DominionSalt Limited

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BATCH ANALYSIS CERTIFICATE - BP/Ph Eur GRADE

Dosage Forms: Suitable for the use in the manufacture of injectable dosage forms, peritoneal dialysis solutions, hemodialysis solutions and hemofiltration solutions.

PRODUCT TYPE: Pharmaceutical Sodium Chloride
CAS No.: 7647-14-5
Molecular formula: NaCl
Molecular Weight: 58.44
BATCH/MFD[1]: 25062024

REPORT NO: **31059**
DATE PACKED: 25.06.2024 - 03.07.2024
RETEST[2] DATE: 25.06.2029

PAGE: 1 of 1

RESULTS

Tests Performed *(Methods as per Pharmacopoeia)*	**RESULT**			**BP 2023/Ph Eur 11.0 (0193) SPECIFICATION**
Appearance	Conforms			White or almost white, crystalline powder
Chlorides Identification	Conforms			Conforms
Sodium Identification	Conforms			Conforms
Appearance of Solution	Conforms			Clear and Colourless
Acidity	0.00	ml	(max)	NMT 0.5ml 0.01M NaOH
Alkalinity	0.20	ml	(max)	NMT 0.5ml 0.01M HCl
Bromides *as Br*	Conforms			100 ppm (max)
Ferrocyanides	Conforms			Conforms
Iodides	Conforms			Conforms
Nitrites	Conforms			Conforms
Phosphate *as* PO_4	Conforms			25 ppm (max)
Sulphates *as* SO_4	Conforms			200 ppm (max)
Aluminium *as Al*	Conforms			0.2 ppm (max)
Arsenic *as As*	Conforms			1 ppm (max)
Barium	Conforms			Conforms
Iron *as Fe*	Conforms			2 ppm (max)
Magnesium & Alkaline-earth metals	0.3	ml	(max)	NMT 2.5ml 0.01M EDTA *(100 ppm max calculated as Ca)*
Potassium *as K*	60	ppm	(max)	500 ppm (max)
Loss on Drying (at packing)	0.02	%w/w	(max)	0.5% $^{w}/_{w}$ (max)
Bacterial endotoxins	<1.00	EU/g		<5 EU/g
Assay *as NaCl*	99.62			99.0-100.5% $^{w}/_{w}$
Residual Solvents	No class 1, 2 or 3 solvents are used in the manufacture of Pharmaceutical Sodium Chloride			

ADDITIONAL ANALYSIS	**ACTUAL RANGE**		
Filtration Rate (Minimum after 2 litres of 20.15% w/v brine solution)	Minimum	414	ml/min
	Maximum	462	ml/min

< = Less Than
NMT = Not more than
u = micron

Note: 1. Batch/MFD in ddmmyyyy format is the date manufacture commenced. This date is also the traceable batch code.
2. Due to the stable nature of Sodium Chloride, Dominion Salt as permitted under PIC/s GMP guide PE-009 for API's, states a retest date in lieu of an expiry date.
3. This product has been produced at Dominion Salt Mount Maunganui site
4. All results reported are on a wet matter basis with the exception of the Assay test which is reported on a dried basis.
5. The samples have been collected and analysed in accordance with our documented sample plan.
6. All methods have been performed in Dominion Salt's on site Laboratory. Methods (unless stated) are documented in the Laboratory's Test Method Manual and will be made available upon request in writing to the Quality Manager
7. Supply of this salt is subject to the terms of trade of Dominion Salt Limited upon request. The laws of New Zealand shall govern all disputes.
8. Storage Conditions: Store unopened in clean, dry conditions

Conforms to Specification: _____

Release Date: 16.07.24
Approved by: _____
Eliska Veckova
QHSE Officer

For Distribution use only:

"Life's most essential mineral, in the world's safest hands."