

Certificate of Analysis

Product name: **Baclofenum**

Batch number / Weight: **21G29-B01-215513 / 5 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	<= ref. susp. II / <= BY5	Conform		
Related substances	Conform	Conform		
Impurity A	<=1,0	<0,1	%	
Total impurities	<=2,0	<0,1	%	
Water	<= 1,0	0,09	%	
Sulphated ash	<= 0,1	0,06	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay	98,0 - 101,0	98,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

03-02-2022

Expiration: 31-01-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.