Dominion Salt Limited

Head Office & N.I. Refinery
89 Totara Street, Mount Maunganui 3116, New Zealand
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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]: 16112022

REPORT NO: **29288**
DATE PACKED: 16/11-19/11/22
RETEST[2] DATE: 16/11/2027
PAGE: 1 of 1

RESULTS

Tests Performed *(Methods as per Pharmacopoeia)*	**RESULT**	**BP:2021/Ph Eur 0193 SPECIFICATION**
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
Colourless White Crystalline Powder	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*	8 ppm (max)	500 ppm (max)
Heavy Metals *as Pb*	Conforms	5 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*	99.67	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 333

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 PE007-2 for API's, states a retest date in lieu of an expiry date .
3. This product has been produced at Dominion Salt's N.I. Refinery
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 Works Chemist.
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

Release Date: 05.12.22

Conforms to Specification: _____

Approved by: _____
Eliska Veckova
QHSE Officer

For Distribution use only:

Dominion Salt 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]: 16112022

REPORT NO: **29289**
DATE PACKED: 16/11-19/11/22
RETEST[2] DATE: 16/11/2027
PAGE: 1 of 1

RESULTS

Tests Performed *(Methods as per Pharmacopoeia)*	**RESULT**	**USP-NF 2021 Issue 1 SPECIFICATION**
Appearance of Solution	Conforms	Clear and Colourless
Chlorides Identification	Conforms	Conforms
Sodium 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
Loss on Drying (at packing)	0.02 %w/w (max)	0.5% $^{w}/_{w}$ (max)
Iodides	Conforms	Conforms
Aluminium *as Al*	Conforms	0.2 ug/g (max)
Magnesium & Alkaline-earth metals	0.2 ml (max)	NMT 2.5ml 0.01M EDTA *(0.01 % max calculated as Ca)*
Arsenic *as As*	Conforms	1 ug/g (max)
Barium	Conforms	Conforms
Colourless White Crystalline Powder	Conforms	Conforms
Ferrocyanides	Conforms	Conforms
Sulphates SO_4	Conforms	0.020 % (max)
Iron *as Fe*	Conforms	2 ug/g (max)
Nitrites	Conforms	Conforms
Heavy Metals *as Pb*	Conforms	5 ppm as Pb (max)
Bromides *as Br*	Conforms	0.010 % (max)
Phosphate *as* PO_4	Conforms	0.0025 % (max)
Potassium *as K*	0.0008 % (max)	0.05 % (max)
Assay *as NaCl*	99.67	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 333

< = 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 PE007-2 for API's, states a retest date in lieu of an expiry date .
3. This product has been produced at Dominion Salt's N.I. Refinery
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 siteLaboratory. Methods are documented in the Laboratory's Test Method Manual and will be made available upon request in writing to the Works Chemist.
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: 05.12.22
Approved by: _____
Eliska Veckova
QHSE Officer

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Website: www.domsalt.co.nz

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]: 16112022

REPORT NO: **29290**
DATE PACKED: 16/11-19/11/22
RETEST[2] DATE: 16/11/2027
PAGE: 1 of 1

RESULTS

Tests Performed *(Methods as per Pharmacopoeia)*	**RESULT**	**JP XVIII /2021 SPECIFICATION**
Sodium Identification	Conforms	Conforms
Chlorides 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
Sulphates *as* SO_4	Conforms	200 ppm (max)
Phosphate *as* PO_4	Conforms	25 ppm (max)
Bromides *as Br*	Conforms	100 ppm (max)
Colourless White Crystalline Powder	Conforms	Conforms
Ferrocyanides	Conforms	Conforms
Iodides	Conforms	Conforms
Heavy Metals *as Pb*	Conforms	3 ppm (max)
Iron *as Fe*	Conforms	2 ppm (max)
Barium	Conforms	Conforms
Magnesium & Alkaline-earth metals	0.2 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)	0.02 %w/w (max)	0.5% $^{w}/_{w}$ (max)
Assay *as NaCl*	99.67	99.0-100.5% $^{w}/_{w}$

< = 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 333

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 PE007-2 for API's, states a restest date in lieu of an expiry date .
3. This product has been produced at Dominion Salt's N.I. Refinery
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 Works Chemist.
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

Release Date: 05.12.22

Conforms to Specification: Mengat

Approved by: _____
Eliska Veckova
QHSE Officer

For Distribution use only:

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MICROBIOLOGICAL BATCH ANALYSIS CERTIFICATE

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

BATCH/MFD[1]: 16112022

REPORT NO: **29291**
DATE PACKED: 16/11-19/11/22
RETEST[2] DATE: 16/11/2027
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 PE007-2 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 N.I. Ltd. (Original reports are available upon written request to the Works Chemist).
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: 05.12.22

Conforms to Specification: _____

Approved by: _____
Eliska Veckova
QHSE Officer

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