

CalPlus™ (Brand of Calcium Chloride Dihydrate), USP

Multi-Compendial

Suitable for Use in Hemodialysis



Material No.: 1336-01

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Revision No.: 0

## Product Specification

Meets B.P. Chemical Specifications, Meets F.C.C. Requirements, Meets E.P. Chemical Specifications, Meets U.S.P Requirements, Meets J.P. Chemical Specifications, GMP Manufactured Product

Test	Specification
USP – Assay (CaCl <sub>2</sub> · 2H <sub>2</sub> O)	99.0 – 107.0 %
USP – Identification A	Passes Test
USP – Identification B	Passes Test
USP – pH of 5% Solution at 25°C	4.5 – 9.2
USP – Iron, Aluminum, and Phosphate	Passes Test
USP – Magnesium and Alkali Salts	≤ 1.0 %
USP – Aluminum (Al)(µg/g)	≤ 1
Endotoxin Concentration (EU/g)	≤ 10
FCC – Assay (CaCl <sub>2</sub> · 2H <sub>2</sub> O)	99.0 – 107.0 %
FCC – Identification A	Passes Test
FCC – Identification B	Passes Test
FCC – Arsenic (As)	≤ 3 mg/kg
FCC – Magnesium and Alkali Salts	≤ 1.0 %
FCC – Lead (Pb)	≤ 5 mg/kg
FCC – Fluoride (F)	≤ 0.004 %
Appearance (White crystals or granules)	Passes Test
EP/BP – Assay (CaCl <sub>2</sub> · 2H <sub>2</sub> O)	97.0 – 103.0 %
EP/BP – Identification A	Passes Test
EP/BP – Identification B	Passes Test
EP/BP – Identification C	Passes Test
EP/BP – Appearance of Solution	Passes Test
EP/BP – Acidity or Alkalinity	Passes Test
EP/BP – Sulfate (SO <sub>4</sub> )	≤ 300 ppm
EP – Aluminum (Al)	≤ 1 ppm
EP/BP – Iron (Fe)	≤ 10 ppm
EP/BP – Magnesium and Alkali Metals	≤ 0.5 %
JP – Assay (CaCl <sub>2</sub> · 2H <sub>2</sub> O)	96.7 – 103.3 %
JP – Identification	Passes Test

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For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

Avantor Performance Materials, LLC

100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

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Test	Specification
JP – pH (1 in 20)	4.5 – 9.2
JP – Clarity and Color of Solution	Passes Test
JP – Sulfate (SO <sub>4</sub> )	≤ 0.024 %
JP – Hypochlorite	Passes Test
JP – Iron, Aluminum or Phosphate	Passes Test

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GMP Manufactured Product

Food GMP Manufactured Product

Bulk Food Chemical

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

Elemental Impurities (USP 232, EP 5.20) – Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Suitable for use in hemodialysis.

Packaging Site: Paris Mfg Ctr & DC

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