

# 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 XVII/2016 Specification	TYPICAL
Sodium Identification	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Chlorides Identification	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Appearance of Solution	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Acidity	NMT 0.5ml 0.01M NaOH	Conforms <sup>1</sup>
Alkalinity	NMT 0.5ml 0.01M HCl	Conforms <sup>1</sup>
Sulphate as SO <sub>4</sub>	Max 200 ppm	Conforms <sup>1</sup> (<50 ppm)
Bromide as Br	Max 100 ppm	Conforms <sup>1</sup> (<50 ppm)
Iodides	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Heavy Metals as Pb	Max 3 ppm	Conforms <sup>1</sup>
Iron as Fe	Max 2 ppm	Conforms <sup>1</sup>
Barium	Conforms <sup>1</sup>	Conforms <sup>1</sup>
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 <sub>2</sub> O <sub>3</sub>	Max 2 ppm	Conforms <sup>1</sup> (<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 <sup>1</sup>

ADDITIONAL INFORMATION	TYPICAL RANGE
<b>Filtration Rate</b> (minimum after 2 litres of 20.15% w/v saline filtered through a 0.45 micron filter at 15" Hg)	300-450ml/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 XVII.

#### 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 ddmmyyyy

**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.

Authorised by:	Title:	Sign:	Date:
JAMES NATZKA	QUALITY MANAGER		09/07/2019