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Lake Grassmere & South Island Refinery

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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

REPORT NO: 31537

CAS No.:

7647-14-5

DATE PACKED: 20-27/11/2024

PAGE:

RETEST² DATE: 20/11/2029

1 of 1

Molecular formula: NaCl Molecular Weight: 58.44 BATCH/MFD1: 20112024

	R	ESULTS			
Tests Performed	RESULT		BP 2023/Ph Eur 11.0 (0193)		
(Methods as per Pharmacopoeia)	KEGGET			SPECIFICATION	
Appearance	Conforms			White or almost white, crystalling powder	
Chlorides Identification		Conf	orms		Conforms
Sodium Identification		Conf	orms		Conforms
Appearance of Solution		Conf	orms	nat -	Clear and Colourless
Acidity	0.00)	ml	(max)	NMT 0.5ml 0.01M NaOH
Alkalinity	0.25	i	mì	(max)	NMT 0.5ml 0.01M HCI
Bromides as Br		Conforms			100 ppm (max)
Ferrocyanides		Conf	orms		Conforms
lodides	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		Conf	orms		2 ppm (max)
Magnesium & Alkaline-earth metals	0.2		ml (max)		NMT 2.5ml 0.01M EDTA (100 ppm max calculated as Ca
Potassium as K	15		ppm	(max)	500 ppm (max)
Loss on Drying (at packing)	0.07	0.07 %w/w (max)		0.5% ^w / _w (max)	
Bacterial endotoxins	<1.00 EU/g		J/g	<5 EU/g	
Assay as NaCl	99.86			99.0-100.5% ^w / _w	
Residual Solvents	No class 1, 2 or 3 solvents are used in the Sodium Ch				
ADDITIONAL ANALYSIS	ACTUAL RANGE			< = Less Than	
Filtration Rate (Minimum after 2 litres	Minimum	429	mi/	min 'min	NMT = Not more than
of 20.15% w/v brine solution)	Maximum 546 ml/min			u = micron	

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

Release Date: 06 12 24

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:6 M	Approved by:
For Distribution use only:	



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BATCH ANALYSIS CERTIFICATE - INJ GRADE PYROGEN FREE U.S.P.

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

REPORT NO: 31538

DATE PACKED: 20-27/11/2024

RETEST² DATE: 20/11/2029

BATCH/MFD¹: 20112024 **PAGE**: 1 of 1

		RESULT:	S			
Tests Performed	DEGIN T		USP-NF 2023 Issue 3			
(Methods as per Pharmacopoeia)	RESULT			SPECIFICATION		
Appearance		Conforms			White or almost white, crystalling powder	
Chlorides Identification		Conf	orms		Conforms	
Sodium Identification		Conf	orms		Conforms	
Appearance of Solution		Conf	orms		Clear and Colourless	
Acidity	0.0	0	mi	(max)	NMT 0.5ml 0.01M NaOH	
Alkalinity	0.2	5	mt	(max)	NMT 0.5ml 0.01M HCl	
Bromides as Br		Cont	forms	-	100 ppm (max)	
Ferrocyanides	i -	Cont	forms		Conforms	
lodides		Conf	forms		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		Conf	orms		2 ppm (max)	
Magnesium & Alkaline-earth metals	0.2	0.2		(max)	NMT 2.5ml 0.01M EDTA (100 ppm max calculated as Ca	
Potassium as K	15	15		(max)	500 ppm (max)	
Loss on Drying (at packing)	0.0	0.07		0.07 %w/w (max)		0.5% ^w / _w (max)
Assay as NaCl		99.86		99.0-100.5% ^w / _w		
Residual Solvents	No class 1	, 2 or 3 s		he manufacture of Pharmaceutica lloride		
ADDITIONAL ANALYSIS		ACTUAL RANGE			< = Less Than	
Filtration Rate (Minimum after 2 litres	Minimum	429	ml/	/min	NMT = Not more than	
of 20.15% w/v brine solution)	Maximum	546	ml/min		u = micron	

Note: 1. Batch/MFD in ddmmyyyy format is the date manufacture commenced. This date is also the traceable batch code.

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

 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: 06.12.24 Approved by: Eliska Veckova QHSE Officer
For Distribution use only:	

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



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BATCH ANALYSIS CERTIFICATE - JP 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: 20112024 REPORT NO: 31539

DATE PACKED: 20-27/11/2024 RETEST² DATE: 20/11/2029

PAGE:

1 of 1

Tests Performed					JP18th edition XVIII/2021
	RESULT				
(Methods as per Pharmacopoeia)					SPECIFICATION
Appearance		Conforms			White or almost white, crystalline
/ Appearation		Comonis			powder
Appearance of Solution		Conforn	าร		Clear and Colourless
Sodium Identification		Conform	าธ		Conforms
Chlorides Identification		Conforn	าร		Conforms
Acidity	0.0	0	ml	(max)	NMT 0.5ml 0.01M NaOH
Alkalinity	0.2	5	ml	(max)	NMT 0.5ml 0.01M HCl
Sulphates as SO ₄	Conforms				200 ppm (max)
Phosphate as PO ₄	Conforms				25 ppm (max)
Bromides as Br	Conforms				100 ppm (max)
lodides		Conforms			Conforms
Ferrocyanides	Conforms				Conforms
Iron as Fe		Conforms			2 ppm (max)
Barium		Conforms			Conforms
Magnesium & Alkaline-earth metals	0.2	1		(NMT 2.5ml 0.01M EDTA
wagnesium & Alkaime-earth metals	0.2	-	ml	(max)	(100 ppm max calculated as Ca)
Arsenic as As ₂ O ₃	Conforms				2 ppm (max)
Loss on Drying (at packing)	0.07 %w/w (max)		/w (max)	0.5% ^w / _w (max)	
Assay as NaCl	99.86				99.0-100.5% ^w / _w
ADDITIONAL ANALYSIS	AC	ACTUAL RANGE			< = Less Than
Filtration Rate (Minimum after 2 litres	Minimum	429	r	nl/min	NMT = Not more than
of 20.15% w/v brine solution)	Maximum	Maximum 546 ml/min		nl/min	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 restest 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 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. Storage Conditions: Store unopenend in clean, dry conditions

Conforms to Specification:	Release Date: Approved by:	/	
For Distribution use only:			



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MICROBIOLOGICAL BATCH ANALYSIS CERTIFICATE

PRODUCT TYPE: Pharmaceutical Sodium Chloride

CAS No.: 7647-14-5

BATCH/MFD¹: 20112024

REPORT NO: 31540

DATE PACKED: 20-27/11/2024 **RETEST² DATE:** 20/11/2029

PAGE: 1 of 1

RESULTS

TESTS PERFORMED (Methods as per Pharmacopoeia)	RESULT	SPECIFICATION <5 EU/g	
Bacterial Endotoxins (Pyrogen)	<1.00 EU/g		
Microbial limit test:			
Total aerobic count	<10 CFU/g	not more than 100 CFU/g	
Yeasts and Moulds	<1 CFU/g	not more than 100 CFU/g	
Heat Resistant Microbes(@ 80°C for 10 mins)	ND Not detected/g	Not detected/g	
Pathogenic Organisms:			
Escherichia Coli	ND Not detected/g	Not detected/g	
Staphylacoccus aureus	ND Not detected/g	Not detected/g	
Pseudomonas aeruginosa	ND Not detected/g	Not detected/g	
Salmonetla spp.	ND Not detected/100g	Not detected/100g	

ND = Not Detected or Absent

- 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.

Release Date: 06.12.24

- 3. All the above tests have been performed by laboratories contracted to Dominion Salt Mount Maunganui site (Original reports are available upon written request to the Quality Manager).
- 4. The samples have been collected and analysed in accordance with our documented sample plan.
- 5. < = less than > = greater than
- 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.

Conforms to Specification:GM	Approved by: Eliska Veckova QHSE Officer
For Distribution use only:	