EP Impurity F

Identification

Chemical Name :

2,2'-(oxybis(methylene))bis(4-(2-(tert-butylamino)-1-hydroxyethyl)phenol)

Alt. Name

: Salbutamol BP Impurity F ;
Salbutamol Dimer Ether ; Albuterol
USP Related Compound E

CAT No.

: KMA078016

CAS No.

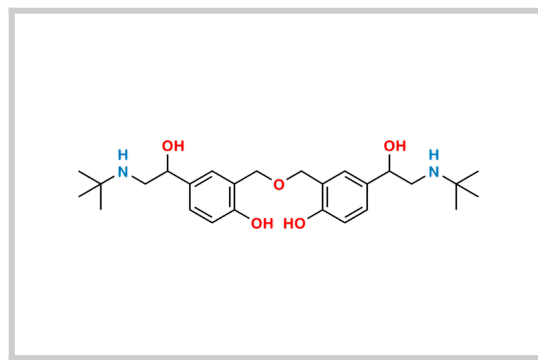
: 147663-30-7

Molecular Formula

: C₂₆H₄₀N₂O₅

Molecular Weight

: 460.6



Analytical Information

Batch No.

: A078016-091-227

Description

: Light Yellow Solid

HPLC Purity

: 94.14 %

Weight Loss By TGA

: 1.08 %

% Potency

: 93.12 %

Solubility

: ACN : Water (1 : 9)

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 - 1.08(Weight Loss By TGA)] x [94.14(HPLC Purity)]/100 = 93.12 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		21/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		21/02/2025

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA