PRODUCT SPECIFICATION

PURE DRIED VACUUM SALT (PDV)

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(USP) PHARMACEUTICAL SALT		
COMPONENTS	**USP 39/2016 Specification**	**TYPICAL**
Appearance of Solution	Conforms [1]	Conforms [1]
Chlorides Identification	Conforms [1]	Conforms [1]
Sodium Identification	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
Loss on drying (at packing)	Max 0.5%	<0.1%
Iodides	Conforms [1]	Conforms [1]
Aluminium as Al	Max 0.2 µg/g	Conforms [1]
Magnesium & Alkaline earth metals	NMT 2.5ml 0.01M EDTA (0.01% max calculated as Ca)	<0.2ml 0.01M EDTA (<0.0008% as Ca)
Arsenic as As	Max 1 µg/g	Conforms [1] (<0.01 µg/g)
Barium	Conforms [1]	Conforms [1]
Ferrocyanide (any form)	Conforms [1]	Conforms [1]
Sulphate as SO_4	Max 0.020%	Conforms [1] (<0.005%)
Iron as Fe	Max 2 µg/g	Conforms [1] (<0.2 µg/g)
Nitrites	Conforms [1]	Conforms [1]
Heavy Metals as Pb	Max 5 ppm	Conforms [1]
Bromide as Br	Max 0.010%	Conforms [1] (<0.005%)
Phosphate as PO_4	Max 0.0025%	Conforms [1]
Potassium as K	Max 0.05%	< 0.005%
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 USP.

GRADE DESCRIPTION:
USP is an extremely high purity certified vacuum salt particularly suited to customers manufacturing premium grade products to the United States Pharmacopoeia standard. It is 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: lose 1.25g/ml, compacted 1.43g/ml

COMPLIANCE: - ***Certified to United States Pharmacopeia (USP 38/NF33 – 2015)***
- *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 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.

Issue Date: 22.11.16
Issue No: 15