

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/MFD¹: 25062024

REPORT NO: 31059
DATE PACKED: 25.06.2024 - 03.07.2024
RETEST² DATE: 25.06.2029

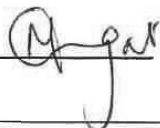
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RESULTS


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 (max)
Bacterial endotoxins	<1.00	EU/g		<5 EU/g
Assay as NaCl	99.62			99.0-100.5% % _w
Residual Solvents	No class 1, 2 or 3 solvents are used in the manufacture of Pharmaceutical Sodium Chloride			
ADDITIONAL ANALYSIS		ACTUAL RANGE		< = Less Than NMT = Not more than μ = micron
Filtration Rate (Minimum after 2 litres of 20.15% w/v brine solution)	Minimum	414	ml/min	
	Maximum	462	ml/min	

- 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."