

PRODUCT SPECIFICATION



PURE DRIED VACUUM SALT (PDV)

Head Office & N.I. Refinery

Lake Grassmere & S.I. Refinery

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| (USP) PHARMACEUTICAL SALT | | |
|-----------------------------------|--|---------------------------------------|
| COMPONENTS | USP 40/2017 Specification (USP 40/NF35) | 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) | 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 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: loose 1.25g/ml, compacted 1.43g/ml

- COMPLIANCE:**
- *Certified to United States Pharmacopoeia*
 - *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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