

Certificate of Analysis

Productname: **Baclofenum**
Number of analysis/Inspection Code: 1 / KEUR-186805B
Batchnumber: **20J01-F06-374467**
Reference code / No.: 1305 / 205022017
Analysed according to: **PH.EUR10.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	<= ref. susp. II / <= BY5	Conform		2% m/V in 1M NaOH
Related substances	Conform	Conform		HPLC
Impurity A	<=1,0	0,0	%	
Total impurities	<=2,0	0,1	%	
Water (Karl Fischer)	<= 1,0	0,1	%	
Sulphated ash	<= 0,1	0,0	%	
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Baclofen	98,0 - 101,0	100,2	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/03/20

Expiration: 01-2023

Conclusion: APPROVED

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