

PURE DRIED VACUUM SALT – SODIUM CHLORIDE (NaCl)

Pharmaceutical - USP	
Components	USP-NF 2023 Issue 3 specification
Appearance	White or almost white, crystalline powder
Chlorides Identification	Conforms
Sodium Identification	Conforms
Aluminium <i>as Al</i>	0.2 ug/g (max)
Arsenic <i>as As</i>	1 ug/g (max)
Barium	Conforms
Ferrocyanides	Conforms
Iodides	Conforms
Iron <i>as Fe</i>	2 ug/g (max)
Bromides <i>as Br</i>	0.010 % (max)
Phosphate <i>as PO₄</i>	0.0025 % (max)
Potassium <i>as K</i>	0.05 % (max)
Magnesium & Alkaline-earth metals	NMT 2.5ml 0.01M EDTA (0.01 % max calculated as Ca)
Nitrites	Conforms
Sulphates <i>SO₄</i>	0.020 % (max)
Appearance of Solution	Clear and Colourless
Acidity	NMT 0.5ml 0.01M NaOH
Alkalinity	NMT 0.5ml 0.01M HCl
Loss on Drying (at packing)	NMT 0.5% ^w / _w (max)
Assay <i>as NaCl</i>	99.0-100.5% ^w / _w
Residual Solvents	No class 1, 2 or 3 solvents are used in the manufacture of Pharmaceutical Sodium Chloride
Filtration Rate:	Typical Range:
2ltr of 20.15% ^w / _v saline filtered through a 0.45 micron filter at 15" Hg.	300-450 ml/min

NOTES: NMT = Not More Than ppm = µg/g = mg/kg = (% x 10,000)

COUNTRY OF ORIGIN:
Made in New Zealand

BULK DENSITY:
Nominally: Loose 1.25 g/ml, compacted 1.43 g/ml

GRADE DESCRIPTION:

USP in an extremely high purity certified vacuum salt particularly suited to customers manufacturing premium grade products to the United States Pharmacopoeia standard. It is suitable for the use in the injectable dosages forms, peritoneal dialysis solutions, Haemodialysis solutions and Hemofiltration solutions.

COMPLIANCE:

- » Certified to United States Pharmacopoeia
- » MoH Licence to Manufacture Medicines
- » GMP – Medsafe Certified
- » ANZ Food Standards Code
- » NZFSA Approved Food Safety Programme
- » National Programme 3
- » NOT a genetically modified food as defined under 1.5.2 of the ANZ Food Standards Code
- » Free from known Allergens
- » Halal Certified
- » Kosher Certified
- » Dominion Salt is ISO 9001, FSSC 22000 certified

PACKAGING:

25kg Heavy Gauge Polyethylene Bag (no outer)

25kg Multiwall paper sack with light gauge polyethylene liner

Packaging material complies with US FDA regulations Title 21, parts 170-199

BATCH MARKS:

Batch marking on the packaging is in the form DDMMYYYY

PALLETS:

25kg packs: Standard pallet configuration is 48 x 25kg bags (1.2 tonnes per pallet)

All salt is stretch wrapped and capped on pallets with a pallet sheet between the pallet and the salt.

Authorised by:	Title:	Sign:	Date:
Glen Matthews	Quality Manager		07/11/2023

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