



Certificate of Analysis

1.08212.0500 Parteck® PLX 188 (Poloxamer 188) (stabilized with 70ppm BHT)
EMPROVE® ESSENTIAL Ph Eur,NF
Batch F2318412

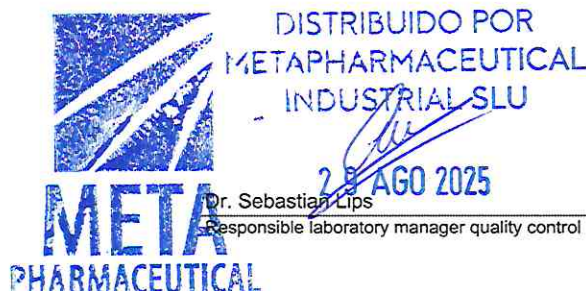
	Spec. Values	Batch Values
Identity (IR-spectrum)	passes test	passes test
Identity (Average relative molecular mass)	passes test	passes test
Content of oxyethylene moieties (H-NMR)	79.9 - 83.7 %	82.3 %
Appearance	white to almost white, waxy substance	passes test
Appearance of solution (100 g/l, CO ₂ -free 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	6.0
pH (100 g/l, CO ₂ -free water)	5.0 - 7.5	6.5
Average relative molecular mass	7680 - 9510	8673
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	≤ 1 ppm	< 1 ppm
Dioxane (HS-GC) (NF) ¹	≤ 5 ppm	< 5 ppm
Propylene oxide (HS-GC) (NF) ¹	≤ 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 %	0.5 %
Particle size (d10)	5 - 30 μm	17 μm
Particle size (d50)	40 - 70 μm	68 μm
Particle size (d90)	90 - 240 μm	172 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 (*).

¹ measured value from external service laboratory

Corresponds to Ph. Eur., NF

Date of manufacture (DD.MM.YYYY) 08.05.2024
Date of examination (DD.MM.YYYY) 14.10.2024
Minimum shelf life (DD.MM.YYYY) 31.05.2026



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