

Certificate of Analysis

BACLOFEN

Batch number: 203012417

Code: QBCF-0005-000

Manufacturing date: 18/01/2024

Batch size: 425 kg

Retest date: 01/2027

Specification: Ph. Eur., S/2-0005.20 ed.03

Manufacturer: Zakłady Farmaceutyczne POLPHARMA S.A.

Delivered to: BE, MAGIS-PHARMA NV

Test	Requirements	Result
Appearance <i>Ph. Eur., visual examination</i>	white or almost white powder, odourless or practically odourless	white powder, odourless
Solubility <i>Ph. Eur.</i>	slightly soluble in water, very slightly soluble in methanol and 98% ethanol, practically insoluble in acetone, insoluble in chloroform; it dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides	conforms
Identification - IR spectrum <i>Ph. Eur., M/2-0005.01</i>	comparison with reference substance spectrum	conforms
Appearance of solution (0.50 g/25 mL of 1M NaOH) <i>Ph. Eur., M/2-0005.01</i>	the solution is not more opalescent than reference suspension II and not more intensely coloured than reference solution BY5	conforms
Related substances (HPLC) <i>Ph. Eur., M/2-0005.01</i>		
impurity A	not more than 1.0 %	less than 0.05 % (QL)
any unspecified impurity	not more than 0.10 %	less than 0.05 % (QL)
total impurities	not more than 2.0 %	less than 0.05 % (QL)
Water <i>Ph. Eur., M/2-0005.01</i>	not more than 1.0 %	0.03 %
Sulfated ash <i>Ph. Eur., M/2-0005.01</i>	not more than 0.1 %	0.01 %
Assay calculated on anhydrous substance <i>Ph. Eur., M/2-0005.01</i>	98.0 % to 101.0 %	100.0 %
Residual solvents (GC): <i>Annex 2 do CEP, M/2-0005.20</i>		
methanol	not more than 800 ppm	325 ppm
Particle size: <i>POLPHARMA, M/2-0005.40</i>		
D (v, 0.1)	for information	6.6 µm
D (v, 0.5)	for information	43 µm
D (v, 0.9)	for information	171 µm

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CONCLUSION: This material complies with the requirements.

Current version: Ph. Eur. 11

Esignature for COA

Dispositioned by: Beata Wielewicka
Head of Certification Team

Disposition date: 13/02/2024

CoA signed by: Beata Wielewicka
Head of Certification Team

Sign date: 16/05/2024

This document was signed electronically and is valid without handwritten signature