



Certificate of Analysis

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 (MgSO4)	<4 mg/kg	<= 4 mg/kg
Selenium *)	DIN EN ISO 17294-2 (MgSO4)	<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.

检 验 报 告 单

CERTIFICATE OF ANALYSIS第 1 页，共 1 页page 1 of 1

品 名 Name of product		磺胺噻唑钠 Sulfathiazole Sodium	报告日期 Report Date	2025年08月08日 August 8, 2025
批 号 Lot NO.		250201	生产日期 Manufacture Date	2025 年 02 月 February, 2025
数 量 Net weight		30kg	有效期至 Expiry Date	2028 年 02 月 February, 2028
检验项目 ANALYTICAL ITEMS		标准规定值 SPECIFICATION		检验结果 ANALYTICAL RESULTS
性 状 Description		白色或淡黄色的结晶颗粒或粉末。 A white or yellowish crystalline particle or powder.		白色结晶性粉末 White crystalline powder
熔点 Melting range		200℃~203℃		201℃~202℃
鉴别1 Identification1		本品的红外吸收图谱应与对照的图谱一致。 Conforms to RS.		与对照图谱一致 Conforms to RS
鉴别2 Identification2		呈芳香第一胺类鉴别反应。 Is the first identification of aromatic amines.		呈正反应 Positive reaction
鉴别3 Identification3		水溶液显钠盐鉴别反应。 Identification of sodium salt in aqueous solution.		呈正反应 Positive reaction
碱度 Alkalinity		pH9.0~10.0。		9.8
有关物质 Related substances		≤0.5%		<0.5%
重金属 Heavy metals		≤20ppm		符合 Complies
干燥失重 Loss on drying		6.0-10.0%		8.0%
微生物限度 Microbial limit	需氧菌总数 Total number of aerobic bacteria	不得过10 ³ cfu/g Not more than 10 ³ cfu/g 不得过10 ² cfu/g Not more than 10 ² cfu/g		<10cfu/g <10cfu/g
	霉菌和酵母菌总数 Total number of mold and yeast			
含 量 Assay		以干品计，含 C ₉ H ₈ N ₃ NaO ₂ S ₂ 应不小于 99.0%且不大于 101.0% NLT 99.0% and NMT 101.0% of C ₉ H ₈ N ₃ NaO ₂ S ₂ ,calculated on the dried basis99.0-1001.0%		99.5%
检验依据 According to		英国药典 BP2012		
结 论 Conclusion		合格 Complies		

检验者：吴玉妹
Analyst:

复核者：王美芳
Checker:

负责人：缪彩珍
Supervisor:

TALC ANALYSIS CERTIFICATE

BR-CQL-F-055

Data: 18/05/2023

Folha: 1/5



CERTIFICATE OF ANALYSIS

PRODUCT: TALMAG PHARMA-S

BATCH: CPA1162Y

QTY. (t): 25,000

PRODUCTION/DATE (S):

10/06/2024

INVOICE: 000016/24

QUANTITY SHIPPED: 25,000

CONTROLLED PARAMETERS	METHOD	RESULTS	SPECIFICATION
Whiteness L* (CIE)	(%) BR-CQL-A-027	96,4	Mín. 95,5
Soluble in HCl	(%) BR-CQL-A-003	0,6	Máx. 2,0
Residue on 200# (75µm)	(%) BR-CQL-A-004	1,4	Máx. 1,5
Loose density	(g/cm³) BR-CQL-A-007	0,35	0,35 / 0,45
Loss on ignition	(%) USP **	5,3	Máx. 7,0
Total aerobic microorganisms	(UFC/g) USP **	<10	Máx. 100
Total of yeasts and molds	(UFC/g) USP **	<10	Máx. 10
Gram negative rods	- USP **	Absent	Absent in 10 g
<i>P. aeruginosa</i>	- USP **	Absent	Absent in 10 g
<i>E. coli</i>	- USP **	Absent	Absent in 10 g
<i>S. entérica</i>	- USP **	Absent	Absent in 10 g
<i>S. aureus ssp</i>	- USP **	Absent	Absent in 10 g
<i>C. albicans</i>	- USP **	Absent	Absent in 10 g
<i>Clostridium spp.</i>	- USP **	Absent	Absent in 10 g

NOTE

- Representative results for batch (25,000 tons)
- Whiteness (L*) - Minolta CM600D Illum. C; Obs. 2°
- Expiration date: 60 months (provided it is kept on the established conditions and in its original packaging).
- Invoice:
- N° DCB: 08264
- N° of CAS registry: 14807-96-6
- ** Current version
- This batch of TALMAG PHARMA-S was manufactured using Good Manufacturing Practices for Pharmaceutical Excipients (IPEC-PQG)

9. Expiration Date 10/06/2029

APPROVAL

Ricardo Alves Donato
Eng. Químico
CRQ-BA: 07301585

Ricardo Alves Donato
Quality Control - Brumado - Bahia, Brasil

Date of Issue: 27/06/2024

PRODUCTION UNIT

IMI FABI TALCO S/A

Vila Catiboaba, s/n.º - PARTE Phone: (11) 3080-2772

Zip Code: 46118-396 - Brumado-BA E-mail: info@imifabi.com

State Registration: 132.689.560 NO

CNPJ (Registration of Corporate Taxpayers): 24.809.672/0001-00

TALC ANALYSIS CERTIFICATE



BR-CQL-F-055

Data: 18/05/2023

Folha: 2/5

Method USP-NF 2023 – Specification – Analytical Result

PRODUCT: TALMAG PHARMA-S

Compendium: CBRA1H24

BATCH: CPA1162Y

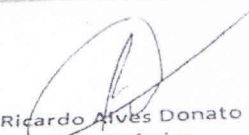
Coa: VL097/2023

PARAMETERS	SPECIFICATION	RESULTS	INTERPRETATION
Identification *			
ID A.	To pass test	Passes test	Meets USP
ID B	To pass test	Passes test	Meets USP
ID C	To pass test	Passes test	Meets USP
Absence of asbestos **			
** X-Ray Diffraction	To pass test	Passes test	Meets USP
Loss on ignition <733> (1075°C)	≤ 7.0%	5.1%	Meets USP
Magnesium <852>	17.0% - 19.5%	18.2%	Meets USP
Iron <852>	≤ 0.25%	0.06%	Meets USP
Aluminum <852>	≤ 2.0%	0.20%	Meets USP
Calcium <852>	≤ 0.9%	0.05%	Meets USP
Lead <852>	≤ 0.001%	< 0.0002% (< 2 ppm)	Meets USP
Water Soluble Substances	≤ 0.1%	0.06%	Meets USP
Acidity and Alkalinity HCl	≤ 0.4 ml	0.3 ml	Meets USP
Acidity and Alkalinity NaOH	≤ 0.3 ml	0.3 ml	Meets USP

NOTE

1. Analyzed by an independent certified laboratory.
2. Analyzes carried out on a medium-term drilling sample, material that will be mined in the next 6 months.

APPROVAL


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CRQ-BA: 07301585

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Quality Control - Brumado - Bahia, Brasil

Date of Issue: 27/06/2024

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TALC ANALYSIS CERTIFICATE



BR-CQL-F-055

Data: 18/05/2023

Folha: 3/5

Method EP 11° Ed – Specification – Analytical Result

PRODUCT: TALMAG PHARMA-S

Compendium: CBRA1H24

BATCH: CPA1162Y

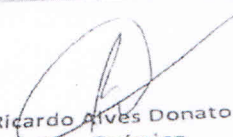
Coa: VL097/2023

PARAMETERS	SPECIFICATION	RESULTS	INTERPRETATION
Identification *			
ID A.	To pass test	Passes test	Meets PhEur
ID B	To pass test	Passes test	Meets PhEur
ID C	To pass test	Passes test	Meets PhEur
Production/Asbestos	To pass test	Passes test	Meets PhEur
Water Soluble Substances	≤ 0.2%	0.06%	Meets PhEur
Magnesium	17.0% - 19.5%	18.2%	Meets PhEur
Iron	≤ 0.25%	0.06%	Meets PhEur
Aluminum	≤ 2.0%	0.20%	Meets PhEur
Calcium	≤ 0.9%	0.05%	Meets PhEur
Lead	≤ 10 ppm	< 2 ppm	Meets PhEur
Loss on ignition <733> (1075°C)	≤ 7.0%	4.8%	Meets PhEur
Acidity and Alkalinity HCl	≤ 0.4 ml	0.3 ml	Meets PhEur
Acidity and Alkalinity NaOH	≤ 0.3 ml	0.3 ml	Meets PhEur

NOTE

1. Analyzed by an independent certified laboratory.
2. Analyzes carried out on a medium-term drilling sample, material that will be mined in the next 6 months.

APPROVAL


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Quality Control - Brumado - Bahia, Brasil

Date of Issue: 27/06/2024

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TALC ANALYSIS CERTIFICATE

BR-CQL-F-055

Data: 18/05/2023

Folha: 4/5



Method JP 18° Ed – Specification – Analytical Result

PRODUCT: TALMAG PHARMA-S

Compendium: CBRA1H24

BATCH: CPA1162Y

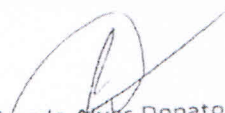
Coa: VL097/2023

PARAMETERS	SPECIFICATION	RESULTS	INTERPRETATION
Identification	To pass test	Passes test	Meets JP
Loss on ignition (1050-1100°C)	≤ 7.0%	4.8%	Meets JP
Acidity and Alkalinity HCl	≤ 0.4 ml	0.3 ml	Meets JP
Acidity and Alkalinity NaOH	≤ 0.3 ml	0.3 ml	Meets JP
Acid Soluble Substances	≤ 2.0%	0.22%	Meets JP
Water Soluble Substances	≤ 4.0 mg	0.02 mg	Meets JP
Magnesium	17.0% - 19.5%	18.2%	Meets JP
Iron	≤ 0.25%	0.06%	Meets JP
Aluminum	≤ 2.0%	0.20%	Meets JP
Calcium	≤ 0.9%	0.05%	Meets JP
Lead	≤ 10 ppm	< 2 ppm	Meets JP
Arsenic	≤ 4 ppm	< 0.1 ppm	Meets JP

NOTE

1. Analyzed by an independent certified laboratory.
2. Analyzes carried out on a medium-term drilling sample, material that will be mined in the next 6 months.

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Nederland

BARCELONA 1935

Cod.: N-R-LAB-005

PAG: 1

Rev.: 03

CERTIFICADO DE ANALISIS / CERTIFICATE OF ANALYSIS

Fecha/Date	Ref./ Ref.	Descripción / Description	Lote / Batch	FP / PD	CP / BB	OC num / PO num
30 /06 /2025	MNE2	Manteca natural	2410300000	30 /06 /2025	12 /2026	R00000379

Natural cocoa butter

Nº Rutina/Nº Routine: 82795 Ref./Ext. :

Lote Proveedor/Batch Supplier:

Análisis / Analysis	Especcs / Specs		Uni.	Resultado Result	Método / Method
	Min	Max			
Color/Colour	Según especificación		N/A	As per spec	PNT-12
Olor/Smell	Según especificación		N/A	As per spec	PNT-12
Sabor/Taste	Según especificación		N/A	As per spec	PNT-12
Acidez/Free Fatty Acids	0,000	1,750	%	1,120	IOCCC 42/1993
Humedad/Moisture	0,000	0,100	%	0,020	PNT-02

Comentarios adicionales/Additional comments:

Seg.esp/As per sp: Según especificaciones/As per specifications

El documento es válido sin firma/The document is valid without signature

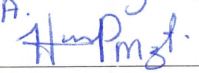
Emitido por/Provided by: Laboratorio Control Calidad/Quality Control Lab



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Nederland, S.A.
DERIVADOS DEL CACAO
Cocoa Products

Ctra. de la Vila 48
08840 Viladecans
(Barcelona) España

	CERTIFICADO DE ANÁLISIS / CERTIFICATE OF ANALYSIS Tribromofenato de Bismuto/ Bismuth Tribromophenate.	
	SITIO DE FABRICACIÓN / MANUFACTURING SITE :	Laboratorios Imperiales S.A. de C.V.
	SITIO DE ANÁLISIS / ANALYTICAL SITE :	Laboratorios Imperiales S.A. de C.V.
	LOTE / BATCH :	4002256010
PRUEBA / TEST :	RESULTADOS / RESULTS :	ESPECIFICACIÓN / SPECIFICATION :
1.- Descripción / Description	Polvo amarillo brillante, amorfo, olor ligeramente característico / Bright yellow, amorphous powder with a faint characteristic odor.	Polvo amarillo brillante, amorfo, olor ligeramente característico / Bright yellow, amorphous powder with a faint characteristic odor.
2.- Identificación para Bi ³⁺ / Identification for Bi ³⁺	Positiva / Positive	Positiva / Positive
3.- % Pérdida al secado / % Loss on drying	0.16 %	≤ 3.00 %
4.- Ensayo como Bi ³⁺ / Assay as Bi ³⁺	46.35 %	40.00 – 49.00 %
5.- Ensayo como Bi ₂ O ₃ / Assay as Bi ₂ O ₃	51.67 %	44.59 – 54.63 %
6.- % Tribromofenol libre / % Free Tribromophenol	2.22 %	≤ 3.30 %
7.- % Recuperación / % Recovery	98.38 %	Mínimo 96.00 % / Minimum 96.00 %
8.- % Sustancias no precipitadas por NH ₄ OH / % Substance not precipitate by NH ₄ OH	0.03 %	≤ 0.50 %
9.- Arsénico / Arsenic	<0.00020 %	≤ 0.00020 %
10.- Cobre / Copper	Pasa prueba / Pass test.	Pasa prueba / To pass test.
11.- Plomo / Lead	Pasa prueba / Pass test.	Pasa prueba / To pass test.
12.- Plata / Silver	Pasa prueba / Pass test.	Pasa prueba / To pass test.
13.- Sulfatos / Sulphate	Pasa prueba / Pass test.	Pasa prueba / To pass test.
14.- Nitratos / Nitrates	Pasa prueba / Pass test.	Pasa prueba / To pass test.
OBSERVACIONES / REMARKS : Ninguna/ None		
FECHA DE MANUFACTURA / MANUFACTURING DATE : 08-AGO-25 FECHA DE REANÁLISIS / RETEST DATE : 07-AGO-31 FECHA DE LIBERACIÓN / RELEASE DATE : 11-AGO-25 GRADO / GRADE : MERCADO USA		
ELABORADO POR / ISSUED BY :  11 Ago 25 NOMBRE / NAME : Oskar Rivera Balderas PUESTO / TITLE : COORDINADOR DE MEJORA CONTINUA / CONTINUOUS IMPROVEMENT COORDINATOR	REVISADO POR / REVIEWED BY :  11 AGO 25 NOMBRE / NAME : Jonathan Jaziel Wbando López PUESTO / TITLE : INSPECTOR DE PROCESOS Y CALIDAD/ QUALITY AND PROCESS INSPECTOR	AUTORIZADO / AUTHORIZED :  PA. 11 Ago 25 NOMBRE / NAME : Claudio Bezanilla Martínez. PUESTO / TITLE : RESPONSABLE SANITARIO / QUALIFIED PERSON

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

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 diluite 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 microm and that of almost all the particles in not greater than 40 microm

ANALISI MATERIA PRIMA	SPECIFICHE	RISULTATI	RAW MATERIAL ANALYSIS	SPECIFICATIONS	RESULTS
PH.EUR.			PH.EUR.		
IDENTIFICAZIONE	Conforme	Conforme	IDENTIFICATION	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
ALTRI TEST			OTHER TESTS		
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
	PHARMACOPEIA
	SUPPLIER'S DECLARATION
	Complies with Ph. Eur.
	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) - ItaliaSede di rappresentanza Via Palermo, 23 - 20057 - Assago (MI) - Italia
CCIAA di Bari - REA n. 432773 - PIO5676410722 - Cap. Soc. € 360,000,00 i.v.Tel +39 0883 1975 111
Fax +39 0883 664 824
Fax 800 085 708
E-mail info@farmalabor.it
Web www.farmalabor.itAZIENDA CON
SISTEMI DI GESTIONE QUALITA'
UNI EN ISO 9001:2015
UNI EN ISO 14001:2015
UNI ISO 45001:2018
CERTIFICATA DA CERTIQUALITY
COMPANY WITH CERTIFIED
MANAGEMENT SYSTEMS
UNI EN ISO 9001:2015
UNI EN ISO 14001:2015
UNI ISO 45001:2018
ISSUED BY CERTIQUALITY

Tre divisioni, un'unità di intenti. Produrre qualità.
Three Departments, a unique will: Produce Quality.



FARMALABOR materie prime

FARMALABOR pack

FARMALABOR tech

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

Sede di rappresentanza Via Palermo, 23 - 20057 - Assago (MI) - Italia

CCIAA di Bari - REA n. 432773 - PI05676410722 - Cap. Soc. € 360,000,00 i.v.

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Web www.farmalabor.it

AZIENDA CON
SISTEMI DI GESTIONE QUALITÀ
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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-nitrofuran-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>



Manufactured By: SHANDONG FANGXING TECHNOLOGY DEVELOPMENT CO.,LTD.

Analyst: 刘秀明

Checker: 李 岚

Supervisor: 曹茂凯

FINAL BATCH DISPOSITION

Approved

Rejected

By: _____

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 /
-------------------------	--	---------------------------------

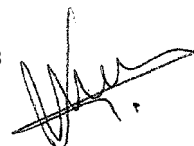
Produced by : 1620 TSS Iberia SAU - 50015 ZARAGOZA - Spain - FR
Batch S1M310101 Quantity 5,000 TO
Production date 05.11.2024 Retest date 11.2027
Inspection lot number 100001547149 Inspection date 10.02.2025

Test	Unit of measure	Test result	Specification	Test Method	Remark
Identification A		conform	conform	4001	Analysis
Specific optical rotation	°	53,1	52,5 - 53,3	4001	Analysis
Identification B		conform	conform	4002	Analysis
Identification E		conform	conform	4019	Analysis
Appearance of solution		conform	conform	4004	Analysis
Conductivity	µS/cm	3	<= 20	4020	Analysis
Sum of impurities A and B	%	0,2	<= 0,4	4301	Analysis
Impurity C	%	< 0,05	<= 0,20	4301	Analysis
Impurity D	%	0,06	<= 0,15	4301	Analysis
Unspecified impurities	%	< 0,05	<= 0,10	4301	Analysis
Total impurities	%	0,3	<= 0,5	4301	Analysis
Dextrin		conform	conform	4021	Analysis
Soluble starch, sulfites		conform	conform	4022	Analysis
Water	%	8,6	7,5 - 9,5	4014	Analysis
Assay (anhydrous substance)	%/ds	98,6	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
100



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FARMALABOR materie prime

FARMALABOR pack

FARMALABOR tech

CERTIFICATO DI ANALISI - CERTIFICATE OF ANALYSIS

Etichetta

Prodotto - Product	011166_006 ZOLFO PRECIPITATO PH. EUR. - SULFUR PRECIPITATED PH. EUR. - SULFUR		
Conformità - Compliance	EP		
Lotto - Batch Number	R2509873		
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:	15/04/2025	Data rititolazione - Retest date:	31/01/2030
		Data di analisi - Analysis date:	17/04/2025

NUMERO CAS	7704-34-9	CAS NUMBER	7704-34-9
FORMULA MOLECOLARE	S	MOLECULAR FORMULA	S
PESO MOLECOLARE	32,06	MOLECULAR WEIGHT	32,06
ASPETTO	Polvere gialla	APPEARANCE	Yellow powder
PUNTO DI FUSIONE	Ca. 120°C	MELTING POINT	About 120°C
SOLUBILITA'	Praticamente insolubile in acqua Solubile in disolfuro di carbonio Leggermente solubile in oli vegetali	SOLUBILITY	Practically insoluble in water Soluble in carbon disulfide Slightly soluble in vegetable oils
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 microm and that of almost all the particles in not greater than 40 microm

ANALISI MATERIA PRIMA	SPECIFICHE	RISULTATI	RAW MATERIAL ANALYSIS	SPECIFICATIONS	RESULTS
PH.EUR.			PH.EUR.		
IDENTIFICAZIONE	Conforme	Conforme	IDENTIFICATION	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
ALTRI TEST			OTHER TESTS		
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
	SUPPLIER'S DECLARATION
	Complies with Ph. Eur.
	USP curr. ed.

INFORMAZIONI GENERALI	GENERAL NOTICES
SINONIMI	Zolfo magistero
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
PROPRIETÀ	Coadiuvante nel trattamento di stati di cheratosi e di infiammazione
	OTHER NAMES
	Milk of Sulphur
	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
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CERTIFICATO DI ANALISI - CERTIFICATE OF ANALYSIS

Etichetta

Prodotto - Product 011166_006 ZOLFO PRECIPITATO PH. EUR. - SULFUR PRECIPITATED PH. EUR. - SULFUR		
Conformità - Compliance EP		
Lotto - Batch Number R2509873		
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: 15/04/2025	Data rititolazione - Retest date: 31/01/2030	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 fornitici 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

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CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : **1054/25**

Issue Date: **July 22, 2025**

Lot. n°: **2097007502**

Manufacturing date: **May 15, 2025**

Expiry date: **May 14, 2027**

SODIUM TETRABORATE DECAHYDRATE EP

The product is in accordance with the European Pharmacopoeia 11.0 for sodium tetraborate decahydrate

Analysis:

<u>Characteristics</u>		Units	Test	Specific		<u>Analytical chemistry procedure employed</u>
			Results	Min.	Max.	
Description			: Powder, white granules			
Identification			: Positive			European Pharmacopoeia
Appearance of the solution			: According to Ph. Eur.			European Pharmacopoeia
pH of 4 % solution			: 9,3	9,0	9,6	pH-Meter
Ammonium	NH ₄	ppm	< 10	-	10	European Pharmacopoeia
Sulphate	SO ₄	ppm	< 10	-	50	Ion Chromatography
Heavy metals	as Pb	ppm	< 5	-	20	Colorimetry after concentration
Calcium	Ca	ppm	< 100	-	100	Atomic Absorption
Assay	Na ₂ B ₄ O ₇ · 10H ₂ O	%	: 101,9	99,0	103,0	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 3 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



SKW STICKSTOFFWERKE PIESTERITZ GMBH

Analytical department Producer Test Certificate 3.1 according to EN 10 204

Customer	Balkan Pharma		
SKWP order no.	20544785	Customer order no.	4501265498
For queries	Quality management Tel. + 49(0) 33 88 - 72 43 43 / 78 22 42		
Product name	Urea, crystalline pure		
Charge	V 006-2024	Quantity	18,500 TO
Packaging period	15.01.2024 - 17.01.2024		
Best before end	01.2027		

Test criteria		Test method	Values	Test result
IR spectrum (Ph. Eur Identity B)		P-03-18-006	Identical to reference	complied
Appearance of the solution		P-03-18-007	colourless, clear	complied
Behavior against nitric acid (Ph. Eur Identity C)		P-03-18-029	crystallisation	complied
Urea content	%	P-03-18-001	99,0 - 101,5	99,7
Melting point	°C	P-03-18-008	132 - 135	133,4
Biuret	%	P-03-18-021	max. 0,1	0,02
Alkalinity		P-03-18-025	complied	complied
Ammonium	mg/kg	P-03-18-014	max. 500	< 500
Heavy metals (calc. as Pb)	mg/kg	P-03-18-028	max. 10	< 0,1
Copper	mg/kg	P-03-18-016	max. 25	< 0,05
Zinc	mg/kg	P-03-18-016	max. 25	< 0,05
Arsenic	mg/kg	P-03-18-017	max. 3	< 0,05
Sulfated ash	%	P-03-18-002	max. 0,1	< 0,01
Ethanol-insoluble matter	%	P-03-18-003	max. 0,04	< 0,01
Loss on drying	%	P-03-18-004	max. 1,0	0,1
Water	%	P-03-18-009	max. 0,20	0,03

It is confirmed that the product is free from formaldehyde.

The product corresponds in the chemo-physical characteristics to the current version of:

- German "Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuches (LFGB)"
- Regulation (EC) Nr. 1333/2008
- European Pharmacopoeia (Ph.Eur.)
- British Pharmacopoeia (BP)

and is manufactured in accordance to current GMP guidelines (cGMP; ICH Q7A).

SKW Stickstoffwerke Piesteritz GmbH
Lutherstadt Wittenberg, 22.01.2024

Dr. Geisler
Abteilung Analytik

Vorsitzender des Aufsichtsrates: Dr. Miloslav Spěváček · Geschäftsführung: Petr Cingr (Vorsitzender), Carsten Franzke, Torsten Klett
Sitz der Gesellschaft: Lutherstadt Wittenberg · Hausanschrift: Möllensdorfer Straße 13, 06886 Lutherstadt Wittenberg, Internet www.skw.de
Registergericht: Amtsgericht Stendal, HR B-11869, USt-IdNr. DE811446172

Commerzbank
Dresden
BIC: COBADE33XXX
IBAN: DE48 8504 0000 0800 4319 00

Norddeutsche Landesbank
Hannover
NOLADE2HXXX
DE33 2505 0000 0199 8626 65

Hamburg Commercial
Bank AG
HSHNDE33XXX
DE45 2105 0000 1001 3591 47

Raiffeisenlandesbank
Oberösterreich
RZOODE77XXX
DE92 7402 0100 0008 6078 48





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 ² /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.

Report no.: 2314831

1/1



DIN EN ISO 9001
DIN EN ISO 14001**
DIN EN ISO 45001**
DIN EN ISO 50001**
DIN EN ISO/IEC 17025**

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Fax +49 40 32523-285



江苏天和制药股份有限公司

JIANGSU TIANHE PHARMACEUTICAL CO.,LTD

中国 江苏省江都经济开发区三江大道 1 号 No.1 Sanjiang Road, Economic development zone, Jiangdu, Jiangsu, China
电话 PHONE:0514-86820810 传真 FAX:0514-86820808 邮箱 E-mail:jstianhe3@jstianhezy.com

检验报告单
CERTIFICATE OF ANALYSIS

J.ZL.00.228.2.0

品名 PRODUCT: Sulfacetamide Sodium	报告编号 CERTIFICATE NO: 0001		
批号 BATCH NO: S01-2504001	报告日期 CERTIFICATE DATE: 2025.07.21		
批量 BATCH SIZE: 500kg	生产日期 DATE OF MANUFACTURE: 2024.01.20		
有效日期 EXPIRY DATE: N/A	复测期 RETEST DATE: 2028.01.		
检验项目 Items	标准 Specifications	方法 Method	检验结果 Results
Characters		EP	
Appearance	White or yellowish-white, crystalline powder		White crystalline powder
Solubility	Corresponds		Corresponds
Identification			
B	Conform to the RS spectrum	EP(2.2.24)	Corresponds
F	Gives reaction of sodium	EP(2.3.1)	Corresponds
Test			
Appearance of solution	Clear and $\leq GY_4$	EP(2.2.2)	Corresponds
pH	8.0-9.5	EP(2.2.3)	9.3
Related substances		EP(2.2.29)	
Impurity A	$\leq 0.2\%$		0.03%
Single unspecified impurities	$\leq 0.10\%$		0.04%
Total impurities	$\leq 0.5\%$		0.09%
Sulfates	$\leq 200\text{ppm}$	EP(2.4.13)	$< 200\text{ppm}$
Water	6.0%~8.0%	EP(2.5.12)	7.1%
Assay(anhydrous)	99.0% ~ 101.0%	EP(2.5.8)	99.8%
Residual solvent		In house	
Ethanol	$\leq 0.5\%$		0.007%
Microbial clearance		In house	
TAMC	$\leq 10^2\text{cfu/g}$		1cfu/g
TYMC	$\leq 10^1\text{cfu/g}$		1cfu/g
Bile tolerant enterobacteria(GN)	None per 1g		N.D
Pseudomonas aeruginosa	None per 1g		N.D
Staphylococcus aureus	None per 1g		N.D
结论 CONCLUSION:	The above mentioned product conforms to purchasing specification		
备注 REMARKS:			
Prepared by/Date(QC)	Reviewed by/Date(QC)	Approved by/Date(QA)	
周建 2025.07.21	张小明 2025.07.21	王飞 2025.07.21	

Certificate of Analysis



Company
LANXESS Chemical B.V.
Montrealweg 15, harbour 4322
3197 KH BOTLEK ROTTERDAM
Netherlands

Date: 16.04.2025

Material No. 62609761		Material Description PUROX® BPHARMA ULTRA PURE GRADE BENZOIC ACID IN 25 KG BAG (55 BAGS PER PALLET)		
Customer Product No. 491170				
Customer Order Data				
Order No. 4000348088/000010		Your Order No. 4570111378		Ship-to Party 4000283592 DSV Air & Sea GmbH
Delivery Data				
Delivery No. 5000612938/000010	Delivered Quantity 2.750,000 KG	Planned Delivery Date 11.04.2025	Vehicle ID IS12SWT	
Batch 25063	Delivered Quantity 5.500,000 KG	Date Of Manufacture 05.02.2025	Best Before 05.02.2027	Production Plant Manufactured at Montrealweg 15, 3197 KH Rotterdam-Botlek, The Netherlands
This material meets the requirements of the latest editions of FCC, USP/NF, EP, BP, JP, ChP, E210. A sample was taken according to procedure; the result of analysis was:				

Certificate of Analysis



Batch	Material Description	Delivery No.	Planned Delivery Date
25063	PUROX® B PHARMA ULTRA PURE GRADE BENZOIC ACID IN 25 KG BAG (55 BAGS PER PALLET)	5000612938/000010	22.04.2025

Inspection Method / Characteristic	Result	Specification	Unit
1) AM 001 + 002; GC + HPLC Assay 1)	99,99	>= 99,98	%
2) AM 001: Gas chromatography Benzyl benzoate	0	<= 30	ppm
3) AM 004 : Spectrophotometric Color (molten product)	10	<= 25	APHA
4) IR Identification: passes the test2)3)			
5) AM 003 Karl-Fischer titration Water: max. 0.1%2)3)			
6) AM 002 HPLC Phthalic Acid: max. 50 mg/kg2)3)			
7) AM 005 ICP-AES Heavy Metals: max. 10 mg/kg2)3)			
8) AM 005 ICP-AES Iron: max. 1 mg/kg2)3)			
9) AM 006 Spectrophotometric Phenol: max. 2 mg/kg2)3)			
10) AM 007 Argentometric Chloride: max. 10 mg/kg2)3)			
11) AM 008 Microcoulometric Halogenated Compounds: max. 10 mg/kg2)3)			
12) AM 007 + AM 008 Total Chlorine: max. 10 mg/kg2)3)			

Certificate of Analysis



Batch	Material Description	Delivery No.	Planned Delivery Date
25063	PUROX® B FOOD/PHARMA ULTRA PURE GRADE BENZOIC ACID IN 25 KG BAG (55 BAGS PER PALLET)	5000612938/000010	22.04.2025
Inspection Method / Characteristic		Result	Specification
13)			
AM 011 Sulphated Ash:			
max. 0.01% ²⁾³⁾			
14)			
AM 009 Oxidizable Substances:			
max. 0.2 ml 0.02 mol KMnO ₄ /g ²⁾³⁾			
15)			
AM 011 Residue on Ignition:			
max. 0.05% ²⁾³⁾			
16)			
AM 010 Carbonizable Substances			
(matching fluid):			
max. Q ₂ ³⁾			
17)			
AM 012: Turbidity (20% solution in ethanol):			
max. 4.0 NTU ²⁾³⁾			
18)			
AM 013 Solidification point :			
121.5 – 122.5°C ²⁾³⁾			

1) Assay: 100% - total organic impurities

2) We confirm the conformity with the specification.

3) Analysis performed on periodic basis.

Purox® B Food/Pharma ultra pure grade Benzoic acid may contain < 0.5 mg/kg Cd, Pb; < 1 mg/kg Ag, As, Bi, Co, Cr, Cu, Hg, Mn, Ni, Sb, Sn, V, Zn

The data presented above relate to characteristics. They do not represent any assurance or warranty. This information does not release the customer from the obligation to carry out incoming inspections of goods, either as agreed or as required under the regulations.

This information has been issued by computer and is valid without signature.

In case of enquiries please contact: FF_COA@lanxess.com



GMP/ISO Certificate

华阴市锦前程药业有限公司

JQC (Huayin) Pharmaceutical Co., Ltd

Manufacturing Add.: Yuquan Road Huayin City Shaanxi Province P.R.China. PC:714203 Tel:+86-913-4356058/009; Fax:+86-913-4356066

分析报告单

CERTIFICATE OF ANALYSIS

STP-QS-464-T1-02

1/1

产 品 名 称 Product name	水杨酸 Salicylic acid		生 产 日 期 Manufacturing Date	2025.01.22
批 号 Batch No.	YC2501020		检 验 日 期 Test Date	2025.01.24
数 量 Quantity	1125kg		报 告 日 期 Issued Date	2025.01.25
检 验 依 据 Reference Spec.	欧洲药典 11.0 Ph.Eur.11.0		有 效 期 至 Expiry Date	2028.01.21
检查项目 Test items	规格 Specifications			检验结果 Test Results
性状 Characters	白色或几乎白色，结晶性粉末或白色或无色针状晶体，微溶于水，易溶于乙醇（96%），微溶于二氯甲烷 A white, or almost white, crystalline powder or white or colourless, acicular crystals, slightly soluble in water, freely soluble in ethanol (96 percent), sparingly soluble in methylene chloride.			符合规定 Complies
鉴别 Identification	A. 熔点 158 °C -161 °C Melting point 158 °C to 161 °C			159.0-160.5°C
	B. 红外吸收图谱应与标准品图谱一致 The IR spectrum of sample complies with Salicylic acid CRS			符合规定 Complies
	C. 呈正反应 Positive			符合规定 Complies
溶液外观 Appearance of solution	溶液应澄清 Solution is clear and colourless			溶液澄清 Solution is clear and colourless
相关物质 Related substances	Impurity A:	4-羟基苯甲酸 4-hydroxybenzoic acid	≤0.1%	0.001%
	Impurity B:	4-羟基间苯二甲酸 4-hydroxyisophthalic acid	≤0.05%	0.002%
	Impurity C:	苯酚 Phenol	≤0.02%	N.D
	其它杂质 Any other impurities		≤0.05%	N.D
	总杂质 Total impurities		≤0.2%	0.002%
氯化物 Chlorides	≤100ppm NMT100ppm			< 100ppm
硫酸盐 Sulfates	≤200ppm NMT200ppm			< 200ppm
重金属 Heavy metals	≤20ppm NMT20ppm			< 20ppm
干燥失重 Loss on drying	≤0.5% NMT0.5%			0.02%
硫酸盐灰分 Sulfated ash	≤0.1% NMT0.1%			0.02%
含量（以干品计） Assay (dried substance)	含 C ₇ H ₆ O ₃ 为 99.0%-100.5% Contains C ₇ H ₆ O ₃ 99.0%-100.5%			99.6%
【结论】 Conclusion	本品按欧洲药典 11.0 检验。结果[符]合规定 The product comply with the requirements of Ph.Eur.11.0			

负责人/日期:

QA 放行人/日期:

复核者/日期:

报告者/日期:

Q. M/Date:

QA Releaser/Date:

Reviewer/Date:

Reported by/Date:

2025.01.25

2025.01.25

2025.01.25

2025.01.25

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

Birkamidon Rohstoffhandels GmbH
 Wilhelmsaue 12 A • 10715 Berlin • Germany
 Telefon (030) 822 62 75, (030) 822 62 08 - 09
 Telefax (030) 827 040 47
 E-mail: info@birkamidon.com
www.birkamidon.com

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 ²	-	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

Customer
BRENNTAG SRL
CORP A SI CORP B, JUDET ILFOV
STR. GARII 2BIS
077040 CHIAJNA
ROMANIA

Certificate recipient
BRENNTAG SRL
Raluca Avadanei
CORP A SI CORP B, JUDET ILFOV
STR. GARII 2BIS
077040 CHIAJNA
ROMANIA

Transport	4112123853	Batch number	DOC0442571
Delivery note	74453348 900003	Order	6202547 000010
Shipping date	25.02.2025	Customer ref.	4570116833
Packaging	147 bag	Transport ID	MS23ADM MS06DTS

BICAR PHARMA EXC 13/27 SODIUM BICARBONATE

Industrial origin DOMBASLE-SUR-MEURTHE

Batch number DOC0442571 / **Quantity** 3.675 kg

Appearance : A white or almost white, crystalline powder.

Solubility : Soluble in water, practically insoluble in ethanol 96 per cent.

When heated in the dry state or in solution, it gradually changes into sodium carbonate.

Characteristics	Units	Value	Specification	Method	Ref
Total alkalinity (NaHCO ₃)	%	100,1	99,0 - 100,5	Solvay	1
Bicarbonate (NaHCO ₃)	%	99,9	>= 99,0	Solvay	1
PHE Identification A, B, C	-	Conform	Conform	Euro PH 2.3.1	2
Identification Bicarbonate	-	Conform	Conform	Euro PH 2.3.1	2
Identification Sodium	-	Conform	Conform	Euro PH 2.3.1	2
Appearance - Limpidity	-	Clear	Clear	Euro PH 2.2.1	2
Appearance - Colouring	-	Colourless	Colourless	Euro PH 2.2.2-2	2
Carbonates (pH Solution 5%)	-	8,0	<= 8,6	Euro PH 2.2.3	1
Test normal Carbonate	-	Faint pink color	Faint pink color	USP	2
Chlorides (Cl)	ppm	< 20	<= 150	Solvay	3
Sulfates (SO ₄)	ppm	4	<= 150	Solvay	1
Sulfur Compounds (SO ₄)	ppm	4	<= 150	Solvay	1
Ammonium (NH ₄)	ppm	< 20	<= 20	Euro PH 2.4.1	2
Arsenic (As)	ppm	< 0,4	<= 2,0	Solvay	1
Calcium (Ca)	ppm	74	<= 100	Solvay	1
Iron (Fe)	ppm	0,1	<= 5,0	Solvay	1
Heavy metals (Pb)	ppm	< 5	<= 5	Solvay	2
Loss on drying (H ₂ O)	%	< 0,10	<= 0,25	USP 731	2
Test insoluble substances	-	Complete/clear	Complete/clear	USP	2
Free flowing density	kg/dm ³	1,01	0,80 - 1,30	Solvay	3
European Pharmacopoeia	-	Conform 11th ed.	Conform 11th ed.		1
US Pharmacopoeia	-	Conform USPNF 2024	Conform USPNF 2024		1
< 0,315 mm	%	99,9	>= 95,0	Solvay	1
< 0,125 mm	%	12,2	<= 20,0	Solvay	1
Production date		13.02.2025			
Retest date		13.02.2028			

SOLVAY

**SOLVAY
OPERATIONS
FRANCE S.A.S.****SOLVAY Product Data Sheet**

CoA Healthcare products

SPE – B 05.01.42 - 04/2016 - ED. 1**Customer**BRENNTAG SRL
CORP A SI CORP B, JUDET ILFOV
STR. GARII 2BIS
077040 CHIAJNA
ROMANIA**Certificate recipient**BRENNTAG SRL
Raluca Avadanei
CORP A SI CORP B, JUDET ILFOV
STR. GARII 2BIS
077040 CHIAJNA
ROMANIA**Transport** 4112123853**Delivery note** 74453348 900003**Shipping date** 25.02.2025**Packaging** 147 bag**Batch number** DOC0442571**Order** 6202547 000010**Customer ref.** 4570116833**Transport ID** MS23ADM

MS06DTS

Container (s)

- 1 - Analysis made on each batch
- 2 - Analysis made weekly
- 3 - Analysis made once per month

The Solvay methods have been validated in our laboratory. The specifications are as defined in the product data sheet.

This product is manufactured under GMP conditions (IPEC-PQG GMP for excipients)

This product is suitable to be used as pharmaceutical excipient. It is not authorized as active pharmaceutical ingredient (API)

This product is not intended to be used for parenteral applications or peritoneal dialysis.

Residual solvents: Test not applicable, no organic solvent is used in the manufacturing process.

This Certificate was automatically produced and is valid without signature.

This certificate is issued on the basis of analytical results recorded in the Laboratory informatic database system. Data are entered in such system after validation by managers in charge of these analytical controls.

ManufacturerSOLVAY OPERATIONS FRANCE S.A.S.
2 RUE GABRIEL PERI
54110 DOMBASLE-SUR-MEURTHE
FRANCE**Product released**

By Paul PERSAVALLI

Date 17.02.2025 Time 09:17:44



鲁维制药集团有限公司

Luwei Pharmaceutical Group Co.,Ltd.

Shuangfeng Industrial Park Zichuan District Zibo 255190 China

Tel: 0086 533 6220996 Fax: 0086 533 6220993

Report No.:LWPC-1C₁-24-02-014

CERTIFICATE OF ANALYSIS

Date:Mar.08,2024

Product Name	ASCORBIC ACID	
Analysis Standard	BP /USP /EP /FCC/E300	
Batch No.	1240112007	
Quantity	18000kgs	
Manufacture Date	Feb.,2024	
Shelf Life	4 Years	
Net/Gross Weight	25.0kgs/26.3kgs	
Analysis Contents	Analysis Standard	Analysis Results
Characteristics	White or almost White crystals Crystalline Powder	Pass
Identification	Positive Reaction	Positive
Melting Point	About 190℃	191.20℃
PH(5% solution in water)	2.1-2.6	2.36
PH(2% solution in water)	2.4-2.8	2.57
Clarity Of Solution	Clear	Clear
Colour Of Solution	≤BY ₇	<BY ₇
Copper	≤5ppm	<5ppm
Heavy Metals	≤10ppm	<10ppm
Mercury	≤0.1ppm	<0.1ppm
Lead	≤2ppm	<2ppm
Fe	≤2ppm	<2ppm
Arsenic	≤3ppm	<3ppm
Cadmium(Cd)	≤1ppm	<1ppm
Oxalic Acid	≤0.2%	<0.2%
Loss on Drying	≤0.4%	<0.4%
Sulphate Ash(Residue On Ignition)	≤0.1%	<0.1%
Specific Optical Rotation	+20.5° -+21.5°	+20.88°
Organic Volatile Impurities	Pass	Pass
Assay	99.0%-100.5%	99.67%
Conclusion	The Above-Mentioned Product Conforms To BP/USP/EP/FCC/E300	

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 Pharmacopoeia 11.0 for Boric Acid

Analysis:

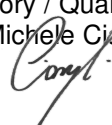
<u>Characteristics</u>		Units	Test	Specific		<u>Analytical chemistry procedure employed</u>
			Results	Min.	Max.	
Description		:	Powder, white granules			
Identification		:	Positive			
Appearance of the solution		:	According to Ph. Eur.			
Solubility in alcohol		:	According to Ph. Eur.			
Organic matter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



CERTIFICATE OF ANALYSIS

Material - Information

Insp. Lot No.	10000819683	Batch No.	SP15003159
Product Des.	SIMBASE METHYLENE BLUE (BB9)	EINECS No.	200-515-2
CAS No.	61-73-4	C.I. Name	Basic Blue 9
C.I. No.	52015		

Characteristics	Method	Specification	UOM	Result
Appearance		Dark Greenish to Dark Brownish Powder		Complies
Identification (A, B, C, D)				Pass
Solubility at 0.1% (Distilled Water)		Similar to Standard		Pass
Arsenic (as As)		(Max.) 8.00	mg/kg	2.60
Iron		Passes Test		Pass
Lead (as Pb)		(Max.) 20.00	mg/kg	1.90
Zinc		Pass Turbidity Test		Pass
Loss on Drying (105°C)		8.00-15.00	%	9.90
Total colour/Assay		96.00-101.00	%	99.00
Wavelength of Maximum Absorption (λ max) in 1:1 IMS:DI Water		658.0-664.0	nm	664.0
Specific Absorption (E 1%/1cm) at λ max		(Min.) 2300.0		2510.0
REACH REGISTRATION DECLARATION: We confirm that above product is Not REACH Registered. No obligation of REACH registration due to less than 1 ton\calendar year quantity and/or low volume sales meaning not viable for registration.				Complies
Shelf Life				26.02.2030
Storage				Ambient temperature. Please keep away from light and moisture.

The compliance to the above mentioned specification can be verified using respective methods of analysis.

Disclaimer : Above information is correct at the time of issue but may be subject to alteration. The information on the specification remains the property of ROHA Group (JJT Group companies). Information is correct to the best of our knowledge and it should not be construed as warranty. Users should conduct their own tests to determine the suitability of this product/data for this purpose. Users must satisfy themselves suitability of product, ingredients in accordance with regulations applicable and suitability of product in end application. Roha Group (JJT Group Companies) shall not be liable for any claims or losses of any nature arising directly or indirectly from use of the information, data or other material on this document.



Certificate of Analysis

Send To: DSV SOLUTIONS COM. DRAGOMIRESTI VALE, DE 287/1-D1 DRAGOMIRESTI VALE 077096 ROMANIA A KM 13A A1	Shipment Number	SB00067324
	Quantity Shipped	16.500 KG
	Batch Number	2328
	Prod. in week of dd/mm/yy	10/07/24
	Expiration Dt	9/07/27

Product Description	PUROX®S GRAINS PURE GRADE SODIUM BENZOATE IN 25 KG BAGS / 55 BAGS PER PALLET
CAS Number:	532-32-1
EINECS:	208-534-8
REACH:	01-2119460683-35-0000
Vehicle ID:	FMBU0082338

Test Description	Minimum	Maximum	Test Result
Acidity mg NaOH/g	0,00	0,40	0,00
Alkalinity mg HCl/g	0,00	0,37	0,06
Assay % (m/m) 1)	99,90	100,00	99,99
Color (10% (m/m) sol in H ₂ O) APH	0	10	1
Loss on Drying % (m/m)	0,0	1,0	0,1
Phenol mg/kg	0,0	2,0	0,1
Appearance			WHITE GRAN
Odor			ODORLESS
Identification	To Pass	--	Passes Test
Insoluble Matter	To Pass	--	Passes Test
Taste and Odor	To Pass	--	Passes Test
Heavy Metals mg/kg	0	10	<10
Iron mg/kg	0	1	<1
Mercury mg/kg	0,0	0,1	<0,1
Sulphate mg/kg	0	50	<50
Chloride mg/kg	0	50	<50
Halogenated Compounds mg/kg	0	25	<25
Total Chlorine mg/kg	0	75	<75
Phthalic Acid mg/kg	0	50	<50
Turb (10% (m/m) sol water) NTU	0,0	0,5	<0,5
Oxidiz Substs ml 0.02 mol KMnO ₄ /g	0,00	0,10	<0,10
Organic Volatile Impurities	To Pass	--	Passes Test
Polycyclic Acids	To Pass	--	Passes Test

- * Purox S grains, pure grade sodium benzoate
- * contains <0,5 mg/kg: Cd, Pb and <1 mg/kg: Ag, As,
- * Bi, Co, Cr, Cu, Mn, Ni, Sb, Sn, V, Zn.
- * 1) Assay: 100% - total organic impurities
- * This material meets the latest requirements
- * of FCC, USP/NF, Ph.Eur, BP, JP, E211.
- * All tests are performed according to EKC BV
- * Methods of Analysis (latest edition).

Yours Faithfully,

Walter Mekkelholt, Quality Manager

Certificate is password controlled, computer generated, thus not requiring a signature

Address
Fascinatio Boulevard 230
3065 WB Rotterdam
The Netherlands

Manufacturing Address
Montrealweg 15
3197 K H Rotterdam
The Netherlands

Communication
www.emeraldmaterials.com
E-mail Purox.info@emeraldmaterials.com
FAX +31 (0)20 794 8466

Emerald Kalama Chemical, B.V.

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常州市阳光药业有限公司
CHANGZHOU SUNLIGHT PHARMACEUTICAL CO.,LTD

检验报告单

Certificate of Analysis

编号: RD-TS/F0001-7/10

实施日期: 2023-08-15

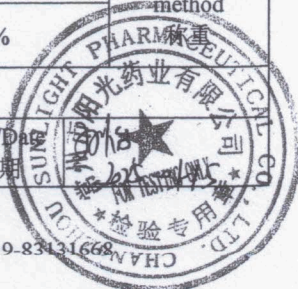
Product name: Benzocaine 产品名称: 苯佐卡因		Date of manufacture 生产日期		Jan.04,2025		Date of Expiry 有效期至		Jan.03,2028	
Package: 25kg/Fiber drum 包装: 25kg/纸板桶		Batch number 产品批号		C0012501004		Batch size 批 量		1059.80kg	
Testing specifications 检验标准		Current EP11.0 现行 EP11.0 (理化&仪器 Physicochemical&Instrument) ChP2020(微生物 Microbiological)				Series number of testing 检验单号		ZJC001250004EP/ZJC001250004EP/ ZJC001250004	
Items tested 检测项目		Specification 标准规定				Result 检测结果		Method 检测方法	
Characters 性 状		Appearance: White or almost white, crystalline powder or colorless crystals 外观:白色或几乎白色, 结晶性粉末或无色结晶				White crystals 白色结晶		Visual 目测	
		Solubility: Very slightly soluble in water, freely soluble in ethanol(96%). 溶解性:极微溶于水, 易溶于乙醇(96%)				Conforms 符合规定		Visual 目测	
Identification 鉴 别		IR should comply with the standard spectrum 红外图谱应与对照品图谱一致				Conforms 符合规定		EP2.2.24	
Loss on drying 干燥失重		≤0.5%				0.01%		EP2.2.32	
Sulphated ash 硫酸盐灰分		≤0.1%				0.04%		EP2.4.14	
Related substances 有关物质		未知单个杂质 Any unspecified impurity≤0.10%				Not detected 未检出		EP2.2.29	
		总杂质 Total impurities≤0.2%				Not detected 未检出			
Assay(dried substance) 含量 (以干燥品计)		99.0-101.0%				99.9%		EP2.5.8	
Total aerobic microbial count 需氧菌总数(ChP)		Not more than 10 ³ cfu/g 不得超过 10 ³ cfu/g				<10 cfu/g		ChP2020	
Total yeasts and molds count 酵母菌和霉菌总数(ChP)		Not more than 10 ² cfu/g 不得超过 10 ² cfu/g				<10 cfu/g			
E.Coli 大肠埃希菌(ChP)		Negative 不得检出				Not detected 未检出			
Staphylococcus aureus 金黄色葡萄球菌(ChP)		Negative 不得检出				Not detected 未检出			
Pseudomonas aeruginosa 铜绿假单胞菌(ChP)		Negative 不得检出				Not detected 未检出			
Granularity 粒度		Not less than 90% of particles pass 20 mesh 能通过 20 目筛的颗粒及粉末不得小于 90%				97%		Weighing method	
		Not more than 90% of particles pass 40 mesh 能通过 40 目筛的颗粒及粉末不得大于 90%				58.0%			
Conclusion 结论		Qualified 合格							
Reporter/Date 报告人/日期		2025-01-14		Review/QC Director/Date 审核人/QC 主任/日期		2025-01-14		Approve/Qualified person/Date 放行人/质量授权人/日期	

COS No.: R1-CEP 2004-008-Rev 06

Manufactured by: Changzhou Sunlight Pharmaceutical Co., Ltd. 生产商:常州市阳光药业有限公司 TEL: 0519-83131668

ADD: 216 Yunnan West Road, Benniu Town, Xinbei District, Changzhou City, Jiangsu Province, China

地址: 中国江苏省常州市新北区奔牛镇运南西路 216 号



Certificate of Analysis

Mat.-No 1000175
Product Benzyl Benzoate BP98
Your Product 462084

Batch-No 0000206635
No. of Analysis 10000070697

Characteristic	Value	Unit	Lower Limit	Upper Limit
Appearance (sensorial)	Corresponds	clear liquid		
Colour (sensorial)	Corresponds	colourless to pale yellowish		
Relative density (20/20)	1,121		1,118	1,122
Refractive index (at 20° C)	1,569		1,568	1,570
Infrared spectrum	corresponds BP			
Acid Value	0,10			0,56
Solidification point	20,0	°C	17,0	
Sulfated Ash	0,1	%		0,1
Chromatographic Profile	corresponds			
Benzylbenzoate	99,8	A%	99,0	

Observations/ Remarks: corresponds to BP

Date of manufacture 28.04.2024 Date of retest 27.04.2027

Created JR
Date 15.05.2024

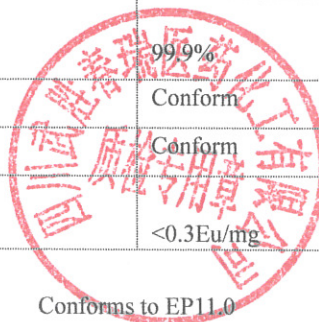
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四川武胜春瑞医药化工有限公司
Sichuan Wusheng Chunrui Medicine Chemical Co., Ltd.

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℃~158℃ B. IR E. It gives reaction(a) of chlorides	155.0℃-156.0℃ 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	报告人 REPORTER		



2025.07.21

2025.07.21



Macco Organiques, s.r.o.

Innovative organics, it's a matter of life...

CERTIFICATE OF ANALYSIS
No.: FCH6180 (20/2023/231213) -2023
Calcium chloride dihydrate
Ph. Eur. 11th, FCC11, E509

Customer: **Brenntag Austria GmbH**
France

Order No. 4521597477
Batch No. C5859
Manufacturing Date 17.10.2023
Re-test Date 17.10.2027

Appearance and Solubility: White or almost white, crystalline powder, hygroscopic. Freely soluble in water, soluble in ethanol (96%)

Parameter	Specification	Result on Ph. Eur.
Identity	A: Chlorides	complies
	B: Calcium	complies
	C: Limit of the assay	complies
	97.0 - 103.0 per cent	101.5 %
Assay		
Appearance of solution	Clear, NM intensely coloured than ref.	
	solution Y6	complies
Acidity or alkalinity	NMT 0.2 mL of 0.01M HCl/NaOH	complies
Sulfates	Maximum 300 ppm	<300 ppm
Aluminium	Maximum 1 ppm	<1 ppm
Iron	Maximum 10 ppm	<10 ppm
Magnesium and alkali metals	Maximum 0.5 per cent	<0.5 %
Parameter	Specification	Result on FCC
Assay	99.0-107.0 %	101.5 %
Arsenic	NMT 3 mg/kg	<3 mg/kg
Fluoride	NMT 0.004 %	<0.004 %
Lead	NMT 5 mg/kg	<5 mg
Magnesium and Alkali salts	NMT 20 mg (NMT 4.0 %)	<4.0 %
Parameter	Specification	Result on E509
Magnesium and Alkali salts	NMT 5% (as sulphates)	<5 %
Fluoride	NMT 40 mg/kg	<40 mg/kg
Arsenic	NMT 3 mg/kg	<3 mg/kg
Lead	NMT 2 mg/kg	<2 mg/kg
Mercury	NMT 1 mg/kg	<1 mg/kg

Approved by Manager of Quality Control: Eliška Hepnarová

Originally produced by **Macco Organiques, s.r.o., Czech Republic**

Eliška
Hepnarová

Digitally signed by
Eliška Hepnarová
Date: 2023.10.26
13:53:44 +02'00'



Potassium Chloride
Ph. Eur., injectable grade, API

Customer: **SC Balkan Pharmaceuticals SRL**
Moldova (the Republic of)

Order No. Customer: email 28.5.2025
Order No. Macco: 30/2025/251117
Batch No.: 3425000397
Manufacturing Date: 31-MAY-2025
Retest Date: 30-MAY-2028

Appearance (Ph.Eur.): White or almost white, crystalline powder or colourless crystals.
Solubility (Ph.Eur.): Freely soluble in water, practically insoluble in anhydrous ethanol.

Parametr	Specification	Results of Ph. Eur.
Identification - Chlorides	Identified	Identified
Identification - Potassium	Identified	Identified
Clarity of solution	Clear	Clear
Colour of solution	Colourless	Colourless
Acidity/Alkalinity	Complies	Complies
Bromide	Max. 0.1 %	<0.1 %
Iodide	Complies	Complies
Sulfate	Max. 300 ppm	13 ppm
Aluminium	Max. 1.0 ppm	<0.1 ppm
Iron	Max. 20 ppm	<1 ppm
Magnesium and alkali earth metals	Max. 200 ppm	12 ppm
Sodium	Max. 0.1 %	<0.1 %
Loss on Drying	Max. 1.0 %	<0.1 %
Assay	99.0-101.0 %	100.0 %

Parametr	Specification	Results of Microbial Parameters
TAMC	Max. 2000 CFU/g	<10 CFU/g
TYMC	Max. 200 CFU/g	<10 CFU/g

Parametr	Specification	Results of BE
Bacterial Endotoxins	Max. 3 EU/g	<3 EU/g

Approved by Manager of Quality Control: Eliška Hepnarová

We herewith confirm that this product meets current editions of the pharmacopoeias mentioned in this certificate.
This certificate does not release the customer from product check-in on receipt.
This Certificate of Analysis has been approved electronically and is valid without a signature.

Date of issue: 25.06.2025

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		conforms		conforms	-
according to the regulations					
Residual Solvents		Impossible due to		conforms	-
according ICH-guideline		production process			
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

CERTIFICATE OF ANALYSIS

PRODUCT:	COLLOIDAL SILVER
BATCH NUMBER:	C25-0246

DETERMINATIONS	SPECIFICATIONS	RESULTS	METHOD
Appearance	Green or bluish-black metallic shiny flakes or powder, hygroscopic	CORRECT	Ph.Eur 11
Characteristics: solubility	Freely soluble or soluble in water, practically insoluble in ethanol and methylen chloride	CORRECT	Ph.Eur 11
Identification A	Violet color	CORRECT	Ph.Eur 11
Identification B	Precipitate soluble in water	CORRECT	Ph.Eur 11
Identification C. Reaction of silver	White precipitated dissolves on dilute ammonia	CORRECT	Ph.Eur 11
Solution S	Complete	CORRECT	Ph.Eur 11
Alkalinity	$\geq 1,5$ ml NaOH 0,1N	2,2	Ph.Eur 11
Silver Ions	No precipitate	CORRECT	Ph.Eur 11
Sensitivity to electrolytes	No opalescence	CORRECT	Ph.Eur 11
Water insoluble substances	$\leq 1,0$ %	0,1	Ph.Eur 11
Loss on drying 80°C	$\leq 8,0$ %	1,1	Ph.Eur 11
Silver content	70,0 - 80,0 %	70,6	Ph.Eur 11

MANUFACTURING DATE: 26/03/2025	RETEST DATE: 26/03/2027
RELEASE DATE: 16/04/2025	16/04/2025

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





BULLETIN D'ANALYSES - CERTIFICATE OF ANALYSIS

Date :	30-May-25	Date de production : Manufacturing date :	May 2025
Lot n° Batch #	Stellux AI-PF (EP Lanolin) L06036/2	Date de péremption : Expiry date :	May 2027

	Current EP	Specifications	Results
Identification A-B – Identification A-B.....	---	---	Conform
Acidité – FFA-Free Fatty Acids (%).....	2.5.1.	0.50 max	0.40
Indice d'acide - Acid value	2.5.1.	1 max	0.80
Humidité - Moisture (%).....	2.2.32.	0.50 max	0.10
Point de fusion - Melting point (°C)	2.2.16.	36 – 42	41.0
Point de goutte - Dropping point (°C).....	2.2.17. (Method B)	38 – 44	43.0
Cendres - Ash (%).....	2.4.14.	0.15 max	0.03
Indice de saponification -Saponification value (mg KOH/g)....	2.5.6.	90 – 105	98.4
Indice d'iode - Iodine value (g I ₂ /100g)	2.5.4. (Wijs)	28 – 38	33.7
Indice de peroxyde - Peroxide value (meq O ₂ /kg).....	2.5.5. (Method A)	20 max	10.9
Alcalinité – Water-soluble acids & alkalies.....	---	---	Conform
Substances oxydables – Oxidizable substances *.....	---	---	Conform
Paraffines – Paraffins *	---	1 max	Conform
Chlorures - Chlorides (ppm)	---	150 max	<150
Absorption d'eau - Water absorption (%)	---	200 min	250 min
Teneur en BHT - Degree of BHT (ppm)	---	200 max	Conform
Pesticides – Pesticides (ppm).....	GC	1 max	0.077
Couleur - Colour @ 80°C.....	Gardner	10 max	8.0

* Analysis performed every year on 10 consecutive batches. Accepted by: Isabelle Locment – Quality Manager

STELLA S.A.
Rue des Garennes 9 B
7700 MOUSCRON
Tél. +32 (0) 56 56 18 42
Fax +32 (0) 56 56 18 48

S.A. au capital de 1 950 000 euros
Zoning industriel - Rue des Garennes, 9 B - B-7700 Mouscron - BELGIQUE
Tél. 32 (0) 56 56 18 42 - Fax 32 (0) 56 56 18 48 - stella@stella.fr
R.C. Tournai 60.577 - TVA BE 0425 151 097



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CERTIFICAT PESTICIDES - PESTICIDES CERTIFICATE

Stellux AI-PF (EP Lanolin) – Batch # L06036/2

Organochlorinated pesticides (ppm)			Organophosphorated pesticides (ppm)		
	Results	Specifications		Results	Specifications
Tecnazène	n.d.	< 0.050	Propétamphos	n.d.	< 0.500
Alpha-Hexachlorocyclohexane	n.d.	< 0.050	Diazinon	0.077	< 0.500
Hexachlorobenzène	n.d.	< 0.050	Dichlofenthion	n.d.	< 0.500
Béta-Hexachlorocyclohexane	n.d.	< 0.050	Chlorpyrifos-méthyle	n.d.	< 0.500
Lindane	n.d.	< 0.050	Fenchlorphos	n.d.	< 0.500
Delta-Hexachlorocyclohexane	n.d.	< 0.050	Malathion	n.d.	< 0.500
Heptachlore	n.d.	< 0.050	Chlorpyrifos	n.d.	< 0.500
Aldrine	n.d.	< 0.050	Bromophos	n.d.	< 0.500
Heptachlore-époxyde	n.d.	< 0.050	Pirimiphos-éthyle	n.d.	< 0.500
O,p'-DDE	n.d.	< 0.050	Chlorfenvinphos E	n.d.	< 0.500
Alpha-Endosulfan	n.d.	< 0.050	Chlorfenvinphos Z	n.d.	< 0.500
Dieldrine	n.d.	< 0.050	Bromophos-éthyle	n.d.	< 0.500
P,p'-DDE	n.d.	< 0.050	Tétrachlorovinphos	n.d.	< 0.500
O,p'-DDT	n.d.	< 0.050	Ethion	n.d.	< 0.500
Endrine	n.d.	< 0.050	Carbophénouthion	n.d.	< 0.500
Beta-Endosulfan	n.d.	< 0.050	Phosalone	n.d.	< 0.500
O,p'-DDD	n.d.	< 0.050	Coumaphos	n.d.	< 0.500
P,p'-DDD	n.d.	< 0.050			
P,p'-DDT	n.d.	< 0.050			
Méthoxychlore	n.d.	< 0.050			
TOTAL (ppm) :	n.d.		TOTAL (ppm) :	0.077	

Pyrethroid pesticides (ppm)		
	Results	Specifications
Cyhalothrine (2 isomères)	n.d.	< 0.500
Cis-Permethrine	n.d.	< 0.500
Trans-Permethrine	n.d.	< 0.500
Cyperméthrine (4 isomères)	n.d.	< 0.500
Fenvalérate (2 isomères)	n.d.	< 0.500
Deltaméthrine	n.d.	< 0.500
TOTAL (ppm) :	n.d.	

	Results	Specifications
TOTAL PESTICIDES (ppm)	0.077	< 1ppm

n.d. = below detection limit

PRO02/01-B

STELLA S.A.
Rue des Garennes 9 B
7700 MOUSCRON
Tél. +32 56 56 18 42
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S.A. au capital de 1 950 000 euros
Zoning industriel - Rue des Garennes, 9 B - B-7700 Mouscron - BELGIQUE
Tél. 32 (0) 56 56 18 42 - Fax 32 (0) 56 56 18 48 - stella@stella.fr
R.C. Tournai 60.577 - TVA BE 0425 151 097



CLOSE TO NATURE



ELTON CORPORATION SA ROMANIA

Campului street, 5
077145 Comuna Pantelimon
JUDETUL ILFON
ROMANIA

02/06/25 - FL

DECLARATION OF QUALITY & CONFORMITY

We, STELLA S.A. Zoning Industriel – Rue des Garennes 9 B - B 7700 MOUSCRON, Belgium – do certify that the below described products, delivered to ELTON CORPORATION SA ROMANIA, are processed according to ISO 9001 Quality standards and comply with the BP 98 & the European Pharmacopeia III Edition 1997 criteria.:

Product	Anhydrous Lanolin – pharma grade
Commercial designation	STELLUX AI PF
Batch	L06036/2

The above mentioned products are not hazardous to health and are environment-friendly according to EC rules & regulation.

To whom it may concern,

STELLA S.A.
Rue des Garennes 9 B
7700 MOUSCRON
Tél. +32/56.56.18.42
Fax +32/56.56.18.48





Mouscron, janvier 2025

ATTESTATION BSE TSE / **BSE TSE STATEMENT**

Lanoline Stellux AIPF (NS)- Lanoline Stellux AIPF (BHT) - Lanoline Stellux AIPF (E200)
Lanoline Stellux HA (NS) – Lanoline Stellux HA (BHT) – Lanoline Stellux HA (E200)
Lanoline Stellux AILP (NS)- Lanoline Stellux AILP (BHT) - Lanoline Stellux AILP (E200)
Lanoline Stellux AI10-40(NS)- Lanoline Stellux AI10-40 (BHT) - Lanoline Stellux AI10-40 (E200)
Lanoline Stellux AI (NS)- Lanoline Stellux AI (BHT) - Lanoline Stellux AI (E200)
Stellanol (NS)– Stellanol (BHT) – Stellanol (E200)
Stellanol PF(NS) – Stellanol PF (BHT) – Stellanol PF (E200) – Stellanol Liquide PF (E200)
Lanodur (E200) – Lanodur C (E200)
Alcool de lanoline SSR EP (E200)
Woolgrease Fatty Acids

Nous, Stella SA, domiciliés 9B, rue des Garennes, B-7700 Mouscron, Belgique, attestons que les références listées ci-dessus sont d'origine animale (ovine) à partir de graisses de laine obtenues à partir de la laine du mouton vivant, ce dernier étant tondu tous les ans pour son bien-être.

Les graisses de laine sont strictement issues de laines originaires de pays exclus de tout risque de contamination BSE (Australie, Nouvelle Zélande, Argentine et Uruguay) et collectées sur des animaux sains et vivants (Moutons d'élevage, exclusivement).

Ces références sont en conformité avec :

- La note explicative EMA/410/Rev.3 du 5 mars 2011 concernant la réduction du risque de transmission des agents des encéphalopathies spongiformes animales par les médicaments à usage humain et vétérinaire.

La matière première utilisée dans leur fabrication provient d'animaux de pays pour lesquels selon les listes tenues par l'Office international des épizooties (OIE):

- Aucun bétail né dans le pays concerné n'est tombé malade de l'ESB depuis 1990 ;
- Au cours des cinq dernières années (à partir du moment de la récupération du matériel), la tremblante du mouton s'est produite avec une fréquence ne dépassant pas des cas isolés conformément aux recommandations de l'Office International des Epizooties (OIE).

Nos conditions de traitement de la matière première sont équivalentes à celles décrites dans la réglementation.

- Le règlement CE 1069/2009 (Cat. 3).



We, Stella SA, domiciled at 9B, rue des Garennes, B-7700 Mouscron, Belgium, certify that the references listed above are of animal (ovine) origin from wool fats obtained from the wool of alive sheep, the latter being shorn every year for its well-being. Wool fats are strictly obtained from wool originating in countries excluded from any risk of BSE contamination (Australia, New Zealand, Argentina and Uruguay) and collected from healthy and live animals (exclusively farmed sheep).

These references complies with:

- *Explanatory note EMA / 410 / Rev.3 of 5 March 2011 concerning the reduction of the risk of transmission of agents of animal spongiform encephalopathies by medicinal products for human and veterinary use.*

The starting material used in their manufacture originates from animals from countries in which, according to the lists kept by the Office International of Epizooties (OIE) :

- *No cattle born in the concerned country has fallen ill with BSE since 1990 and*
- *During the last five years (from the moment of recovery of the material) Scrapie has occurred with a frequency of not more than isolated cases - pursuant to the Office International of Epizooties (OIE)*

Our process conditions of entering raw materials are equivalent to those described in the regulation.

- *Regulation 1069/2009 (Cat. 3).*

Isabelle Locment,
Responsable Assurance Qualité



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STELLA S.A. – 9bis rue des Garennes 7700 Mouscron, Belgium

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			
ContentsSpecification:CEP(R1-CEP 2004-016-Rev 03) (SOP.7.1.073) +Customer’ s RequirementResults of analysis 项 目标 准: CEP(R1-CEP 2004-016-Rev 03) (SOP.7.1.073) +客户要求检验结果					
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≤10³cfu/g 需氧菌总数≤10³cfu/g		<1×10²cfu/g	
		(2) TYMC≤10²cfu/g 霉菌、酵母菌总数≤10²cfu/g		<1×10¹cfu/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	
Conclusion: Conforming to CEP(R1-CEP 2004-016-Rev 03)+Customer’ s Requirement.					
结论: 符合 CEP(R1-CEP 2004-016-Rev 03)+客户要求。					

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)

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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
CHARACTERS			
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
IDENTIFICATION			
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
TESTS			
Appearance of solution	Solution S is clear and not more intensely colored than reference solution BY ₆ .		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



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Website: www.synnatcharma.com

Format No. : QC/GEN/34/FT-03
Effective date: 16.10.2023

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
ADDITIONAL TESTS			
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: Rane
Date : 08/07/25

CERTIFICATE OF ANALYSIS

PRODUCT:	SILVER PROTEINATE
BATCH NUMBER:	PTOR24-0354

DETERMINATIONS	SPECIFICATIONS	RESULTS	METHOD
Characteristics	Light yellow-brown to brown powder. Odourless. Hygroscopic	CORRECT	FRENCH Ph. IX
Characteristics: solubility	Practically insoluble in alcohol and ether. Slowly but easily soluble in water.	CORRECT	FRENCH Ph. IX
Identification A. Reaction of silver	White precipitate dissolves on dilute ammonia	CORRECT	FRENCH Ph. IX
Identification B.	Colorless	CORRECT	FRENCH Ph. IX
Identification C.	Violet color	CORRECT	FRENCH Ph. IX
Solution S	Complete	CORRECT	FRENCH Ph. IX
Appearance of solution	Without residue after 30 min	CORRECT	FRENCH Ph. IX
Alkalinity	= > 1.5 ml NaOH 0.1N	3.3	FRENCH Ph. IX
Silver Salts	No opalescence	CORRECT	FRENCH Ph. IX
Silver content	7.5 -8.5 %	7.8	BELGIUM Ph. VI
Loss on drying	< = 8 %	3.7	BELGIUM Ph. VI

MANUFACTURING DATE: 11/06/24

 RETEST DATE: 11/06/27
10/07/24



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TERESA BARRENA
QUALITY ASSURANCE

检 验 报 告 单

CERTIFICATE OF ANALYSIS

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品 名 Name of product	结晶磺胺 4-aminobenzene sulfonamide	报告日期 Report Date	2025 年 07 月 11 日 July 11, 2025
批 号 Lot NO.	250508	生产日期 Manufacture Date	2025 年 05 月 May, 2025
数 量 Net weight	75kg	有效期至 Retest Date	2028 年 05 月 May, 2028
检验项目 ANALYTICAL ITEMS	标准规定值 SPECIFICATION		检验结果 ANALYTICAL RESULTS
Appearance	White crystalline granule or powder		White crystalline granule
Solubility	Dissolves in solutions of alkali hydroxides		Conforms
Identification	Comply with EP standard		Conforms
Melting point	164.5°C ~ 166.0°C		165.1°C ~ 165.6°C
Acidity	NMT. 0.2ml		符合 Conforms
Clarity of solution	Should be clear		符合 Conforms
Related substances	Any single impurity NMT0.5%		Conforms
	Total impurities NMT1.0%		Conforms
	Purity NLT 99.0%		99.74%
Loss on drying	Not more than 0.5%		0.07%
Sulfated ash	NMT. 0.1%		0.05%
Microbiological limits	TAMC<1000cfu/g TYMC<100cfu/g		Conforms
含量 Assay	含C ₆ H ₈ N ₂ O ₂ S应不小于98.0% NLT 99.0% of C ₆ H ₈ N ₂ O ₂ S		99.8%
检验依据 According to	EP11		
结 论 Conclusion	合格 Complies		

检验者: 王美芳
Analyst:复核者: 严银凤
Checker:负责人: 缪彩珍
Supervisor: