

(BP/Ph Eur) PHARMACEUTICAL SALT

COMPONENTS	BP:2019/Ph Eur 0193 Specification	TYPICAL
Chlorides Identification	Conforms ¹	Conforms ¹
Sodium Identification	Conforms ¹	Conforms ¹
Appearance of Solution	Clear and Colourless	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)	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 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.

Authorised by:	Title:	Sign:	Date:
JAMES NATZKA	QUALITY MANAGER		09/07/2019