

Specification

Magnesia 4155
Calcium chloride-2-hydrate,
EP, USP, E 509

Article No.:	5415500
Specification Type:	API
Version:	4
Issue Date:	30/06/2021
Manufacturer's Designation:	Calcium chloride dihydrate, EP (010A), USP (012), E 509 (106), pyrogen free
Manufacturing Site:	Macco Organiques, s.r.o. Zahradní46c Bruntál 792 01, Czech

Appearance (EP)	white to off-white, crystalline powder, hygroscopic
Appearance (E 509)	white, hygroscopic powder or deliquescent crystals
Odour	odourless
Solubility (E 509)	soluble in water and in ethanol
Solubility (EP)	freely soluble in water, soluble in ethanol (96 %)
Assay (USP)	99.0 - 107.0 %
Assay (EP)	97.0 - 103.0 %
Assay (E 509) (on anhydrous basis)	Min. 93.0 %
Identification (Ca)	complies
Identification (Cl)	complies
Appearance of solution	clear, not more intensely coloured than reference solution Y6
Acidity / alkalinity	max. 0.2 ml of 0.01 M HCl / NaOH
Pb	max. 2 ppm
Hg	max. 1 ppm
As	max. 3 ppm
Fe	max. 10 ppm
F	max. 40 ppm
SO ₄	max. 300 ppm
Al	max. 1 ppm
Mg and alkali metals (EP)	max. 0.5 %
Mg and alkali salts (USP)	max. 1.0 %
Mg and alkali salts (as sulphates) (E 509)	max. 5 %
Fe, Al, PO ₄	complies
Residual solvents	no organic solvents are used in the production, the product meets the requirements of USP, EP and EMA/CHMP/ICH/82660/2006 for residual solvents

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Bacterial endotoxins	max. 3 I.U./g
pH value (50 mg/ml)	4.5 - 9.2

Released by: 30/06/2021, David Roether

Parameters indicated in this specification are based on our current, carefully determined knowledge. It is the users own responsibility to test and analyze materials and therefore corroborate that products are adequate for their applications.

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