

PRODUCT SPECIFICATION



PURE DRIED VACUUM SALT (PDV)

Sodium Chloride

塩化ナトリウム

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NaCl: 58.44

(JP) PHARMACEUTICAL SALT		
COMPONENTS	JP XVI/2011 Specification	TYPICAL
Sodium Identification	Conforms ¹	Conforms ¹
Chlorides Identification	Conforms ¹	Conforms ¹
Appearance of Solution	Conforms ¹	Conforms ¹
Acidity	NMT 0.5ml 0.01M NaOH	Conforms ¹
Alkalinity	NMT 0.5ml 0.01M HCl	Conforms ¹
Sulphate as SO ₄	Max 200 ppm	Conforms ¹ (<50 ppm)
Bromide as Br	Max 100 ppm	Conforms ¹ (<50 ppm)
Iodides	Conforms ¹	Conforms ¹
Heavy Metals as Pb	Max 3 ppm	Conforms ¹
Iron as Fe	Max 2 ppm	Conforms ¹
Barium	Conforms ¹	Conforms ¹
Magnesium & Alkaline earth metals	NMT 2.5ml 0.01M EDTA (100 ppm max calculated as Ca)	<0.2ml 0.01M EDTA (<8 ppm as Ca)
Arsenic as As ₂ O ₃	Max 2 ppm	Conforms ¹ (<0.03 ppm)
Loss on drying (at packing)	Max 0.5% (1g, 130°C, 2 hours)	<0.1%
Assay as NaCl	99.0-100.5%	Conforms ¹

ADDITIONAL INFORMATION	TYPICAL RANGE
Filtration Rate (minimum after 2 litres of 20.15% w/v saline filtered through a 0.45 micron filter at 15" Hg)	150-300ml/min

Notes: NMT = Not more than < Less than > Greater than ppm = µg/g = mg/kg = (% x 10,000)
1. Conforms to limit test prescribed in JP XVI.

GRADE DESCRIPTION:

JP is an extremely high purity certified vacuum salt particularly suitable for the use in the manufacture of injectable dosage forms, peritoneal dialysis solutions, hemodialysis solutions and hemofiltration solutions.

COUNTRY OF ORIGIN: Product of New Zealand

GRAIN SIZE: Typically 85-100% passing 500 microns
Typically 0-18% passing 250 microns

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

COMPLIANCE:

- Certified to Japanese Pharmacopoeia (JP XVI)
- MoH Licence to Manufacture Medicines
- GMP- Medsafe Certified
- ISO 9001 certified

PACK: 25kg Multiwall paper sack with light gauge polyethylene liner.
Packaging material complies with US FDA regulations Title 21, parts 170-199

Batch Marks: The batch marking on our packaging is in the form ddmmyyy

Pallets: Standard pallet configuration is 48 x 25 kg 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.

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