CERTIFICATE OF ANALYSIS

(Certificate No. KMB008001-01)

Release Date: 19/07/2022 **Re-test Date:** 18/07/2025

Baclofen EP Impurity A

Identification

Chemical Name :
4-(4-chlorophenyl)pyrrolidin-2-one

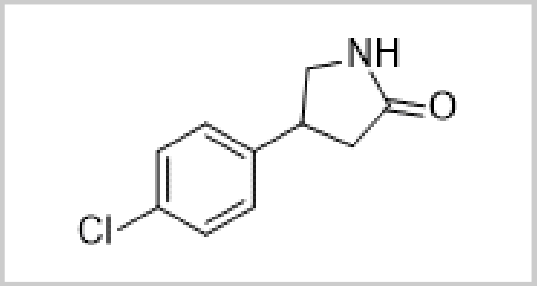
Alt. Name : Baclofen USP Related Compound A

CAT No. : KMB008001

CAS No. : 22518-27-0

Molecular Formula : C10H10ClNO

Molecular Weight : 195.65



Analytical Information

Batch No.	: BAC-RC-A-030-223	**Solubility**	: ACN
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 99.95 %	**IR**	: Confirm
Weight Loss By TGA	: 0.48 %	**1H NMR**	: Confirm
% Potency	: 99.47 %		

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 - 0.48(Weight Loss By TGA)] x [99.95(HPLC Purity)]/100 = 99.47 %
Remarks : COA Re-generated on 05.06.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		05/06/2024
Reviewed & Approved By	Quality Control	Jatin Patel		05/06/2024

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