

CERTIFICATE OF ANALYSIS

(Certificate No. KMA003012-01)

Release Date: 08/04/2025

Re-test Date: 07/04/2028

Acebutolol Related Compound I

Identification

Chemical Name :

N-[3-Acetyl-4-[(2RS)-3-(ethylamino)-2-hydroxypropoxy]phenyl]butanamide (as per EP); N-{3-Acetyl-4-[3-(ethylamino)-2-hydroxypropoxy]phenyl}butyramide (as per USP); N-Desisopropyl-N-Ethyl Acebutolol

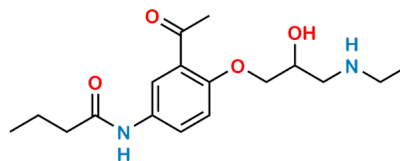
Alt. Name : Acebutolol USP Related Compound I

CAT No. : KMA003012

CAS No. : 441019-91-6

Molecular Formula : C₁₇H₂₆N₂O₄

Molecular Weight : 322.4



Analytical Information

Batch No. : ACE-RC-I-030-068

Solubility : Acetonitrile

Description : Yellow Solid

Mass : Confirm

HPLC Purity : 69.23 %

IR : Confirm

Weight Loss By TGA : 1.03 %

¹H NMR : Confirm

% Potency : 68.52 %

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 - 1.03(Weight Loss By TGA)] x [69.23(HPLC Purity)]/100 = 68.52 %
-Re-tested on 08.04.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		10/04/2025
Reviewed & Approved By	Quality Control	Jatin Patel		10/04/2025

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