

# PRODUCT SPECIFICATION



## PURE DRIED VACUUM SALT (PDV)

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(BP/Ph Eur) PHARMACEUTICAL SALT		
COMPONENTS	BP:2017/Ph Eur 0193 Specification	TYPICAL
Chlorides Identification	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Sodium 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	<0.1ml 0.01M NaOH
Alkalinity	NMT 0.5ml 0.01M HCl	<0.3ml 0.01M HCl
Bromide as Br	Max 100 ppm	Conforms <sup>1</sup> (<50 ppm)
Ferrocyanide (any form)	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Iodides	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Nitrites	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Phosphate as PO <sub>4</sub>	Max 25 ppm	Conforms <sup>1</sup>
Sulphate as SO <sub>4</sub>	Max 200 ppm	Conforms <sup>1</sup> (<50 ppm)
Aluminium as Al	Max 0.2 ppm	Conforms <sup>1</sup>
Arsenic as As	Max 1 ppm	Conforms <sup>1</sup> (<0.01 ppm)
Barium	Conforms <sup>1</sup>	Conforms <sup>1</sup>
Iron as Fe	Max 2 ppm	Conforms <sup>1</sup> (<0.2 ppm)
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)
Potassium as K	Max 500 ppm	< 50 ppm
Heavy Metals as Pb	Max 5 ppm	Conforms <sup>1</sup>
Loss on drying (at packing)	Max 0.5%	<0.1%
Bacteria endotoxins	<5 EU/g	Conforms <sup>1</sup>
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 BP.

### GRADE DESCRIPTION:

BP 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 British Pharmacopoeia*
  - *Certified to European Pharmacopoeia (Ph Eur 0193)*
  - *MoH Licence to Manufacture Medicines*
  - *GMP- Medsafe Certified*
  - *ISO 9001 certified*

**PACK:**                   **Either:** 25kg Heavy gauge Polyethylene Bag (no outer)  
                                  **or**       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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