

PURE DRIED VACUUM SALT – SODIUM CHLORIDE (NaCl)

Pharmaceutical – BP/Ph Eur	
Components	BP 2026/Ph Eur 11.7 (0193) specification
Appearance	White or almost white, crystalline powder
Chlorides Identification	Conforms
Sodium Identification	Conforms
Appearance of Solution	Clear and Colourless
Acidity	NMT 0.5ml 0.01M NaOH
Alkalinity	NMT 0.5ml 0.01M HCl
Bromides <i>as Br</i>	100 ppm (max)
Ferrocyanides	Conforms
Iodides	Conforms
Nitrites	Conforms
Phosphate <i>as PO₄</i>	25 ppm (max)
Sulphates <i>as SO₄</i>	200 ppm (max)
Aluminium <i>as Al</i>	0.2 ppm (max)
Arsenic <i>as As</i>	1 ppm (max)
Barium	Conforms
Iron <i>as Fe</i>	2 ppm (max)
Magnesium & Alkaline-earth metals	NMT 2.5ml 0.01M EDTA (100 ppm max calculated as Ca)
Potassium <i>as K</i>	500 ppm (max)
Loss on Drying (at packing)	0.5% w/w (max)
Bacterial endotoxins	<5 EU/g
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:
After 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:

BP/Ph Eur is an extremely high purity certified vacuum salt particularly suited to customers manufacturing premium grade products to the British Pharmacopoeia / European standard. It is suitable for the use in the injectable dosages forms, peritoneal dialysis solutions, Haemodialysis solutions and Hemofiltration solutions.

COMPLIANCE:

- » Certified to British Pharmacopoeia
- » Certified to European 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:
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