



Hefei TNJ Chemical Industry Co.,Ltd.

### Certificate of Analysis

Product Name	Procaine hydrochloride	Version	English
CAS Number	51-05-8	Report Code	T1718122922-1
Lot Number	20181249	Manuf. Date	2018/12/19
Lot Quantity	1000.000kg	Test Date	2018/12/19
Net Weight	25.000kg/Fiber drum	Expiry Date	2022/12/18
Gross Weight	27.500kg/Fiber drum	Workshop	
Test Standard	EP8.0/USP39		

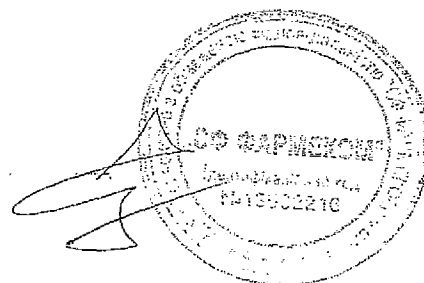
Item	Standard	Results
Identification	A, B, E, It appears positive reaction	conform
Sulphated ash,%	$\leq 0.1$	0.06
Melting point, <sup>°C</sup>	154~158	154.5~155.5
Heavy metals,%	$\leq 0.0005$	conform
Loss on drying,%	$\leq 0.5$	0.09
Assay (on dry basis),%	99.0~101.0	99.7
Appearance of solution	Clear and colorless	conform
Related substances, %	$\leq 0.05$	conform
Appearance	A white crystalline powder or White crystals	conform
PH	5.0~6.5	5.7

Conclusion: Product complies with EP8.0/USP39

The above-mentioned data shall constitute the agreed contractual product quality, are also controlled as part of our quality assurance program. These data implies no legally binding guarantee of certain properties or of fitness for any specific purpose.

Reporter Liu Li

Approver of COA release Du Xuewu





SALINEN AUSTRIA

CERTIFICATE OF ANALYSIS

Laboratory: Salinen Austria AG

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"PHARMASAL" – Chemically Pure Salt  
Sodium Chloride for pharmaceutical use, Natrii chloridum  
according to European Pharmacopoeia, BP, USP, JP

Lot number: CR5010419  
Retest date: 01.04.2022  
Production date: 01.04.2019 - 06.04.2019

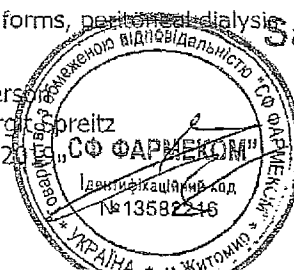
		Specification	Unit	Result	Unit
Identification	Na+	positive		conforms	-
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,5 - 100,5	%	99,97	%
Bromides	Br-	<= 100	ppm	<= 100	ppm
Iodides	I-	<= 10	ppm	<= 10	ppm
				conforms Ph. Eur	
Sulfate	SO4 2-	<= 200	ppm	<= 200	ppm
Phosphate	PO4 3-	<= 25	ppm	<= 25	ppm
Nitrite	NO2-	<= 0,01	abs.	<= 0,01	abs.
Heavy metals	as Pb	<= 3	ppm	<= 3	ppm
Iron	Fe	<= 2	ppm	<= 2	ppm
Aluminium	Al	<= 0,2	ppm	<= 0,2	ppm
Arsenic	As	<= 1	ppm	<= 1	ppm
Potassium	K	<= 500	ppm	<= 500	ppm
Barium	Ba	<= 10	ppm	<= 10	ppm
				conforms Ph. Eur	
Magnesium & alkaline-earth metals	calc. as Ca	<= 100	ppm	<= 100	ppm
Ferrocyanides	[Fe(CN)6]4-	conforms	-	conforms	-
Insoluble matters		<= 50	ppm	<= 50	ppm
Loss on drying		<= 0,5	%	<= 0,5	%
Appearance of solution		clear, colourless		conforms	-
Acidity or Alkalinity according to the regulations		conforms		conforms	-
Residual Solvents according ICH-guideline		Impossible due to production process		conforms	-
Bacterial Endotoxins		< 5	I.U./g	< 5	I.U./g
TAMC		<= 10	CFU/g	<= 10	CFU/g
TYMC		<= 10	CFU/g	<= 10	CFU/g

This lot conforms with the current Ph. Eur, USP, BP and JP monographs. In compliance with the guidelines on good manufacturing practice for active pharmaceutical ingredients (ICH Q7).  
Store in a clean and dry place, nmt. 70% rel. Humidity.

It is suitable for the use in the manufacture of injectable dosage forms, peritoneal dialysis solutions, hemodialysis solutions and hemofiltration solutions.

*Birgit Spreitz*  
19.04.2019

Qualified Person  
Dipl.-Ing. Birgit Spreitz  
Date: 19.04.2019



Salinen Austria AG

Labor

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**Certificate of quality**

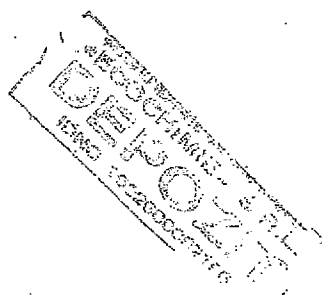
Product name:	Potassium permanganate		
Supplier's batch No:	494101	Specification No:	ST-IXO 3647-1/2003
Manufacture date:	01-01-2019	Producer's batch No:	1309-2-3053
Expiry date:	01-01-2023	Country origin:	US

Buyer: **ECOCHEMIE SRL**  
Valea Crucii 2/85, 2062 Chisinau  
Customer number : 48263

Parameter:	According to specification:	Result:
Potassium permanganate content, %(m/m)	$\geq 98,5$	98,9
Water insoluble matter, %(m/m)	$\leq 1,0$	0,1

This product is not food, feed or pharmaceutical grade. Therefore, this product can neither be used as ingredient/additive in the manufacturing of food, feed or pharmaceutical products. The use of the product is in the responsibility of the purchaser.

We confirm that the product meets the requirements specified in this technical data sheet.



This document has been prepared on the basis of producer's certificate of quality.

Please refer to the supplier's lot number when you comment on quality of supplied product.  
Typical value does not constitute technical specification limits and can not be the reason to complain.  
Any information contained herein is based on our current knowledge and does not release the customer from undertaking his own examination.



This document has been generated by computer system Diferros and it is valid without a signature.  
Conforming to PN-EN 10204-3.1.B standard

Responsible person - Violetta Pańcził, Phone: +48 77 4721 530

**DIFERROS**



# G. AMPHRAY LABORATORIES

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## CERTIFICATE OF ANALYSIS

Name of Product : POTASSIUM IODIDE BP  
Batch No. : P-093/19 Q.C. No. : G-19/0419  
Date of Manufacture : Apr-2019 GAS No. : 7681-11-0  
Date of Expiry : Mar-2024 Batch Size : 1100 Kg

TESTS	LIMITS	RESULTS
Appearance	White or almost white powder or colourless crystals.	A White Crystalline Powder
Solubility	Very soluble in water, freely soluble in glycerol, soluble in ethanol (96%).	Complies
Identification	Test (A) : Gives reactions of Iodides Test (B) : Gives reactions of Potassium	Complies Complies
Appearance of Solution	A 10% w/v solution in carbon dioxide free water is clear and colorless	Complies
Alkalinity	Not more than 0.5 ml of 0.01 M HCl	0.12 ml of 0.01 M HCl
Iodate	No blue colour develops	Complies
Sulfates	Maximum 150 ppm	Complies
Thiosulfates	A blue colour is produced	Complies
Iron	Maximum 20 ppm	Complies
Heavy Metals	Maximum 10 ppm	Complies
Loss on drying	Maximum 1.0 %	0.32%
Assay (on dried basis)	Between 99.0 % to 100.5 % of KI	99.3%

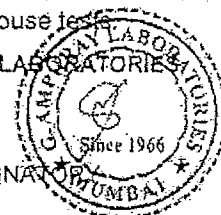
### Additional In-house Tests

Particle Size	Mesh Size -16	100% Passing Through
Bulk Density after 50 Tapped	For Information	1.53 g/ml
Storage Condition	Store in a dry place and protect from Heat, Moisture, Light, Dust and other contaminations.	

REMARK : The batch complies with respect to the above mentioned BP 2016 & In-house tests.

For G. AMPHRAY LABORATORIES

AUTHORISED SIGNATURE



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## CERTIFICATE OF ANALYSIS

Name of Product :	IODINE	Q.C. No. :	G-19/0644
Batch No. :	I-061/19	CAS No. :	7553-56-2
Date of Manufacture :	Jul-2019	Batch Size :	900 Kg
Date of Expiry :	NA		

TESTS	LIMITS	RESULTS
Description	A greyish violet, brittle plates or fine crystals with a metallic sheen, odour irritant. It volatilises slowly at room temperature.	A Greyish-violet prilled crystals with metallic sheen, irritant odour.
Solubility	Very slight soluble in water, Very soluble in concentrated solution of Iodides, Soluble in ethanol (96%), Slightly soluble in Glycerol.	Complies
Identification	Test (A) When heated gently it gives violet vapours which condense forming a bluish-black crystalline sublimate.	Complies
	Test (B) A saturated solution yield a blue colour in the presence of starch solution which disappears when the solution is heated & reappears when its cool	Complies
Limit of non volatile residue	Not more than 0.05%	0.04%
Limit of Bromide & Chlorides	Meets the requirement	Complies
Sulphate	Maximum 150 ppm	Complies
Heavy Metal	Not more than 10 ppm	Complies
Assay	Not less than 99.5 %	99.8%

REMARK : The batch complies with respect to the above mentioned In-house tests.

For G. AMPHRAY LABORATORIES

AUTHORISED SIGNATORY

