

CERTIFICATE OF ANALYSIS

(Certificate No. KMA003005-01)

Release Date: 08/04/2025

Re-test Date: 07/04/2028

Acebutolol Related Compound B

Identification

Chemical Name :

N-[3-acetyl-4-[(2RS)-2-hydroxy-3-[(1-methylethyl)amino]propoxy]phenyl]acetamide (as per EP) N-{3-Acetyl-4-[2-hydroxy-3-(isopropylamino)propoxy]phenyl}acetamide (as per USP)

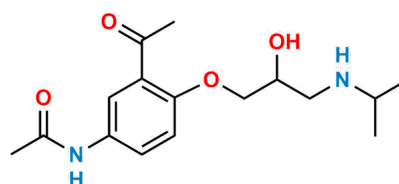
Alt. Name : Diacetolol (EP) ; Acebutolol USP
Related Compound B ; Diacetol ;
Acetylacetolol ; (±)-Diacetolol

CAT No. : KMA003005

CAS No. : 22568-64-5

Molecular Formula : C₁₆H₂₄N₂O₄

Molecular Weight : 308.4



Analytical Information

Batch No. : ACE-RC-B-030-082

Description : Off White Solid

HPLC Purity : 97.08 %

Weight Loss By TGA : 0.93 %

% Potency : 96.18 %

Solubility : Acetonitrile

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 - 0.93(Weight Loss By TGA)] x [97.08(HPLC Purity)]/100 = 96.18 %
-Re-tested on 08.04.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		29/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		29/05/2025

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