



Certificate of Analysis

1.00844.0000 Ethanolamine EMPROVE® ESSENTIAL Ph Eur,BP,NF
Batch K56235144

	Spec. Values		Batch Values	
Assay (acidimetric)	98.0 - 100.5	%	99.8	%
Assay (acidimetric, calc. on anhydrous substance)	99.0 - 101.0	%	99.8	%
Identity (IR-spectrum)	conforms		conforms	
Appearance	Clear, colorless or pale yellow liquid.		Clear, colorless or pale yellow liquid.	
Appearance of solution (Ph Eur)	conforms		conforms	
Refractive index (n 20/D)	1.453 - 1.459		1.455	
Density (d 20/4)	1.014 - 1.017	g/cm ³	1.015	g/cm ³
Relative Density (d 20/20)	1.016 - 1.019		1.017	
Specific gravity (d 25/25)	1.013 - 1.016		1.014	
Weight per mL	1.014 - 1.023	g	1.020	g
Distilling range (167 °C - 173 °C)	≥ 95	%	98.0	%
Fe (Iron)	≤ 0.00001	%	≤ 0.00001	%
Related substances (GC) (Diethanolamine)	≤ 0.5	%	< 0.1	%
Related substances (GC) (Triethanolamine)	≤ 0.5	%	< 0.1	%
Related substances (GC) (any other impurity)	≤ 0.5	%	< 0.5	%
Related substances (GC) (Sum of all impurities)	≤ 2.0	%	< 2.0	%
Related substances (GC) (Unspecified impurities) (Ph Eur)	≤ 0.10	%	< 0.10	%
Related substances (GC) (Total) (Ph Eur)	≤ 0.3	%	< 0.3	%
Residual solvents (ICH Q3C)	...excluded by production process		...excluded by production process	
Residue on ignition (600 °C)	≤ 0.1	%	< 0.02	%
Water (according to Karl Fischer)	≤ 0.25	%	≤ 0.25	%

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 (*).

Min. shelf life: see product label

Date of manufacture (DD.MM.YYYY) 01.09.2024

Date of examination (DD.MM.YYYY) 29.10.2024

Christian Herrmann

Responsible laboratory manager quality control

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