

CERTIFICATE OF ANALYSIS

(Certificate No. KMS024009-01)

Release Date: 26/08/2025

Re-test Date: 25/08/2028

Salmeterol EP Impurity D

Identification

Chemical Name :

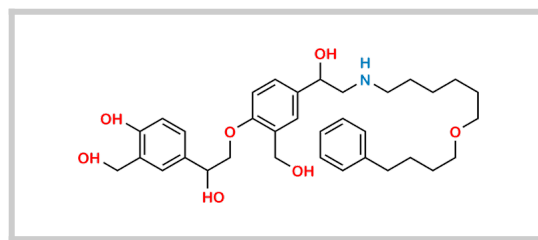
4-(1-Hydroxy-2-(4-(1-hydroxy-2-((6-(4-phenylbutoxy)hexyl)amino)ethyl)-2-(hydroxymethyl)phenoxy)ethyl)-2-(hydroxymethyl)phenol

CAT No. : KMS024009

CAS No. : 1391052-04-2

Molecular Formula : C₃₄H₄₇NO₇

Molecular Weight : 581.8



Analytical Information

Batch No. : S024009-102-226

Description : Light Brown Thick Syrup

HPLC Purity : 98.83 %

Weight Loss By TGA : 0.29 %

% Potency : 98.54 %

Solubility : ACN : Water (9:1)

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 - 0.29(Weight Loss By TGA)] x [98.83(HPLC Purity)]/100 = 98.54 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		26/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		26/08/2025

Attachments : COA, HPLC, MASS, ¹H NMR, ¹³C NMR, IR and TGA