

Product name : BACLOFEN

Batch number :

25004541

Storage condition :

At room temperature/max 25°C, in tight container.

Manufacturing date :

29-MAR-2025

Release date :

03-JUL-2025

Retest Date:

29-MAR-2030

Analysis number : 208175

	LIMITS	UNITS	RESULTS
CHARACTERS			
Description	White to off-white crystalline powder		Complies
Appearance of solution : Clarity	NMT reference suspension II		Complies
Appearance of solution : Color	NMT BY5		Complies
Polymorphism by IR	≥ 1.0		2.6
IDENTIFICATION			
Identification IR (USP)	Positive		Complies
Identification IR (Ph.Eur.)	Positive		Complies
Identification HPLC	Positive		Complies
TESTS			
Sulphated ash	NMT 0.1 %		Complies
Residual solvents by GC : Ethanol	< 500 ppm		Complies
Residual solvents by GC : 2-Propanol	< 500 ppm		Complies
Residual solvents by GC : n-Butanol	< 1000 ppm		Complies
Residual solvents by GC : Toluene	< 500 ppm		Complies
Particle size by laser diffraction :		µm	110
Particle size by laser diffraction D90%			
Particle size by laser diffraction :		µm	41
Particle size by laser diffraction D50%			

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	LIMITS	UNITS	RESULTS
Particle size by laser diffraction : Particle size by laser diffraction D10%		µm	11
ASSAY			
Water by KF	≤ 1.0	%	0.21
Assay by titration / anhydrous substance	≥ 99.0 / ≤ 101.0	%	100.0
Assay by HPLC / anhydrous basis (USP)	≥ 98.0 / ≤ 102.0	%	101.0
IMPURITIES			
Organic impurities by HPLC : Baclofen related compound A (LOD 0.025 %, LOQ 0.05 %)	≤ 0.4	%	0.00
Organic impurities by HPLC : Any individual unspecified impurity (LOD 0.025 %, LOQ 0.05 %)	≤ 0.10	%	0.00
Organic impurities by HPLC : Total impurities (LOD 0.025 %, LOQ 0.05 %)	≤ 1.0	%	0.00

Observation / Comment :

Notes no: 128/26

Specifications: PCAS Finland, Ph.Eur., USP

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This batch has been manufactured according to cGMP requirements.

Batch released on : 03-JUL-2025 12:37 GMT + 2.00**By :** Johanna Paavilainen QA Manager**CoA checked and edited on :** 17-MAR-2026 13:24 GMT + 2.00**By :** Rainer Salonen QA Expert

This document was signed electronically.