

## ZHEJIANG HAISEN PHARMACEUTICAL CO., LTD.

## 浙江海森药业股份有限公司

## Certificate of Analysis/检验报告书

Product Name 产品名称	Metamizole Sodium Monohydrate (Metamizole Sodium, Analgin) 安乃近		
Batch Number 批号	2125040237	Quantity 数量	1000Kg
Mfg Site 生产场地	10-1	Packing Specification 规格	25Kg/drum
Mfg Date 生产日期	2025.04.07	Retest Date 复验期	2028.04.06
Certificate No. 报告编号	2125040237R2	Report Date 报告日期	2025.04.18
Storage condition 储存条件	Protected from light 遮光保存		
<b>Contents</b>	<b>Specification: CEP(R1-CEP 2004-016-Rev 03) (SOP.7.1.073)</b>	<b>Results of analysis</b>	
	<b>+Customer's Requirement</b>		
<b>项目</b>	<b>标准: CEP(R1-CEP 2004-016-Rev 03) (SOP.7.1.073) +客户要求</b>	<b>检验结果</b>	
Appearance 性状	White or almost white crystalline powder 白色或类白色结晶性粉末	Almost white crystalline powder 类白色结晶性粉末	
Solubility 溶解性	Very soluble in water, slightly soluble in ethanol (96 percent), practically insoluble in methylene chloride	Conform 符合	
Identification 鉴别	(1) Comparing with the spectrum obtained with CRS 红外光吸收图谱应与对照品图谱相一致	Conform 符合	
	(2) Positive 呈正反应	Conform 符合	
	(3) Positive 呈正反应	Conform 符合	
	(4) Reaction of sodium 钠盐反应	Conform 符合	
Appearance of solution 溶液性状	Meets the requirements 符合规定	Conform 符合	
Acidity or alkalinity 酸碱度	Meets the requirements 符合规定	Conform 符合	
Related substances 有关物质	(1) Impurity C: not more than 0.5% 杂质 C: 不得超过 0.5%	<0.03%	
	(2) Impurity E: not more than 0.15% 杂质 E: 不得超过 0.15%	0.04%	
	(3) Unspecified impurities: for each impurity, not more than 0.05% 未指定杂质: 均不得超过 0.05%	0.03%	
	(4) Total impurities: not more than 0.5% 总杂质: 不得超过 0.5%	0.1%	
Sulfates 硫酸盐	≤0.1%	<0.1%	
Loss on drying 干燥失重	4.9%~5.3%	5.1%	
Assay(dried substance) 含量(以干品计)	99.0%~101.0%	99.2%	
Residual Solvents (GC) 残留溶剂	(1) Methanol: not more than 0.3% 甲醇: 不得过 0.3%	Not detected 未检出	
	(2) Ethanol: not more than 0.5% 乙醇: 不得过 0.5%	0.01%	
Microbial limit 微生物限度	(1) TAMC≤10 <sup>3</sup> cfu/g 需氧菌总数≤10 <sup>3</sup> cfu/g	<1×10 <sup>2</sup> cfu/g	
	(2) TYMC≤10 <sup>2</sup> cfu/g 霉菌、酵母菌总数≤10 <sup>2</sup> cfu/g	<1×10 <sup>1</sup> cfu/g	
	(3) E.Coli: Not detectable 大肠埃希菌: 不得检出	Not detected 未检出	
Endotoxin 细菌内毒素	≤0.14EU/mg	<0.14EU/mg	
<b>Conclusion: Conforming to CEP(R1-CEP 2004-016-Rev 03)+Customer's Requirement.</b>			
<b>结论: 符合 CEP(R1-CEP 2004-016-Rev 03)+客户要求。</b>			

DIRECTOR OF QC DEPT (负责人) CHECKER (复核人)

CAI YUEJUN (蔡跃军)

浙江海森药业股份有限公司  
ZHEJIANG HAISEN PHARMACEUTICAL CO., LTD.

REPORTER (报告人)

FANG KAIKAI (方凯凯)

第 1 页 共 1 页

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Add: Xiangtan Village, Liushi Street, Dongyang City, Zhejiang Province 322104, China. Tel: 86-579-86773108

地址: 浙江省东阳市六石街道香潭村, 邮编: 322104, 电话: 0579-86773108



**CERTIFICATE OF ANALYSIS**

Product Name :	PAPAVERINE HYDROCHLORIDE BP/Ph.Eur.	Report Date :	21.06.2025
Batch / Lot No. :	64020525	Mfg. Date :	23.04.2025
Quantity :	10.00 Kg	Expiry/Retest Date :	22.04.2030

Test Parameter	Specification	Result	
<b>CHARACTERS</b>			
Appearance	White or almost white, crystalline powder or white or almost white crystals.	White Crystalline Powder, Complies	
Solubility			
In water	Sparingly soluble in water.	Complies	
In Ethanol (96%)	Slightly soluble in Ethanol (96%).	Complies	
<b>IDENTIFICATION</b>			
A. Infrared absorption Spectrophotometry	Sample spectrum should be concordant with the spectrum of Papaverine HCl Working Standard.	Complies	
B. Thin-layer chromatography	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.	Complies	
C. Melting point (°C)	Between 146°C and 149°C	147.8°C, Complies	
D. Reaction of chlorides	A curdled, white precipitate is formed.	Complies	
<b>TESTS</b>			
Appearance of solution	Solution S is clear and not more intensely colored than reference solution BY <sub>6</sub> .	Complies	
pH	Between 3.0 and 4.0.	3.43, Complies	
Related substances by Liquid chromatography (% w/w)	Impurity-A	Not more than 0.1 %.	*ND, Complies
	Impurity-B	Not more than 0.1 %.	*ND, Complies
	Impurity-C	Not more than 0.1 %.	*ND, Complies
	Impurity-D	Not more than 0.1 %.	*ND, Complies
	Impurity-E	Not more than 0.1 %.	*ND, Complies
	Impurity-F	Not more than 0.1 %.	*ND, Complies
	Any unknown impurity	Not more than 0.1 %.	*BDL, Complies
	Total Impurities	Not more than 0.5 %.	*BDL, Complies
Loss on drying (% w/w)	Maximum 0.5 %.	0.16%, Complies	
Sulphated ash (% w/w)	Maximum 0.1 %.	0.02%, Complies	
Assay (% w/w)	Between 99.0 % and 101.0 % (dried substance).	100.0%, Complies	



**CERTIFICATE OF ANALYSIS**

Product Name :	PAPAVERINE HYDROCHLORIDE BP/Ph.Eur.	Report Date :	21.06.2025
Batch / Lot No. :	64020525	Mfg. Date :	23.04.2025
Quantity :	10.00 Kg	Expiry/Retest Date :	22.04.2030

Test Parameter	Specification		Result
<b>ADDITIONAL TESTS</b>			
Residual solvents (by GC-HS)	Chloroform	Not more than 60 ppm.	*BQL, Complies
	Toluene	Not more than 100 ppm.	10 ppm, Complies
	Mesitylene	Not more than 70 ppm.	*BQL, Complies
Microbial analysis	Total bacterial count	Not more than 100 cfu/gm	20 cfu/gm, Complies
	Total yeast/ Mould count	Not more than 10 cfu/gm	<10 cfu/gm, Complies
	Pathogens		
	Escherichia Coli	Should be absent	Absent, Complies
	Salmonellae	Should be absent	Absent, Complies
	Pseudomonas aeruginosa	Should be absent	Absent, Complies
Staphylococcus aureus	Should be absent	Absent, Complies	
Bacterial Endotoxin	Not more than 2.5 EU/mg		Less than 2.5 EU/mg, Complies

**STORAGE:** Preserve Papaverine Hydrochloride in a well-closed containers and protected from light.

**REMARKS:** The above batch ~~complies/does not comply~~ with the prescribed standards of quality as described above.

**For HSGC:**

\*LOQ: Limit of Quantification

\*BQL: Below Quantification Limit

**For HPLC:**

\*BQL: Below Quantification limit: 0.05 %

\*ND: Not Detected

\*BDL: Below detection limit

Name of the Solvent	LOQ Value
Mesitylene :	2 ppm
Chloroform :	7 ppm
Toluene :	3 ppm



Prepared by : KB  
Date : 08/07/25

Reviewed by :  
Date : 08/07/25

Approved by: Rani  
Date : 08/07/25



## Epsom Salt

chemically pure, FCC

B.M.P. Bulk Medicines &  
Pharmaceuticals GmbH  
PO Box 11 48  
D-22801 Norderstedt

2021-06-04  
Werk Werra, Standort HA  
Rene Schaub  
Quality Control

☎ 06620/791377  
✉ rene.schaub@k-plus-s.com  
Page 1/1

Manufacturer:	K+S Minerals and Agriculture GmbH	K+S Batch No.:	2121000065
K+S Order No.:	7100147430	Manufact. Date:	2021-05-27
Delivery /-Item No.:	7200340538 / 000010	Date of minimum	
Quantity:	24 TO	durability:	2026-05-27
Loading date:	2021-06-02	K+S Specification:	74961 359-2 (S02)
Cust. Order No.:	37170		

### General information:

Manufacturer's address: Bertha-von-Suttner-Str. 7, 34131 Kassel, Germany  
Manufacturing site's address: Hattorfer Str., 36269 Philippsthal, Germany

Chemical Name: Magnesium Sulphate Heptahydrate

Characters: colorless crystal or a granular crystalline powder

Solubility: readily soluble in water, slowly soluble in glycerine, and sparingly soluble in alcohol

Parameter	Method of Analysis	Result	Specification
Assay (Dried Basis)	calculated	99.8 %	>= 99.5 %
Loss on Ignition	gravimetry	50.8 %	40.0 .. 52.0 %
Identity Reaction	ICP - AES	corresponds	o.K.
Lead *)	DIN EN ISO 17294-2 (MgSO <sub>4</sub> )	<4 mg/kg	<= 4 mg/kg
Selenium *)	DIN EN ISO 17294-2 (MgSO <sub>4</sub> )	<30 mg/kg	<= 30 mg/kg
Magnesium Sulphate	calculated	49.1 %	%
Sodium	ICP - AES	0.001 %	%
Potassium	ICP - AES	0.037 %	%
Calcium	ICP - AES	0.001 %	%
Chloride	volumetry	0.003 %	%

\*) not tested on each batch

Electronically released by Rene Schaub on 2021-06-02

This certificate does not relieve the purchaser from examining the product upon delivery and gives no assurance of suitability of the product for any particular purpose.



Inspection certificate  
DIN EN 10204, 3.1 (January 2005)  
(German version EN 10204 : 2004)

Hansen & Rosenthal GmbH & Co. KG, Am Sandtorkai 64, D-20457 Hamburg

SC ASTRON Chemicals srl  
Sos. Dudesti-Pantelimon 19, Sector 3  
RO-033091 Bucharest  
Fax: +40 212551723

Date: 2024-10-25

Product name : PIONIER 2901  
White Petroleum Jelly  
PH.EUR./USP  
Batch number : 1612804  
Order No. : 41264948  
Order No. / Date : 2024/03-H&R / 04/10/24  
Qty - net weight : 32 piece(s)/5440 kg  
Manufacture date : 2024-09  
Retest date : 2027-09

Date of delivery: 2024-10-28



Test	Method	Issue	Unit	Analysis
Kin. Viscosity 100 °C	DIN EN ISO 3104	2024-04	mm <sup>2</sup> /s	6.905
Cone Penetration 25 °C	DIN 51580	2008-06	mm/10	166
Drop Point	ASTM D 3954	2015-01	°C	58.6
Purity	Latest Edition USP/NF			conform
Purity	Latest Edition Ph. Eur.			conform
Testing of identity	Latest Edition Ph. Eur.			conform
Drop Point	Ph. Eur. 2.2.17		°C	56.1
Appearance/aspect	Latest Edition Ph. Eur.			conform
Acidity or alkalinity	Latest Edition Ph. Eur.			conform
Cone Penetration 25 °C	Ph. Eur. 2.9.9		mm/10	166
Polycyclic aromatic hydrocarbons	Latest Edition Ph. Eur.			conform
Sulfated ash	Ph. Eur. 2.4.14		Mass.-%	< 0.05

Issued by Herr Baumgart, Tel.: 040/781108-603

Complying with Ph.Eur. latest edition means meeting the Ph.Eur. 11

This certificate has been issued by EDP and is not to be signed.

This data do not release you from the entry control. These data are no binding warranty for the qualification of the product for a certain purpose.

The results printed above are related to the sample object only. Reprinting, even abstractly, is prohibited.

The sampling was based on the DIN EN ISO 3170.



## CERTIFICATO DI ANALISI - CERTIFICATE OF ANALYSIS

### Etichetta

<b>Prodotto - Product 002453 ZINCO OSSIDO - ZINC OXIDE</b>		
<b>Conformità - Compliance</b>	EP	
<b>Lotto - Batch Number</b>	2102106	
<b>Produttore - Manufacturer</b>	Farmalabor Srl, Via Moscatello Z.I., 76012 Canosa di Puglia (BT), Italia	
<b>Materia prima - Raw material</b>	QUALITY CHEMICALS - Spagna , Fornal,35-Pol.Ind.Can Comelles Sud, Apdo.de Correos 184 Esparreguera	
<b>Data di produzione - Manufacturing date:</b>	<b>25/03/2025</b>	<b>Data rititolazione - Retest date: 25/09/2027</b>
		<b>Data di analisi - Analysis date: 17/04/2025</b>

NUMERO CAS	1314-13-2	CAS NUMBER	1314-13-2
FORMULA MOLECOLARE	ZnO	MOLECULAR FORMULA	1314-13-2
PESO MOLECOLARE	81,4	MOLECULAR WEIGHT	81,4
ASPETTO	Polvere amorfa, soffice, bianca o leggermente	APPEARANCE	Soft, white or faintly yellowish-white, amorphous powder
PUNTO DI FUSIONE	Ca. 120°C	MELTING POINT	About 120°C
SOLUBILITA'	Praticamente insolubile in acqua Praticamente insolubile in etanolo (96%) Si scioglie in acidi minerali diluit	SOLUBILITY	Practically insoluble in water Practically insoluble in ethanol (96%) It dissolves in dilute mineral acids
GRANULOMETRIA	La dimensione della maggior parte delle particelle non è superiore a 20 micron e quella di quasi tutte le particelle non è superiore a 40 micron	PARTICLE SIZE	The size of most of the particles is not greater than 20 micron and that of almost all the particles in not greater than 40 microm

ANALISI MATERIA PRIMA	SPECIFICHE	RISULTATI	RAW MATERIAL ANALYSIS	SPECIFICATIONS	RESULTS
<b>PH.EUR. IDENTIFICAZIONE</b>	Conforme	Conforme	<b>PH.EUR. IDENTIFICATION</b>	Complies	Complies
ASPETTO DELLA SOLUZIONE	Conforme	Conforme	APPEARANCE OF SOLUTION	Complies	Complies
ODORE	Conforme	Conforme	ODOUR	Complies	Complies
ACIDITA'/ALCALINITA'	Conforme	Conforme	ACIDITY/ALCALINITY	Complies	Complies
CLORURI	<= 100 ppm	< 5	CHLORIDES	<= 100 ppm	< 5
SOLFATI	<= 100 ppm	< 50	SULFATES	<= 100 ppm	< 50
SOLFURI	Conforme	Conforme	SULFIDES	Complies	Complies
CENERI SOLFORICHE	<= 0,2%	0,1	SULFATED ASH	<= 0,2%	0,1
TITOLO	99-101%	99,5	ASSAY	99-101%	99,5
<b>ALTRI TEST</b>			<b>OTHER TESTS</b>		
pH	Conforme	Conforme	pH	Complies	Complies
ACQUA	<= 0.5%	0,2	WATER	<= 0.5%	0,2

CONFORMITA'	COMPLIANCE
FARMACOPEE	Conforme a Ph. Eur.
DICHIARATE DAL FORNITORE	USP ed. vigente
	PHARMACOPOEIA
	Complies with Ph. Eur.
	SUPPLIER'S DECLARATION
	USP curr. ed.

INFORMAZIONI GENERALI	GENERAL NOTICES
SINONIMI	Bianco di zinco
NATURA DEL PRODOTTO	Sintetica
TIPO DI PRODOTTO	Conforme a Farmacopea Prodotto per uso esterno
ALLERGENI	Esente da lattice Non contiene allergeni cosmetici (Reg. 1223/2009/CE)
PESTICIDI	Assenti
MICOTOSSINE	Assenti
SOLVENTI RESIDUI	Nessun solvente organico viene impiegato nel processo produttivo
CONTAMINANTI	Esente da diossina
CONSERVAZIONE	Conservare in contenitori ben chiusi in luogo fresco e asciutto Conservare lontano da fonti di ignizione e calore
PROPRIETA'	Coadiuvante nel trattamento di stati di cheratosi e di infiammazione
	OTHER NAMES
	Zinc white
	PRODUCT SOURCE
	Synthetic origin
	TYPE OF PRODUCT
	Complies with Pharmacopoeia Product for external use
	ALLERGENS
	Latex free The product doesn't contain any cosmetic allergen ingredients (Reg. 1223/2009/EC)
	PESTICIDES
	None
	MYCOTOXINS
	Negative
	RESIDUAL SOLVENTS
	No organic solvents are used in the manufacturing process
	CONTAMINANTS
	Dioxin-free
	STORAGE
	Store in tightly closed containers in a cool, dry place Keep away from sources of ignition and heat
	PROPERTIES
	It is an adjuvant in the treatment of keratosis and inflammation states

### FARMALABOR Srl

**Sede legale** Via Pozzillo II traversa a sx, 1  
76012 Canosa di Puglia (Bt) - Italia

**Sede di rappresentanza** Via Palermo, 23 - 20057 - Assago (MI) - Italia  
CCIAA di Bari - REA n. 432773 - P105676410722 - Cap. Soc. € 360,000,00 i.v.

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AZIENDA CON  
SISTEMI DI GESTIONE QUALITA'  
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Tre divisioni, un'unità di intenti. Produrre qualità.  
Three Departments, a unique will: Produce Quality.

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FARMALABOR **pack**

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## CERTIFICATO DI ANALISI - CERTIFICATE OF ANALYSIS

### Etichetta

**Prodotto - Product** 002453 ZINCO OSSIDO - ZINC OXIDE

**Conformità - Compliance** EP

**Lotto - Batch Number** 2102106

**Produttore - Manufacturer** Farmalabor Srl, Via Moscatello Z.I., 76012 Canosa di Puglia (BT), Italia

**Materia prima - Raw material** QUALITY CHEMICALS - Spagna , Fornal,35-Pol.Ind.Can Comelles Sud, Apdo.de Correos 184 Esparreguera

**Data di produzione - Manufacturing date:** 25/03/2025

**Data rititolazione - Retest date:** 25/09/2027

**Data di analisi - Analysis date:** 17/04/2025

### ANNOTAZIONI

NOTE

Esente dal rischio BSE/TSE  
Esente da OGM  
Esente da sostanze classificate C.M.R. (Reg. 1272/2008/CE)  
Esente da melamina  
Non trattato con ossido di etilene  
Non contiene nanomateriali (Reg. 1169/2011/CE)  
Non trattato con radiazioni ionizzanti  
Prodotto non testato sugli animali  
Adatto alla dieta Halal e Kosher

### NOTES

NOTES

BSE/TSE free  
GMOs free  
Free from C.M.R. substances (Reg. 1272/2008/EC)  
Melamine-free  
Not treated with ethylene oxide  
It does not contain nanoparticles/nanomaterials (Reg. 1169/2011/EC)  
Not treated with ionizing radiations  
The product has not been tested on animals  
Suitable for Halal/Kosher diet

Le specifiche sono state desunte dalle schede forniteci dai produttori. Le informazioni sopra riportate non vi esonerano dall'obbligo di identificare e controllare il prodotto prima dell'uso. L'adozione dei prodotti e di conseguenza l'uso corretto degli stessi sono sotto la totale responsabilità dell'utilizzatore.

All specifications are as provided by the original manufacturer. They do not imply any exemption from identifying and inspecting the product before its use, the final user being fully responsible for the adoption and the correct usage of the product.

**Resp.Sistema di Gestione Integrato Qualità-Ambiente-Sicurezza / Integrated Management System Manager**

**Dott.ssa Monica Piarulli**



Spazio riservato alla Farmacia

DATA RICEZIONE \_\_\_\_\_ NR. INTERNO: \_\_\_\_\_ NR DDT/FATTURA : \_\_\_\_\_  
DATA UTILIZZO \_\_\_\_\_ DATA FINE UTILIZZO : \_\_\_\_\_ QUANTITA': \_\_\_\_\_  
COSTO: \_\_\_\_\_ PREZZO AL PUBBLICO : \_\_\_\_\_ SIGLA RESP.LAB. : \_\_\_\_\_

**FARMALABOR Srl**

**Sede legale** Via Pozzillo II traversa a sx, 1  
76012 Canosa di Puglia (Bt) - Italia

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UNI EN ISO 14001:2015  
UNI ISO 45001:2018  
ISSUED BY CERTIQUALITY

## CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : 1353/25

Issue Date: **May 07, 2025**

Lot. n°: **2.14.1.073999**

Manufacturing date: **March 06, 2025**

Expiry date: **March 05, 2028**

### **BORIC ACID EP**

The product is in accordance with the European Pharmacopeia 11.0 for Boric Acid

<u>Analysis:</u>
------------------

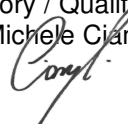
<u>Characteristics</u>	Units	Test	Specific		<u>Analytical chemistry procedure employed</u>
		Results	Min.	Max.	
Description		:	<b>Powder, white granules</b>		
Identification		:	<b>Positive</b>		European Pharmacopoeia
Appearance of the solution		:	<b>According to Ph. Eur.</b>		European Pharmacopoeia
Solubility in alcohol		:	<b>According to Ph. Eur.</b>		European Pharmacopoeia
Organic matter		:	<b>According to Ph. Eur.</b>		European Pharmacopoeia
pH of 3,3 % solution		:	<b>4,0</b>	3,8    4,8	pH-Meter
Chloride	Cl	ppm <	<b>2</b>	-    -	Ion Chromatography
Sulphate	SO <sub>4</sub>	ppm <	<b>5</b>	-    450	Ion Chromatography
Heavy metals	as Pb	ppm <	<b>1</b>	-    15	Colorimetry after concentration
Iron	Fe	ppm <	<b>1</b>	-    -	Colorimetry (Tripyridil Triazine)
Boric Acid	H <sub>3</sub> BO <sub>3</sub>	% :	<b>100,0</b>	99,0    100,5	Potentiometric Titration

► **Shelf life statement/Date Limite d'Utilisation Optimale**

- The product stored in its original and properly sealed containers is chemically stable for at least 5 years from the manufacturing date indicated in the documents.
- Store cool, dry and well-ventilated place, away from strong reducing agents; keep preferably at a temperature between 20°C and 35°C; To avoid:
  - high air humidity
  - sunlight exposure
  - temperatures under -5°C and over 40°C

SCL shall not be held responsible for any and all issues arising from incorrect storage and/or handling of the product.

Laboratory / Quality Control  
Michele Ciampoli



To Whom It May Concern

## HEALTH CERTIFICATE

Invoice date: 02.06.2025  
Contract No.: 8844/2025 dated 06.05.2025  
Delivery: 1 of  
PO No.: 1043  
Page: 1 /

### General Information

Product:	Native <u>Potato Starch</u>	CMR :	
HS Code:	1108 13 00	POL:	European Union
Quality:	Food Grade	POD:	Kishinev, Moldova
Origin:	European Union	Parity:	CIP Kishinev, Moldova
Packing:	25 kg paper bags "Birkamidon Brand", labelled, palletized	Truck:	
Quantity:	1 FTL of 21 mt	ETS:	02.06.2025
Bags per Truck:	840 Total 840	ETA:	09.06.2025
Truck No.:	VLV321/A819KX		

Batch No.:	26/05/2025	Batch No.:	<u>27/05/2025</u>
Production date:	26/05/2025	Production date:	27/05/2025
Expiry date:	31/08/2029	Expiry date:	31/08/2029

We certify that the food grade Potato Starch manufactured on behalf of:

Wilhelmsaue 12 A  
10715 Berlin  
Germany

IS FIT FOR HUMAN CONSUMPTION AND PRODUCED IN HYGIENIC CONDITION FOR EXPORT.

Berlin, 02.06.2025

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**PRODUCT SPECIFICATION**

## Native Potato Starch

Product code: 45  
 HS-Code: 1108 1300  
 Origin: EU

### Sensory Characteristics

Parameter	Description
Colour	White
Taste and odour	Neutral

### Physical-Chemical Characteristics

Parameter	Unit	Minimum	Maximum
Moisture	%	-	20
pH value	-	5.5	8.0
Ash content	%	-	0.35
Viscosity	BU	1,000	-
Sulphur dioxide	ppm	-	10
Macroscopic impurities with tolerance 20 %	pcs/dm <sup>2</sup>	-	50

### Microbiological Characteristics

Parameter	Unit	Minimum	Maximum
Total aerobic bacteria count	cfu/g		50,000
Coliform bacteria	cfu/g		100
Yeast and mould	cfu/g		500
Total Bacillus cereus	cfu/g		10
Total Clostridium botulinum	/1 g	Absent	
Escherichia coli	/1 g	Absent	
Salmonella	/25 g	Absent	

### Packaging

25 kg multiply paper bags; 1000 kg big bags

### Storage

Store in cool, dry, clean and well-ventilated rooms with no off-smells in closed bags, storage temperature: 15°C up to 20°C, relative room humidity: up to 65 %

### Shelf-Life

5 years from date of production

四川武胜春瑞医药化工有限公司  
Sichuan Wusheng Chunrui Medicine Chemical Co., Ltd.

检验报告单

Certificate of Analysis

品名 ITEM	盐酸普鲁卡因 PROCAINE HYDROCHLORIDE		
批号 BATCH NO	20250613	数量 QUANTITY	50KGS
包装 PACKING	25KG 纸板桶 25KG/DRUM	报告编号 LOT NO	20250613
生产日期 PRODUCTION DATE	Jun.04, 2025	有效期 EXPIRY DATE	Jun.03, 2029
检验标准 STANDARD	EP11.0		
指标 INDEX	标准 STANDARD	结果 RESULTS	
外观 APPEARANCE	白色结晶性粉末或无色晶体。 White crystalline powder or colorless crystal	Conform	
鉴别 IDENTIFICATION	A. Melting point: 154°C~158°C B. IR E. It gives reaction(a)of chlorides	155.0°C-156.0°C Conform Conform	
酸度 ACIDITY	PH5.0-6.5	PH=6.0	
溶液外观 Appearance of solution	Clear and colourless	Conform	
干燥失重 LOSS ON DRYING	≤0.5%	0.07%	
重金属 HEAVY METALS	≤0.0005%	Conform	
有关物质 RELATED SUBSTANCES	Any impurity ≤0.05%	Conform	
硫酸盐灰份 SULPHATED ASH	≤0.1%	0.05%	
含量(折干) ASSAY (ON DRY BASIS)	99.0-101.0%	99.9%	
微生物限度 Microbial limit	TAMC ≤100CFU/g TYMC ≤100CFU/g	Conform Conform	
细菌内毒素 BACTERIAL ENDOTOXINS	≤0.6Eu/mg	<0.3Eu/mg	
结论 CONCLUSION	Conforms to EP11.0		
主管 MANAGER	 2025.07.21		报告人 REPORTER 2025.07.21



**CERTIFICATE OF ANALYSIS**

Laboratory Salinen Austria AG

**PHARMASAL HD**

Chemically pure salt, Sodium chloride  
according to Ph. Eur, BP, USP, JP

Lot number: CRS180225  
Retest date: 18.02.2028  
Production date: 18.02.2025 - 21.02.2025

		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
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
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 (Pyrogen free)		< 5	I.U./g	< 5	I.U./g
TAMC		<= 10	CFU/g	<= 10	CFU/g
TYMC		<= 10	CFU/g	<= 10	CFU/g

Appearance: white or almost white, crystalline powder or colorless crystals or white or almost white pearls  
Solubility: freely soluble in water, practically insoluble in anhydrous ethanol

This lot conforms with the current Ph.Eur., USP, BP and JP monographs.  
Store in a clean and dry place, nmt. 70% rel. humidity.

It is suitable for various industrial applications and depending on country specific law in the  
manufacture of peritoneal, hemodialysis and hemofiltration solutions.

Qualified Person: Birgit Spreitz

Date: 06.03.2025

*Birgit Spreitz*  
06.03.2025

**Salinen Austria AG**  
Labor  
Steinkogelstraße 30  
4802 Ebensee  
Tel: +43 6132 1200 0

SHANDONG FANGXING TECHNOLOGY DEVELOPMENT CO.,LTD.

**Certificate of Analysis**

*Nitrofurazone*

BATCH NUMBER	<u>20240504</u>	TEST DATE	<u>Jun. 02,2024</u>
BATCH SIZE	<u>525.8kgs</u>	MANUFACTURE DATE	<u>May. 14,2024</u>
QUANTITY	<u>50kgs</u>	EXPIRATION DATE	<u>May. 13,2027</u>

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT</u>
Appearance:	A yellow or brownish-yellow, Crystalline powder,	<u>Conforms</u>
Solubility:	Very slightly soluble in water, slightly soluble in ethanol(96 pre cent).	<u>Conforms</u>
Identification: A、 B、 C、 D		<u>Conforms</u>
PH:	5.0~7.0	<u>5.83</u>
Related substances: (5-nitrofur-2-yl)methylene diacetate.	Not more than 0.5%.	<u>Conforms</u>
Individual impurity	Not more than 0.5%.	<u>Conforms</u>
Total impurities	Not more than 1.0%.	<u>Conforms</u>
Loss on drying:	Not more than 0.5%.	<u>0.37%</u>
Sulphated ash:	Not more than 0.1%.	<u>0.05%</u>
Assay:	97.0~103.0%.	<u>99.09%</u>



Checker: 李 崧

Supervisor: 曹茂凯

By: \_\_\_\_\_

\_\_\_\_\_  
Rejected

Certificate of analysis AK25000268

Customer requisition HSH012506POH00001002

Mode of delivery drums

Vehicle Num. DB-48-PGA/DB-05-PGA

Net weight 11 000 kg

**Glycerin 99,5% Pharma**

Reference number POLC072524

Batch number 250725E002

Best before date 25.07.2027

	Test result	Quality	Method
Taking of average sample in factory	Make		ČSN 66 1322
Sulfated ash	0,003 %	0,00 - 0,01	Ph. Eur.10.
Glycerol content	99,78 %	99,5 - 100,0	Ph. Eur.10.
Colour APHA/HAZEN	8	0 - 10	ZMA-0032
Odour	Correspond		ZMA-0176
Water content	0,1 %	0 - 0,5	
Esters according to Pharmacopeia	8,2 ml 0,1M HC	8 - 100	Ph. Eur.10.
Appearance	colorless, pure <10	color APHA less than 10	Ph. Eur. 10.

Department of the quality management  
 Issued by Laboratoř Oleochem  
 Date 25.07.2025

ASTRON CHEMICALS SRL (PH)  
SOS. DUDESTI-PANTELIMON N°19  
033091 BUCHAREST-SECTOR3  
ROMANIA

## Certificate of Analysis/Conformity

Shipment date 27.02.2025		
Truck / Trailer / Container CJ 29 MDP		
Delivery item 92427864 000010	Shipment 4060080	Delivery item date 19.02.2025
Order item 3304142 000010		Order item date 31.01.2025
Customer number 57930		Reference from Customer 2025/03-ASTR
Customer variant DQ200 57930 01		

Date format used = dd.mm.yyyy or mm.yyyy

Material DQ200251107	Our reference MERITOSE 200 PHARMA      PACKED GLUCOSE MONOHYDRATE / DEXTROSE	Your reference DQ200251107 /
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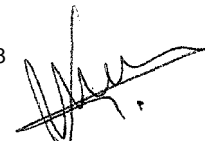
Produced by : 1620 TSS Iberia SAU - 50015 ZARAGOZA - Spain - FR  
Batch S1M310101      Quantity      5,000 TO  
Production date 05.11.2024      Retest date 11.2027  
Inspection lot number 100001547149      Inspection date 10.02.2025

Test	Unit of measure	Test result	Specification	Test Method	Remark
Identification A		<b>conform</b>	conform	4001	Analysis
Specific optical rotation	°	<b>53,1</b>	52,5 - 53,3	4001	Analysis
Identification B		<b>conform</b>	conform	4002	Analysis
Identification E		<b>conform</b>	conform	4019	Analysis
Appearance of solution		<b>conform</b>	conform	4004	Analysis
Conductivity	µS/cm	<b>3</b>	<= 20	4020	Analysis
Sum of impurities A and B	%	<b>0,2</b>	<= 0,4	4301	Analysis
Impurity C	%	<b>&lt; 0,05</b>	<= 0,20	4301	Analysis
Impurity D	%	<b>0,06</b>	<= 0,15	4301	Analysis
Unspecified impurities	%	<b>&lt; 0,05</b>	<= 0,10	4301	Analysis
Total impurities	%	<b>0,3</b>	<= 0,5	4301	Analysis
Dextrin		<b>conform</b>	conform	4021	Analysis
Soluble starch, sulfites		<b>conform</b>	conform	4022	Analysis
Water	%	<b>8,6</b>	7,5 - 9,5	4014	Analysis
Assay (anhydrous substance)	%/ds	<b>98,6</b>	97,5 - 102,0	4301	Analysis

For parameters not appearing on the CoA/CoC or when no result is reported, we certify that the product contained in this shipment meets and conforms to all requirements of the agreed specification.

Compliance: Ph. Eur. and USP-NF monographs in force.

Mrs. Marisa Mas, Quality Manager Tereos Starch & Sweeteners Iberia SAU, Avenida Salvador Allende,  
76-78,50015 Zaragoza - Spain. Acting on behalf Tereos Starch & Sweeteners Belgium NV. Tel. +34 (0) 976 738  
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## CERTIFICATE OF ANALYSIS

PRODUCT: **IODINE - BP**

BATCH NO.: **0625/059/019**

CUSOMER: Balkan Pharmaceuticals SRL

YOUR REFERENCE: 45905687425 17.08.2025

OUR REFERENCE: DDL - 00000055684 - 17/08/2025

QUANTITY: KG 25,00

MANUFACTURING DATE: 01/06/2025

MANUFACTURING DATE: 31/05/2028

	TEST PARAMETER	SPECIFICATION	RESULTS
1	Description	Heavy, grayish-black prills, having a metallic seen with characteristic odor.	Complies
2	Solubility	Freely soluble in carbon disulfide, in chloroform, in carbon tetrachloride, and in ether; soluble in alcohol and in solutions of iodides; sparingly soluble in glycerin; very slightly soluble in water.	Complies
3	Identification test	A. Solutions (1 in 1000) in chloroform and in carbon disulfide have a violet color. B. To a saturated solution add starch-potassium iodide TS. Acceptance criteria: A blue color is produced. When the mixture is boiled, the color vanishes but reappears as the mixture cools, unless it has been subjected to prolonged boiling.	Complies Complies
4	Chloride and Bromide	NMT 0.028%	Complies
5	Nonvolatile matter	NMT 0.05%	Complies
6	Sulpates	NMT 0.05%	Complies
7	Ferrum	NMT 0.01%	Complies
8	Assay (By Titration)	99.80% to 100.5%	99.88 %

THIS REPORT IS A CONFORM AND TRUE COPY OF THE CERTIFICATE OF ANALYSIS ISSUED BY THE SUPPLIER FOR THIS PRESENT BATCH OF PRODUCTION

Marzia Riccelli





Rua Dona Francisca, 11700 - Pirabeiraba  
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Fone / Fax : (47) 3205-7000  
CNPJ: 084689090000240  
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E-mail: comex@incasa.ind.br  
Home page: www.incasa.ind.br  
Joinville Santa Catarina Brasil

JOINVILLE(SC), February 13th, 2024.

### CERTIFICATE OF ANALYSIS

INVOICE NO: 018/24

PURCHASE ORDER NO: 845, 1112 e 1113

IMPORTER: TODINI BV

PRODUCT: Potassium Iodide

MOLECULAR FORM: KI

BATCH NO.	002-013/24	002-137/23	002-138/23	002-139/23	
MANUFACTURING DATE	29/JAN /24	13/DEC /23	13/DEC /23	14/DEC /23	
EXPIRY DATE	28/JAN /28	12/DEC /27	12/DEC /27	13/DEC /27	
QUANTITY ( KG )	1.000,00	1.000,00	1.000,00	1.000,00	
TEST	SPECIFICATIONS	RESULTS			
Appearance	White crystals	White crystals	White crystals	White crystals	White crystals
Assay (dry basis)	99,50% - 100,50%	99,59 %	99,53 %	99,62 %	99,68 %
Iodine	76,12 - 76,89%	76,19 %	76,15 %	76,22 %	76,26 %
Identification for potassium	Positive	Positive	Positive	Positive	Positive
Identification for iodide	Positive	Positive	Positive	Positive	Positive
Appearance of solution	Clear and colorless	Clear and colorless	Clear and colorless	Clear and colorless	Clear and colorless
Alkalinity	Passes test	Passes test	Passes test	Passes test	Passes test
Loss on drying	Max. 1,00%	0,06 %	0,12 %	0,06 %	0,11 %
Iodate	Max. 4 ppm	< 4 ppm	< 4 ppm	< 4 ppm	< 4 ppm
Limit of nitrate, nitrite and ammonia	Passes test	Passes test	Passes test	Passes test	Passes test
Thiosulphate and barium	Passes test	Passes test	Passes test	Passes test	Passes test
Heavy metals	Max. 10 ppm	< 10 ppm	< 10 ppm	< 10 ppm	< 10 ppm
Iron	Max. 20 ppm	< 20 ppm	< 20 ppm	< 20 ppm	< 20 ppm
Sulphates	Max. 150 ppm	< 150 ppm	< 150 ppm	< 150 ppm	< 150 ppm
Odour	Odourless	Odourless	Odourless	Odourless	Odourless

**Observation:** Hygroscopic product. It can become caked.  
Chemicals specifications according to USP 40th and Euro Pharm 8.

Analyst  
Edilene C. B. Dalfovo  
CRQ 13200940

Technical Responsible  
Eng. Harry Weege  
CRQ 13300133

"THIS CERTIFICATE OF ANALYSIS (CoF) IS VALID WITHOUT SIGNATURE. IF ANY MODIFICATIONS ARE MADE IN THIS CoF, THE CoF WILL BE CONSIDERED UNVALUED."