Dominion Salt Limited

Head Office & N.I. 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
CAS No.: 7647-14-5
Molecular formula: NaCl
Molecular Weight: 58.44
BATCH/MFD[1]: 27042023

REPORT NO: **29853**
DATE PACKED: 27/04-06/05/23
RETEST[2] DATE: 27/04/2028

PAGE: 1 of 1

RESULTS

Tests Performed *(Methods as per Pharmacopoeia)*	RESULT			BP 2022/Ph Eur 10.0 (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*	6	ppm	(max)	500 ppm (max)
Heavy Metals *as Pb*	Conforms			5 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*	99.99			99.0-100.5% $^{w}/_{w}$
Residual Solvents	No class 1, 2 or 3 solvents are used in the manufacture of Pharmaceutical Sodium Chloride			

< = Less Than
NMT = Not more than

ADDITIONAL ANALYSIS	ACTUAL RANGE
Filtration Rate (Minimum after 2 litres of 20.15% w/v brine solution)	Minimum 308 ml/min Maximum 429

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: 18.05.23
Approved by:
Glen Matthews
Quality Manager

For Distribution use only:

ORIGINAL

Issue No.: 24

DominionSalt Limited

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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]: 27042023

REPORT NO: **29854**
DATE PACKED: 27/04-06/05/23
RETEST[2] DATE: 27/04/2028

PAGE: 1 of 1

RESULTS

Tests Performed *(Methods as per Pharmacopoeia)*	RESULT			USP-NF 2022 Issue 1 SPECIFICATION
Appearance	Conforms			White or almost white, crystalline powder
Chlorides Identification	Conforms			Conforms
Sodium Identification	Conforms			Conforms
Aluminium *as Al*	Conforms			0.2 ug/g (max)
Arsenic *as As*	Conforms			1 ug/g (max)
Barium	Conforms			Conforms
Ferrocyanides	Conforms			Conforms
Iodides	Conforms			Conforms
Iron *as Fe*	Conforms			2 ug/g (max)
Bromides *as Br^-*	Conforms			0.010 % (max)
Phosphate *as PO_4*	Conforms			0.0025 % (max)
Potassium *as K*	0.0006	%	(max)	0.05 % (max)
Magnesium & Alkaline-earth metals	0.3	ml	(max)	NMT 2.5ml 0.01M EDTA *(0.01 % max calculated as Ca)*
Nitrites	Conforms			Conforms
Sulphates *SO_4*	Conforms			0.020 % (max)
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
Heavy Metals *as Pb*	Conforms			5 ppm as Pb (max)
Loss on Drying (at packing)	0.00	%w/w (max)		NMT 0.5% $^{w}/_{w}$ (max)
Assay *as NaCl*	99.99			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	308	ml/min
	Maximum	429	

< = 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 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: _____

Release Date: 18.05.23
Approved by: _____
Glen Matthews
Quality Manager

For Distribution use only:

ORIGINAL

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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]: 27042023

REPORT NO: **29855**
DATE PACKED: 27/04-06/05/23
RETEST[2] DATE: 27/04/2028

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	0.20	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
Heavy Metals *as Pb*	Conforms			3 ppm (max)
Iron *as Fe*	Conforms			2 ppm (max)
Barium	Conforms			Conforms
Magnesium & Alkaline-earth metals	0.3	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*	99.99			99.0-100.5% $^{w}/_{w}$

ADDITIONAL ANALYSIS	ACTUAL RANGE		
Filtration Rate (Minimum after 2 litres of 20.15% w/v brine solution)	Minimum	308	ml/min
	Maximum	429	

< = Less Than
NMT = Not more than

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 APIs, 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 unopened in clean, dry conditions

Conforms to Specification: _____

Release Date: 18.05.23

Approved by: _____
Glen Matthews
Quality Manager

For Distribution use only:

ORIGINAL

Issue No.: 7

DominionSalt Limited

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MICROBIOLOGICAL BATCH ANALYSIS CERTIFICATE

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

BATCH/MFD[1]: 27042023

REPORT NO: **29856**
DATE PACKED: 27/04-06/05/23
RETEST[2] DATE: 27/04/2028
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 APIs, 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: 18.05.23

Conforms to Specification: Meagat

Approved by:
Glen Matthews
Quality Manager

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