

PRODUCT SPECIFICATION



PURE DRIED VACUUM SALT (PDV)

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(BP) PHARMACEUTICAL SALT		
COMPONENTS	BP:2001 Specification	TYPICAL
Alkalinity as Na ₂ CO ₃	Max 66 mg/kg	<20 mg/kg
Appearance of Solution	Clear and colourless	Conforms ¹
Arsenic as As	Max 1 mg/kg	<0.01 mg/kg
Barium	Conforms ¹	Conforms ¹
Heavy Metals as Pb	Max 5 mg/kg	<4 mg/kg
Iron as Fe	Max 2 mg/kg	<0.2 mg/kg
Magnesium & Alkaline earth metals as Ca	Max 100 mg/kg	<4 mg/kg
Bromide as Br	Max 50 mg/kg	<50 mg/kg
Ferrocyanide (any form)	Conforms ¹	Conforms ¹
Iodide	Conforms ¹	Conforms ¹
Nitrite	Conforms ¹	Conforms ¹
Phosphate as PO ₄	Max 25 mg/kg	< 25 mg/kg
Sulphate as SO ₄	Max 200 mg/kg	< 15 mg/kg
Potassium as K	Max 500 mg/kg	< 20 mg/kg
Aluminium as Al	Max 0.2 mg/kg	< 0.15 mg/kg
Loss on drying (at packing)	Max 0.5%	0.02%
Assay as NaCl	99.0-100.5%	> 99.9%

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)	200-300ml/min

Notes: < Less than > Greater than ppm = mg/kg = (% x 10,000)

1. Conforms to limit test prescribed in BP 2001.

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 2001**
- *Certified against the New Zealand Code of Good Manufacturing Practise (Manufacture and Distribution of therapeutic Goods; Part 1: Manufacture of Pharmaceutical Products). Derived from the agreement of the Pharmaceutical Inspection Convention (PIC) to replace as from January 1992, the basic standards of GMP for Pharmaceutical Products (PH3/83) and supplementary Guidelines thereto by the present Guide which is harmonised with the EEC guide.*
- *Dominion Salt is ISO 9002 certified*

PACK: **Either:** 25kg Heavy gauge Polyethylene Bag (no outer)
 or 25kg Multiwall paper sack with light gauge polyethylene liner.
 or 25kg Carton with polyethylene liner (by arrangement)
Packaging material complies with US FDA regulations Title 21, parts 170-199
Print colour: Orange 151 C and Blue 306C

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

Pallets: **Small packs:** Standard pallet configuration is 48 x 25 kg bags (1.2 tonnes per pallet) The salt is stretch wrapped and capped on pallets with a pallet sheet between the pallet and the salt.

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