

PURE DRIED VACUUM SALT – SODIUM CHLORIDE (NaCl)

Pharmaceutical - JP	
Components	JP 18 th edition XVIII/2021 specification
Appearance	White or almost white, crystalline powder
Appearance of Solution	Clear and Colourless
Sodium Identification	Conforms
Chlorides Identification	Conforms
Acidity	NMT 0.5ml 0.01M NaOH
Alkalinity	NMT 0.5ml 0.01M HCl
Sulphates <i>as SO₄</i>	200 ppm (max)
Phosphate <i>as PO₄</i>	25 ppm (max)
Bromides <i>as Br</i>	100 ppm (max)
Iodides	Conforms
Ferrocyanides	Conforms
Heavy Metals <i>as Pb</i>	3 ppm (max)
Iron <i>as Fe</i>	2 ppm (max)
Barium	Conforms
Magnesium & Alkaline-earth metals	NMT 2.5ml 0.01M EDTA (100 ppm max calculated as Ca)
Arsenic <i>as As₂O₃</i>	2 ppm (max)
Loss on Drying (at packing)	0.5% ^w / _w (max)
Assay <i>as NaCl</i>	99.0-100.5% ^w / _w
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:

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

COMPLIANCE:

- » Certified to Japanese Pharmacopoeia
- » MoH Licence to Manufacture Medicines
- » GMP – Medsafe Certified
- » 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 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

ISSUE DATE: 07/11/23**ISSUE NO:** 09**Head Office** & North Island Refinery

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