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]: 20112024

REPORT NO: **31537**
DATE PACKED: 20-27/11/2024
RETEST[2] DATE: 20/11/2029
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	0.25	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	0.2	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	%w/w	(max)	0.5% $^{w}/_{w}$ (max)
Bacterial endotoxins	<1.00	EU/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 manufacture of Pharmaceutical Sodium Chloride			

ADDITIONAL ANALYSIS	**ACTUAL RANGE**		
Filtration Rate (Minimum after 2 litres of 20.15% w/v brine sclution)	Minimum	429	ml/min
	Maximum	546	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: GM

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 - 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
BATCH/MFD[1]: 20112024

REPORT NO: **31538**
DATE PACKED: 20-27/11/2024
RETEST[2] DATE: 20/11/2029
PAGE: 1 of 1

RESULTS

Tests Performed *(Methods as per Pharmacopoeia)*	RESULT			USP-NF 2023 Issue 3 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	0.25	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	0.2	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	%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 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	429	ml/min
	Maximum	546	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: GM

Release Date: 06.12.24

Approved by: _____
Eliska Veckova
QHSE Officer

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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/MFD[1]: 20112024

REPORT NO: **31539**
DATE PACKED: 20-27/11/2024
RETEST[2] DATE: 20/11/2029

PAGE: 1 of 1

RESULTS

Tests Performed *(Methods as per Pharmacopoeia)*	**RESULT**			**JP18th edition XVIII/2021 SPECIFICATION**
Appearance	Conforms			White or almost white, crystalline powder
Appearance of Solution	Conforms			Clear and Colourless
Sodium Identification	Conforms			Conforms
Chlorides Identification	Conforms			Conforms
Acidity	0.00	ml	(max)	NMT 0.5ml 0.01M NaOH
Alkalinity	0.25	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)
Iodides	Conforms			Conforms
Ferrocyanides	Conforms			Conforms
Iron *as Fe*	Conforms			2 ppm (max)
Barium	Conforms			Conforms
Magnesium & Alkaline-earth metals	0.2	ml	(max)	NMT 2.5ml 0.01M EDTA *(100 ppm max calculated as Ca)*
Arsenic *as* As_2O_3	Conforms			2 ppm (max)
Loss on Drying (at packing)	0.07	%w/w (max)		0.5% $^{w}/_{w}$ (max)
Assay *as NaCl*	99.86			99.0-100.5% $^{w}/_{w}$

ADDITIONAL ANALYSIS	**ACTUAL RANGE**		
Filtration Rate (Minimum after 2 litres of 20.15% w/v brine solution)	Minimum	429	ml/min
	Maximum	546	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 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.
8. Storage Conditions: Store unopenend in clean, dry conditions

Conforms to Specification: GM

Release Date: 06.12.24

Approved by: _____
Eliska Veckova
QHSE Officer

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MICROBIOLOGICAL BATCH ANALYSIS CERTIFICATE

PRODUCT TYPE: Pharmaceutical Sodium Chloride
CAS No.: 7647-14-5

BATCH/MFD[1]: 20112024

REPORT NO: **31540**
DATE PACKED: 20-27/11/2024
RETEST[2] DATE: 20/11/2029
PAGE: 1 of 1

RESULTS

TESTS PERFORMED *(Methods as per Pharmacopoeia)*	RESULT	SPECIFICATION
Bacterial Endotoxins (Pyrogen)	<1.00 EU/g	<5 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
Salmonella 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.
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
6. 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.

Release Date: 06.12.24

Conforms to Specification: GM

Approved by:
Eliska Veckova
QHSE Officer

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