

Todo Droga
Química Mayorista

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

Dosage Form: 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: 20826

CAS No.: 7647-14-5

DATE PACKED: 23-30.08.2017

Molecular formula: NaCl

Molecular Weight: 58.44

RETEST² DATE: 23.08.2022

BATCH/MFD¹: 23082017

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RESULTS

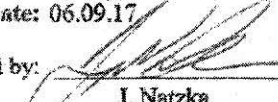
Tests Performed (Methods as per Pharmacopoeia)	RESULT	USP 39/2016 SPECIFICATION
Appearance of Solution	Conforms	Clear and Colourless
Chlorides Identification	Conforms	Conforms
Sodium Identification	Conforms	Conforms
Acidity	0.00 ml (max)	NMT 0.5ml 0.01M NaOH
Alkalinity	0.30 ml (max)	NMT 0.5ml 0.01M HCl
Loss on Drying (at packing)	0.08 %w/w (max)	0.5% w/w (max)
Iodides	Conforms	Conforms
Aluminium as Al	Conforms	0.2 ug/g (max)
Magnesium & Alkaline-earth metals	0.1 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
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	0.0012 % (max)	0.05 % (max)
Assay as NaCl	99.81	99.0-100.5% w/w

< = Less Than
NMT = Not more than
u = micron

ADDITIONAL ANALYSIS	ACTUAL RANGE
Filtration Rate (Minimum after 2 litres of 20.15% w/v brine solution)	Minimum 360 ml/min Maximum 375

- 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 APIs, 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 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

Conforms to Specification: 

Release Date: 06.09.17
Approved by: 
J. Natzka
QC Lab. Supervisor

For Distribution use only: **ORIGINAL**