polpharma

CERTIFICATE OF ANALYSIS

Product: **BACLOFEN**

Code: **QBCF-0005-000** Batch number: **208122117** Batch size: **325 kg**
Manufacturing date: **30.11.2021** Analysis date: **19.01.2022** Retest date: **11.2024**
Manufacturer: **Zakłady Farmaceutyczne Polpharma S.A., POLAND**
Delivered to: **BE, FAC SECUNDUM ARTEM NV**

TEST	TEST METHOD	SPECIFICATION	RESULTS
Appearance	Ph. Eur. visual examination	white or almost white powder, odourless or practically odourless	white powder, odourless
Solubility	Ph. Eur.	slightly soluble in water, very slightly soluble in methanol and 96 per cent ethanol, practically insoluble in acetone, insoluble in chloroform, it dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides	conforms
Identification test B. IR spectrum	Ph. Eur.	comparison with reference substance spectrum	conforms
Appearance of solution (0.50 g / 25 mL of 1M NaOH)	Ph. Eur.	the solution is not more opalescent than reference suspension II and not more intensely coloured than reference solution BY_5	conforms
Related substances (HPLC) impurity A [1)] single unspecified impurity total impurities	Ph. Eur.	not more than 1.0 % not more than 0.10 % not more than 2.0 %	less than 0.05 % (QL) less than 0.05 % (QL) less than 0.05 % (QL)
Water	Ph. Eur.	not more than 1.0 %	0.03 %
Sulfated ash	Ph. Eur.	not more than 0.1 %	0.02 %
Assay calculated on anhydrous substance	Ph. Eur.	98.0 % to 101.0 %	100.0 %
Residual solvents (GC) methanol	POLPHARMA M/2-0005.20	not more than 800 ppm	342 ppm
Particle size D (v, 0.1) D (v, 0.5) D (v, 0.9)	POLPHARMA M/2-0005.40	for information	9.7 µm 55 µm 200 µm

[1)] Impurity A: (4RS)-4-(4-chlorophenyl)pyrrolidin-2-one

CONCLUSION: This material complies with the requirements of the **Ph. Eur. 10, S/2-0005.20 ed. 03.**

Starogard Gdański, 20.01.2022

Certification Team Coordinator
Quality Control Department API
Wielewicka
Beata Wielewicka
20.01.2022

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KRS 0000127044, NIP 592-02-02-822, Initial capital: 100 207 830 PLN (Paid-in capital)
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