

Certificate of Analysis

Product name: Baclofenum

Batch number / Weight: 21F08-B17-213331 / 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:

Agnieszka Pszczółka Qualified Person

29-11-2021

Expiration: 31-01-2024

Conclusion: APPROVED

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