

CERTIFICATE OF ANALYSIS

(Certificate No. KMA003001-01)

Release Date: 07/04/2022

Re-test Date: 06/04/2025

Acebutolol Related Compound I

Identification

Chemical Name :

N-(3-acetyl-4-(3-(ethylamino)-2-hydroxypropoxy)phenyl)butyramide

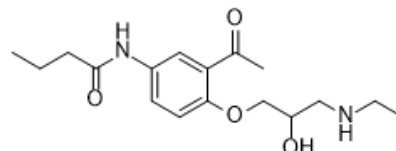
Alt. Name : Acebutolol USP Related Compound I

CAT No. : KMA003001

CAS No. : 441019-91-6

Molecular Formula : C₁₇H₂₆N₂O₄

Molecular Weight : 322.40



Analytical Information

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

Solubility : ACN

Description : Yellow Solid

Mass : Confirm

HPLC Purity : 97.55 %

IR : Confirm

Weight Loss By TGA : 0.96 %

¹H NMR : Confirm

% Potency : 96.61 %

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 - 0.96(Weight Loss By TGA)] x [97.55(HPLC Purity)]/100 = 96.61 %

Remarks : COA Re-generated on 08.06.2024

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 08/06/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 08/06/2024 |

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