

Certificate of Analysis

Product name: Baclofenum
Batch number / Weight: 24E21-B01-003916 / 5 g
Producer / Producer Batch Number: Pharmaceutical Works Polpharma S.A. / 202052326
Analyzed according to: Ph. Eur.
Number of Analysis / Certificate no.: 24E21-B01 / QO0009089

	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	0,03	%	
Total impurities	<=2,0	0,17	%	
Water	<= 1,0	0,04	%	
Sulfated ash	<= 0,1	0,00	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Assay	98,0 - 101,0	99,46	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:

18-12-2024
 Agnieszka Pszczółka
 Qualified Person

Expiration: 30-4-2026

Conclusion: APPROVED

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