

PRODUCT SPECIFICATION



PURE DRIED VACUUM SALT (PDV)

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(BP/Ph Eur) PHARMACEUTICAL SALT		
COMPONENTS	BP:2012/Ph Eur 0193 Specification	TYPICAL
Chlorides Identification	Conforms ¹	Conforms ¹
Sodium Identification	Conforms ¹	Conforms ¹
Appearance of Solution	Conforms ¹	Conforms ¹
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 ¹ (<50 ppm)
Ferrocyanide (any form)	Conforms ¹	Conforms ¹
Iodides	Conforms ¹	Conforms ¹
Nitrites	Conforms ¹	Conforms ¹
Phosphate as PO ₄	Max 25 ppm	Conforms ¹
Sulphate as SO ₄	Max 200 ppm	Conforms ¹ (<50 ppm)
Aluminium as Al	Max 0.2 ppm	Conforms ¹
Arsenic as As	Max 1 ppm	Conforms ¹ (<0.01 ppm)
Barium	Conforms ¹	Conforms ¹
Iron as Fe	Max 2 ppm	Conforms ¹ (<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 ¹
Loss on drying (at packing)	Max 0.5%	<0.1%
Bacteria endotoxins	<5 EU/g	Conforms 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)	200-300ml/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 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)*
 - *Dominion Salt is ISO 9001 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)
 or 10kg Heavy gauge Polyethylene Bag (no outer)

Packaging material complies with US FDA regulations Title 21, parts 170-199

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.

Issue Date: 01.03.2013

Issue No: 12