Certificate of Analysis

Product name: Baclofenum
Batch number / Weight: 25J31-B01-018434 / 5 g
Producer / Producer Batch Number: Pharmaceutical Works Polpharma S.A. / 201022517
Analyzed according to: Ph. Eur.12.1
Number of Analysis / Certificate no.: 25J31-B01 / QO0026726

	Requirement	Result	Unit	Standard remark
Appearance	White or almost white powder	Conform		
Identification	A	Conform		
Appearance of solution	<= ref. susp. II / <= BY5	Conform		
Related substances	Conform	Conform		
Impurity A	<= 0,5	< 0,05	%	
Impurity C	<= 0,15 (for the area of the peak, or the sum of the areas of the 2 peaks)	0,000	%	
Unspecified impurities	<= 0,10 (for each)	< 0,05	%	
Total impurities	<= 1,0	0,00	%	
Water	<= 1,0	0,11	%	
Sulfated ash	<= 0,1	0,03	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Assay	99,0 - 101,0	99,88	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	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 FSNE lab

Release:

22-1-2026
Dominika Sołtysik
Qualified Person

Expiration: 31-1-2028
Conclusion: APPROVED

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

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