



Certificate of Analysis

1.08212.0500 Parteck® PLX 188 (Poloxamer 188) (stabilized with 70ppm BHT)
EMPROVE® ESSENTIAL Ph Eur, NF
Batch F2277212

	Spec. Values		Batch Values	
Identity (IR-spectrum)	passes test		passes test	
Identity (Average relative molecular mass)	passes test		passes test	
Content of oxyethylene moieties (H-NMR)	79.9 - 83.7	%	82.2	%
Appearance	white to almost white, waxy substance		passes test	
Appearance of solution (100 g/l, CO ₂ -free water)	clear and not more intense in color than reference solution BY ₇		passes test	
pH (25 g/l; CO ₂ -free water)	5.0 - 7.5		6.7	
pH (100 g/l, CO ₂ -free water)	5.0 - 7.5		6.4	
Average relative molecular mass	7680 - 9510		9376	
Unsaturation	≤ 0.034	meq/g	0.024	meq/g
Ethylene oxide (HS-GC) (Ph.Eur.)	≤ 1	ppm	< 1	ppm
Dioxane (HS-GC) (Ph.Eur.)	≤ 10	ppm	< 10	ppm
Propylene oxide (HS-GC) (Ph.Eur.)	≤ 5	ppm	< 5	ppm
Ethylene oxide (HS-GC) (NF)*	≤ 1	ppm	< 1	ppm
Dioxane (HS-GC) (NF)*	≤ 5	ppm	< 5	ppm
Propylene oxide (HS-GC) (NF)*	≤ 5	ppm	< 5	ppm
Formaldehyde	≤ 15	ppm	< 1	ppm
Other residual solvents (ICH (Q3C))	excluded by manufacturing process		excluded by manufacturing process	
Ash (600 °C)	≤ 0.4	%	0.1	%
Water (according to Karl Fischer)	≤ 1.0	%	0.3	%
Particle size (d10)	5 - 30	µm	14	µm
Particle size (d50)	40 - 70	µm	57	µm
Particle size (d90)	90 - 240	µm	146	µm

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

* measured value from external service laboratory

Corresponds to Ph. Eur., NF

Date of manufacture (DD.MM.YYYY) 05.04.2023

Date of examination (DD.MM.YYYY) 29.09.2023

Minimum shelf life (DD.MM.YYYY) 30.04.2025

Dr. Sebastian Lips

Responsible laboratory manager quality control

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