

PRODUCT SPECIFICATION

Pure Dried Vacuum Salt - Sodium Chloride (NaCl)

Pharmaceutical – BP/Ph Eur	
Components	BP:2021/Ph Eur 0193 specification
Appearance of Solution	Conforms ¹
Chlorides Identification	Conforms ¹
Sodium Identification	Conforms ¹
Acidity	NMT 0.5ml 0.01M NaOH
Alkalinity	NMT 0.5ml 0.01M HCl
Loss on Drying (at packing)	Max 0.5%
Iodides	Conforms ¹
Aluminium as Al	Max 0.2 µg/g
Magnesium and Alkaline earth metals	NMT 2.5ml 0.01M EDTA (0.01% max calculated as Ca)
Arsenic as As	Max 1 µg/g
Barium	Conforms ¹
Ferrocyanide (any form)	Conforms ¹
Sulphate as SO ₄	Max 0.020%
Iron as Fe	Max 2 µg/g
Nitrites	Conforms ¹
Heavy Metals as Pb	Max 5 ppm
Bromide as Br	Max 0.010%
Phosphate as PO ₄	Max 0.0025%
Potassium as K	Max 500ppm
Bacteria endotoxins	<5EU/g
Assay as NaCl	99.0 – 100.5%
Filtration Rate:	Typical Range
After 2ltr of 20.15% w/v saline filtered through a 0.45 micron filter at 15" Hg.	300 – 450 ml/min

NOTES: NMT= Not More Than ppm = µg/g = mg/kg = (% x 10,000)

1. Conforms to limit test prescribed in the Japanese Pharmacopoeia.

GRADE DESCRIPTION:

BP in an extremely high purity certified vacuum salt particularly suited to customers manufacturing premium grade products to the Japanese Pharmacopoeia standard. It is suitable for the use in the injectable dosages forms, peritoneal dialysis solutions, Haemodialysis solutions and Hemofiltration solutions.

COUNTRY OF ORIGIN:

Made in New Zealand

BULK DENSITY:

Nominally: loose 1.25 g/ml, compacted 1.43 g/ml

COMPLIANCE:

Certified to British Pharmacopoeia
Certified to European Pharmacopoeia (Ph Eur 0193)
MoH Licence to Manufacture Medicines
GMP – Medsafe Certified
 ANZ Food Standards Code
 NZFSA Approved Food Safety Programme
 National Programme 3
NOT a genetically modified food as defined under 1.5.2 of the ANZ Food Standards Code
Free from known Allergens
Halal Certified
Kosher Certified
Dominion Salt is ISO 9001, FSSC 22000 certified

PACKAGING:

25kg Heavy gauge Polyethylene Bag (no outer)
 25kg Multiwall paper sack with light gauge polyethylene liner
Packaging material complies with US FDA regulations Title 21, parts 170-199

BATCH MARKS:

Batch marking on the packaging is in the form DDMMYYYY

PALLETS:

25kg packs: Standard pallet configuration is 48 x 25kg 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:
<i>James Natzka</i>	<i>Quality Manager</i>		<i>03/05/21</i>