CERTIFICATE OF ANALYSIS

(Certificate No. KMA003007-01)

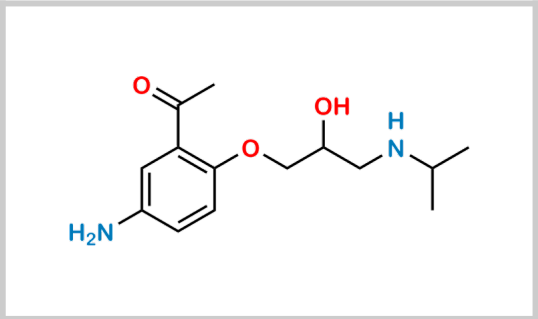
Release Date: 22/11/2025 **Re-test Date:** 21/11/2028

Acebutolol Impurity D

Identification

Chemical Name :
1-[5-Amino-2-[(2RS)-2-hydroxy-3-[(1-methylethyl)amino]propoxy]phenyl]ethanone (as per EP)

Alt. Name	: rac N-Desbutyroyl Acebutolol ; Acetolol
CAT No.	: KMA003007
CAS No.	: 57898-80-3
Molecular Formula	: C14H22N2O3
Molecular Weight	: 266.3



Analytical Information

Batch No.	: ACE-IMP-D-030-071	**Solubility**	: Acetonitrile
Description	: Yellow solid	**Mass**	: Confirm
HPLC Purity	: 92.47 %	**IR**	: Confirm
Weight Loss By TGA	: 0.38 %	**1H NMR**	: Confirm
% Potency	: 92.12 %		

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 - 0.38(Weight Loss By TGA)] x [92.47(HPLC Purity)]/100 = 92.12 %
-Re-tested on 22.11.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		24/11/2025
Reviewed & Approved By	Quality Control	Jatin Patel		24/11/2025

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