

CalPlus™ (Brand of Calcium Chloride Dihydrate), USP
Multi-Compendial
Suitable for Use in Hemodialysis



Material No.: 1336-09
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 ₂ ·2H ₂ 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 ₂ ·2H ₂ 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 ₂ ·2H ₂ 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 ₄)	≤ 300 ppm
EP - Aluminum (Al)	≤ 1 ppm
EP/BP - Iron (Fe)	≤ 10 ppm
EP/BP - Magnesium and Alkali Metals	≤ 0.5 %
JP - Assay (CaCl ₂ ·2H ₂ O)	96.7 - 103.3 %
JP - Identification	Passes Test

>>> Continued on page 2 >>>

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

CalPlus™ (Brand of Calcium Chloride Dihydrate), USP
Multi-Compendial
Suitable for Use in Hemodialysis



Material No.: 1336-09

Test	Specification
JP - pH (1 in 20)	4.5 - 9.2
JP - Heavy Metals (as Pb)	≤ 10 ppm
JP - Clarity and Color of Solution	Passes Test
JP - Sulfate (SO ₄)	≤ 0.024 %
JP - Hypochlorite	Passes Test
JP - Iron, Aluminum or Phosphate	Passes Test
JP - Barium (Ba)	Passes Test
JP - Arsenic (As)	≤ 2 ppm

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


Jamie Ethier
Vice President Global Quality

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