

Certificate of Analysis

Product name: **Baclofenum**

Batch number / Weight: **21K12-B21-222709 / 25 G**

Analysed according to: **Ph.Eur.10**

Number of analysis / Inspection Code **21K12-B21 / INS-21-6461**

Reference Code / No.: **V01380 / 201062126**

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	0,08	%	
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	100,1	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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 EI Spół, CBMiA

Release:
Ewelina Gadzinowska
Qualified Person

19-08-2022

Expiration: 31-05-2024

Conclusion: APPROVED

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

fagron.pl Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl

fagron.pl Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl