



CERTIFICATE OF ANALYSIS

1.37004.1000

Titriplex® III (ethylene dinitrilo tetraacetic acid
disodium salt dihydrate) EMPROVE® EXPERT Ph
Eur,BP,ChP,JP,USP,ACS
Batch E300026341

Batch

	Spec. Values		Batch Values	
Assay (calc. on dried substance)	99.0-101.0	%	99.7	% ✓
Assay (calc. as dihydrate)	99.0-101.0	%	99.7	%
Identification	Complies	-	Complies	- → USP 47
Appearance	White to almost white, crystalline powder	-	Complies	- ✓
Appearance of solution (5%, water)	Clear and colorless	-	Complies	-
✗ Chelating capacity test	Complies	-	Complies	-
✗ In water insoluble matter	Not more than 0.005	%	Complies	%
pH (1%, water)	4.3-4.7	-	4.6	- § → USP 47
pH (5%, water)	4.0-5.0	-	4.4	-
✗ Chloride (Cl)	Not more than 40	ppm	Complies	ppm
✗ Cyanide (CN)	Not more than 1	ppm	Complies	ppm
✗ Heavy metals (as Pb)	Not more than 10	ppm	Complies	ppm
✗ Arsenic (As)	Not more than 1	ppm	Complies	ppm
✗ Calcium (Ca)	Complies	-	Complies	- → USP 47
✗ Iron (Fe)	Not more than 5	ppm	Complies	ppm
Nitrilotriacetic acid	Not more than 0.1	%	0.0	% ✓
✗ Methanol (GC)	Not more than 3000	ppm	<300	ppm
✗ Other residual solvents (ICH Q3C)	Excluded by production process	-	Excluded by production process	-
Loss on drying	8.7 - 11.4	%	9.7	% ✓
Sulphated ash	37.0-39.0	%	38.2	%
Total aerobic microbial count (TAMC)	Not more than 100	CFU/g	<1	CFU/g
Total combined yeast and mold count (TYMC)	Not more than 10	CFU/g	<1	CFU/g
Bile tolerant Gram negative Bacteria	Absence in 1g	-	Complies	-
Candida albicans	Absence in 1g	-	Complies	-
Escherichia coli	Absence in 1g	-	Complies	-
Pseudomonas aeruginosa	Absence in 1g	-	Complies	-
Salmonella	Absence in 10g	-	Complies	-
Staphylococcus aureus	Absence in 1g	-	Complies	-
Bacterial endotoxins (LAL-test)	Not more than 30	IU/g	Complies	IU/g ✗

This document has been produced electronically and is valid without a signature

CERTIFICATE OF ANALYSIS

1.37004.1000

Titriplex® III (ethylene dinitrilo tetraacetic acid
disodium salt dihydrate) EMPROVE® EXPERT Ph
Eur,BP,ChP,JP,USP,ACS
Batch E300026341

Date of manufacture (DD.MM.YYYY): 05.02.2021

Date of examination (DD.MM.YYYY): 24.02.2021

Minimum shelf life (DD.MM.YYYY): 28.02.2026

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 (*).

Corresponds to Ph Eur, BP, ChP, JP, USP and ACS.

Endotoxins and microbiological tests performed by qualified external lab.

Manufactured by Merck S.L.U. Mollet del Vallès (Barcelona).

Dr. Valenti Bou

responsible laboratory manager quality control.

This document has been produced electronically and is valid without a signature

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU PRODUK

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Disodium Edtate	Merck	EP/JP/USP/SP	USP47 / FI VI	Chelating Capacity test in water insoluble matter Chloride Cyanide Heavy metals Arsenic Calcium Iron Methanol Residual Solvent Identifikasi nanoram	Cemaran mikroba disesuaikan dengan CoA	Kelarutan disesuaikan dengan USP 47 Kalsium di sesuaikan dengan USP 47 pH : 4-6 (Usp 47)	AD-01-SBP/135.00	Penyesuaian CoA dari Manufacturer Update SPBB Update SPBB dan Penyesuaian CoA dari Manufacturer

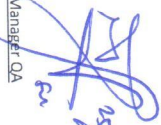
Diperiksa Oleh,

Disetujui Oleh,


23/10/24
Koordinator QC


23/10/24
Koordinator IS


23/10/24
Koordinator QA


25/10/24
Manager QA