



Specification

1.02465.0001 Calcium chloride dihydrate EMPROVE® API Ph Eur, BP, ChP, JP, USP

	Spec. Values		Method
Appearance	conforms		
Assay (complexometric)	99.0 - 103.0	%	In-house
Identity	passes test		In-house
Appearance of solution (10 %; water)	passes test		Ph. Eur., ChP
Acidity or alkalinity	passes test		ChP
pH-value (5 %; water)	4.5 - 8.5		JP, USP
Fluoride (F)	≤ 0.004	%	In-house
Hypochlorite (ClO)	passes test		JP
Sulfate (SO ₄)	≤ 0.01	%	In-house
Heavy metals (as Pb)	≤ 0.0005	%	In-house
Al (Aluminium)	≤ 0.00002	%	In-house
As (Arsenic)	≤ 0.00015	%	In-house
Ba (Barium)	passes test		ChP
Fe (Iron)	≤ 0.0010	%	In-house
Hg (Mercury)	≤ 0.0001	%	In-house
Pb (Lead)	≤ 0.0002	%	In-house
Magnesium and alkali metals	≤ 0.2	%	Ph.Eur.
Substances precipitated by ammonia (Al, Fe, PO ₄)	passes test		USP
Residual solvents (ICH Q3C)	excluded by manufacturing process		
Endotoxins	≤ 3.0	I.U./g	Ph. Eur. 2.6.14, USP <85>, JP <4.01>
Total aerobic microbial count	≤ 100	CFU/g	Ph. Eur. 2.6.12, USP <61>, JP <4.05>
Total yeast and mould count	≤ 100	CFU/g	Ph. Eur. 2.6.12, USP <61>, JP <4.05>

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

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Responsible laboratory manager quality control

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