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CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : **1353/24**

Issue Date: **December 18, 2024**

Lot. n°: **C010424032**

Manufacturing date: **December 09, 2024**
Expiry date: **December 09, 2029**

BORIC ACID EP

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

Analysis:

Characteristics		Units		Test Results	Specific Min.	Specific Max.	Analytical chemistry procedure employed
Description			:	**Powder, white granules**			
Identification			:	**Positive**			European Pharmacopoeià
Appearance of the solution			:	**According to Ph. Eur.**			European Pharmacopoeià
Solubility in alcohol			:	**According to Ph. Eur.**			European Pharmacopoeià
Organic matter			:	**According to Ph. Eur.**			European Pharmacopoeià
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_3BO_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
M[redacted]ipoli

GMP Certificated
华阴市锦前程药业有限公司
JQC (Huayin) Pharmaceutical Co., Ltd
地址:陕西省华阴市玉泉路中国 Add:Yuquan Road Huayin City Shaanxi Province China PC:714203 Tel:(86)913-4356999 Fax:(86)913-4355066

分析报告单
CERTIFICATE OF ANALYSIS

STP-QS-464-T1-02

产品名称 Product name	水杨酸 Salicylic acid		生产日期 Manufacturing Date	2024.02.25
批号 Batch No.	YC2402028		检验日期 Test Date	2024.02.26
数量 Quantity	1125kg		报告日期 Issued Date	2024.02.27
检验依据 Reference Spec.	欧洲药典 11.0 Ph.Eur.11.0		有效期至 Expiry Date	2027.02.24
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 point158 °C to 161 °C			158.6-160.2°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%
	ImpurityC:	苯酚 Phenol	≤0.02%	N.D
	其它杂质 Any other impurities		≤0.05%	0.001%
	总杂质 Total impurities		≤0.2%	0.003%
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%			0.05%
硫酸盐灰分 Sulfated ash	≤0.1% NMT0.1%			0.03%
含量（以干品计） Assay (dried substance)	含 $C_7H_6O_3$ 为 99.0%-100.5% Contains $C_7H_6O_3$ 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: 李文亮 2024.02.27
Q.M/Date:

QA 放行人/日期: 侯耀 2024.02.27
QA Releaser/Date:

复核者/日期: 晴 2024.02.27
Reviewer/Date:

报告者/日期: 李静 2024.02.27
Reported by/Date:

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VAT Registration No PL8130012922.

CERTIFICATE OF ANALYSIS

Material - Information

Insp. Lot No.	10000694964		
Product Des.	**SIMBASE METHYLENE BLUE (BB9)**	Batch No.	SP15002033
CAS No.	61-73-4	EINECS No.	200-515-2
C.I. No.	52015	C.I. Name	Basic Blue 9

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	1.52
Iron		Passes Test		Pass
Lead (as Pb)		(Max.) 20.00	mg/kg	1.77
Zinc		Pass Turbidity Test		Pass
Loss on Drying (105°C)		8.00-15.00	%	11.82
Total colour/Assay		96.00-101.00	%	98.68
Wavelength of Maximum Absorption (λ max) in 1:1 IMS:DI Water		658.0-664.0	nm	660.0
Specific Absorption (E 1%/1cm) at λ max		(Min.) 2300.0		2390.0
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				1825 days from the date of delivery in packed conditions
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.

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SIMPSONS
DYES & PIGMENT SPECIALISTS

Shelf Life Statement

Herewith we confirm that SIMPERM – Organic pigments, SIMPSOL – Solvent Dyes, SIMACID – Acid Dyes, SIMBASE – Basic Dyes, SIMPEARL – Pearlescent pigments, Fluorescent pigments, reagents, biological stains and pH indicators are powder form products. It is observed that these synthetically produced colourants have long shelf life in packed condition. These colourants are sold for technical applications and not recommended for human foodstuff, animal feed, cosmetics, and medicinal use.

Considering above properties; shelf life of 1825 days (5 years) from the date of delivery of product is considered as reasonable and hence declared to buyers on certificate of analysis (COA) as general guide. As such, it is not a trend in industry to provide date of expiry in technical grade synthetic colourants. Downstream users are advised to test the samples, check our documents prior to use and check suitability, stability in end applications. This policy replaces specific date of expiry on COA and other documents.

This information is correct to the best of our knowledge and at the time of writing.

Vidyut Mehta
Manager (Regulatory Affairs & Quality)
e-mail: vidyut.mehta@rohagroup.com

27/10/2022

Date of issue / Дата видачі 07.10.2024

Private Production & Commercial Enterprise

CERTIFICATE OF ANALYSIS No 2/ ЯКІСНЕ ПОСВІДЧЕННЯ № 2

Potato starch / Крохмаль картопляний

Sender/ Відправник	VIMAL PPCE, 70 Shevchenka str., vill. Drozdivka, Chernihiv district, Chernihiv region, Ukraine
Receiver / Отримувач	SRL LITARIX., MD-2044 Chisinau st. Transnistria 5/1
Quantity / Кількість	22 000 kg
Number of bags / Кількість мішків	880
Date of manufacturee / Дата виготовлення	02.10.2024
Batch No. / Номер партії	corresponds to the date of manufacturing / відповідає даті виготовлення
Machine № / Машина №	BH8533TM/ BH6033XF

VALUES / ЗНАЧЕННЯ

No.	Properties / Назва показника	Results / Результат	Standard / Норма	Method / Метод
1.	**Moisture**, %/ Вологість	18.3	17.0 - 20.0	ISI 01-1e/ГОСТ 7698
2.	**Ash, % /** Загальна зола	0.30	0.35	ISI 02-1e/ГОСТ 7698
3.	**Ashes content, not soluble in HCl, % /** Зола, нерозчинна в 10 %HCl	0.029	0.05	ISI 21-1e/ГОСТ 7698
4.	**Acidity, cm^3 /** Кислотність [0,1 mol/dm^3NaOH (0,1 N) / 100g of DS] /	7.4	10.0	ISI 12-1e/ГОСТ 7698
5.	**Black spots, in 1 dm^2 /** Кількість крапок	30	80	ГОСТ 7698
6.	**pH**	6.5	6-8	ISI 26-5e/ГОСТ 7698
7.	**SO_2, %**	Absent	0.005	ISI 20-1e/ГОСТ 7698
8.	**Whiteness**, % / Білизна	93.5	> 90	-
9.	**Top viscosity 4 %, BU /** Пікова в'язкість	1330		ISI 19-6e
10.	**Cooper,** mg/kg / Мідь	< 10	10	-
11.	**Arsenic,** mg/kg / Миш'як	< 0.10	0.10	-
12.	**Cadmium**, mg/kg / Кадмій	< 0.10	0.10	-
13.	**Mercury,** mg/kg / Ртуть	< 0.02	0.02	-
14.	**Lead, mg/kg** / Свинець	< 0.50	0.50	-
15.	**Total aerobic mesophilic count, CFU /g /** Мезофільні аеробні мікроорганізми	< 10000	10000	-
16.	**Yeasts,** CFU /g / Дріжджі	< 10	100	-
17.	**Moulds,** CFU /g / Плісняві гриби	< 10	250	-
18.	**Escherichia coli in 1 g, CFU /g /** Кишкова паличка	Absent	Absent	-
19.	**Salmonella**, CFU /g / Сальмонелла **in 25 g**	Absent	Absent	-
20.	**Appearance /** Колір	White		ГОСТ 7698
21.	**Smell /** Запах	Neutral		ГОСТ 7698
22.	**Shelf life** / Термін зберігання		**5 years** / років	

Terms of certificate validity from 07.10.2024 **till** 07.10.2029/Термін дії сертифікату з 07.10.2024 по 07.10.2029. **A product meets all the requirements of EU and suitable for the use in food industry** / Продукт відповідає вимогам ЄС та придатний для вживання в харчовій промисловості.

STOREAGE: It is strictly forbidden to store the starch with another goods which has a source of any kind of foreign odors. In case of long-term storage which is more than 10 days and in order to keep declared above characteristics of the product the manufacturer recommends to keep prime packing and the temperature which is not higher than 10 °C and humidity level of 75% during the storage.

Laboratory chief / Зав. лабораторією

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Report No.:LWPC-1C$_1$-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**	

APEX HEALTHCARE LIMITED

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Product	BENZOCAINE	**Page No.**	01 of 01
Standard for Release	EP	**Drug Lic. No.**	G/25/1642

Batch No.	BCAH0450524	**Batch Quantity**	652.700 Kgs.
Mfg. Date	MAY-2024	**Date of Sampling**	20/05/24
Exp. Date	APR-2029	**Date of Approval**	29/05/24
A.R. No.	FP/BC/060/24	**Dispatched Qty.**	NA
C.A.S. No.	94-09-7		

Sr. No.	Tests	Acceptance Criteria	Test Result
1.	**Description**	White or almost white, crystalline powder or colorless crystals.	White crystalline powder
2.	**Solubility**	Very slightly soluble in water, freely soluble in ethanol (96 %)	Complies
3.	**A. Identification (By IR)**	The infrared absorption spectrum of Benzocaine is concordant with the reference spectrum.	Complies
	B. Identification (By Melting Point)	Determination- A: 89° C to 92° C Determination- B: the absolute difference between the melting point of the mixture and the value obtained in determination A is not greater than 2° C.	90 ° C 1 ° C
4.	**Related Substances**	Unspecified impurities: NMT 0.10 % Total impurities: NMT 0.2 %	BDL BDL
5.	**Loss on drying**	Not more than 0.5 % w/w	0.15 %
6.	**Sulphated Ash**	Not more than 0.1 % w/w	0.04 %
7.	**Assay**	Between 99.0 % and 101.0 %	99.96 %
8.	**Residual Solvents (By GC-HS)**	Ethanol: NMT 5000 ppm Methanol: NMT 3000 ppm Toluene: NMT 890 ppm	ND 124 ppm ND
9.	**Total Aerobic microbial Count** **Total Yeast & Mould Count**	NMT 100 cfu/g NMT 10 cfu/g	35 cfu/g Nil
10.	**Escherichia coli**	Absent/1 g	Absent

APEX HEALTH CARE LIMITED DMF GRADE

Remarks: The Product Complies with respects to above tests and Prescribed Standard Specification as per EP'11.3.

Name	Mr. Pankaj Pateliya	Mr. Somnath Kokate	Mr. Chetan Sardhara
Designation-Dept.	Executive -QC	Sr. Executive-QC	Asst. Manager -QC
Sign. /Date	15/06/24	15/06/24	15/06/24
	Prepared by	**Reviewed by**	**Approved by**

Mfg. Site Address: Plot no. 4710, 4711, 4707-A/8, 4707-A/9, GIDC Industrial Estate Ankleshwar, Dist.-Bharuch-393002, Gujarat, India. Phone no.: +91 2646 222525/223525/227289.

DÜLLBERG
KONZENTRA

Certificate of Analysis

Mat.-No	1000175
Product	Benzyl Benzoate BP98
Company No	102417
Company	Brenntag SRL
Your Product	462084

Batch-No	0000206635
No. of Analysis	10000070697

Characteristic	Value	Unit	Lower Limit	Upper Limit
Appearance (sensorical)	Corresponds	clear liquid		
Colour (sensorical)	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
Soldification 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 28.04.2023 Date of retest 27.04.2026

Created JR
Date 15.05.2023

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Düllberg Konzentra m.b.H.Hamburg
Registergericht: HamburgHR B 37513
Steuernummer: 49 /615 /00287

Kommanditgesellschaft: Sitz Hamburg
Registergericht: Hamburg HR A 47413
Geschäftsführer: Manfred Düllberg
Christian Düllberg

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BIC: DEUTDEHH

ETİMADEN
İŞLETMELERİ GENEL MÜDÜRLÜĞÜ

PRODUCT SPECIFICATION

Borax Decahydrate

Technical Grade, Powder

$Na_2B_4O_7.10H_2O$

Disodium Tetraborate Decahydrate

CAS #: 1303-96-4 / EC #: 215-540-4

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Chemical Specification

Component	Content
B_2O_3	36.47-38.50 %
Equivalent $Na_2B_4O_7.10H_2O$	99.90-105.45 %
Na_2O	16.24 -17.14 %
SO_4	200 ppm max.
Cl	70 ppm max.
Fe	15 ppm max.

Particle Size Specification

Size	Content
+1.180 mm	0.00% max.
-0.063 mm	30.00% min.

Rev. : 2023/00

Kızılırmak Mahallesi 1443. Cadde No:5 06530 Çukurambar
Çankaya / ANKARA
Tel: (0312) 294 20 00 **Faks:** (0312) 294 21 64
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ETiMADEN İŞLETMELERİ GENEL MÜDÜRLÜĞÜ

PRODUCT TECHNICAL DATA SHEET

BORIC ACID

ETIBORIC ACID

Boric Acid (H_3BO_3)

CAS Number: 10043-35-3

Technical Grade: Granular and Powder

Packaging: 25 kg, 50 kg, 1000 kg

(with or without pallet)

General Information:

Boric acid (also known as boracic acid or ortoboric acid) is a mild acid of boron. Its chemical formula is written as H_3BO_3 (or $B(OH)_3$ and it is available as a white, water-soluble powder. Boric acid is obtained by the reaction of colemanite ore with sulfuric acid or borax and a mineral acid.

The reaction of colemanite ($Ca_2B_6O_{11}.5H_2O$) in the sulfuric acid (H_2SO_4) solution results in boric acid (H_3BO_3)and gypsum ($CaSO_4.2H_2O$). Gypsum crystals are precipitated and boric acid is produced by crystallization.

Usage and Benefits:

Glass: Boric acid is used in the production of special type glasses (oven glasses, glass laboratory materials, etc.) and glass fiber. It prevents devitrification in glass production. It increases the resistance of glass against heat, chemicals and mechanical impacts. Boric acid is used in the production of single-filament fiberglass (textile-grade glass fiber). Higher and more consistent B_2O_3 levels when compared to colemanite, which is another material used for producing textile grade

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For more information:
Technology Development Department
EYS FRM-ETİ-00 17 /23/9/2014-02
Rev. 2021/01

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glass fiber; lack or refractory mineral content (such as Mg, Si, Al, Fe, St, S and As) and low melting point make boric acid more useful. It increases fiberizing in isolation and reinforcement fiber glasses by reducing viscosity. Moreover, it increases the physical and humidity resistance of fibers by reducing their tendency to crystallize.

Ceramics: Boric acid is used as a binder in ceramics. As a result of the addition of boric acid, melting and adhesion occur at lower temperatures. It enhances the resistance of ceramic products to breakage and scratches in the face of physical impacts, and strengthens their chemical resistance. It is used in glazing and enamel coating where sodium is not desired in the formulations. Furthermore, it is used as a reinforce in the production of ceramic wet tiles. It improves condensation properties in porcelain tiles by increasing the vitrification temperature. It is one of the materials used in the production of ceramic and porcelain enamel frit.

Detergent: Boric acid is used as a germicide and bleaching agent. It can be added to soap and detergents due to its water-softening and germicide properties. It has the effect of reducing the washing time and temperature.

Agriculture: Boron is one of the nutrients required by plants. It plays an important role in plant yield, flowering and pollen production and seed development. Boric acid can be used alone or in combination with standard fertilizers in soils with low boron content. It is used in the production of disodium octaborate tetrahydrate, which is used as a boron fertilizer in agriculture, and in the production of herbicides.

Fire retardant: Boric acid is the basic form of borate-based fire retardants which are used to reduce the kindling rate of burning substances. In the recent years, it has become important for giving fire retardant properties to resin-based wooden composite panels and for being used as a protective materials in timber and solid wooden products. It can be used together with disodium octaborate tetrahydrate as flame retardant material in wooden composite materials, marine, yacht and aviation coatings. It is added to fire bricks and mortars to provide resistance against heat or corrosion.

Nuclear energy: It is used for neutron retention in nuclear power plants for reducing the rate of neutron fission generation. Natural boron contains 20% ^{10}B and approximately 80% ^{11}B. ^{10}B has a high cross-sectional area for the retention of low-energy neutrons. When more boric acid is added to the reactor cooler and is allowed to circulate inside the reactor, the probability of neutron fission is reduced. Therefore, boric acid can effectively control the fission rate

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inside the reactor. This method is utilized in Pressurized Water Reactors. Boric acid is also used for keeping the neutron multiplication under control in spent fuel pools containing uranium rods.

Wood protection: Boric acid is used as a protective agent against rotting on dry or wet wooden surfaces. It can also be applied as gel or solution on wooden surfaces. Protective agents with borate compounds are successfully used in marine industry against factors such as moss, fungi and ooze.

Medicine: Boric acid can be used as an antiseptic. Dilute solutions of boric acid can be used as eye-washing solutions. Dilute boric acid solution is also used as an anti-bacterial agent. It can be used for the treatment of external otitis in solution form.

Anti-bacterial agent and for cleaning: In industry, it is used as an anti-corrosive and anti-bacterial material in metal coating processes. It is also used in the production of boron-based herbicide and artificial fertilizer. Sodium perborate, which is used as an oxidizing and bleaching material in cleaning products, is obtained from boric acid.

Lubrication: The colloidal suspensions of boric acid form a good lubricant for ceramic and metal surfaces when they are added to petroleum and vegetable oils and they significantly reduce the friction coefficient.

Various industrial productions: In the petrochemical industry, it catalyzes the oxidation of hydrocarbons in the production of Nylon 66 and increases the efficiency of the conversion of hydroxyl groups into alcohols with further oxidation. It is used in the production of ferro-boron which is used in the production of steel, casting, neodymium-iron-boron magnets and amorphous metals. In metallurgical operations, it reduces the energy consumption by having a positive effect on the fusing temperature; enables the durability of steel to increase and has a plasticizing function when used as a slag-former. It provides support and extra bonding to strength in the steel, glass, cement and aluminum industries. Adding boric acid to papier-mache increases the strength of papier-mache panels, reduces their weight and prevent wrinkling on their surfaces. It plays a role as an enzyme stabilizer in liquid laundry detergents. Boric acid is used as a peptizer in the production of adhesives containing casein and dextrin based starch.

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Physical Properties:

Specific weight	: 1.51 g/cm^3 (20°C)
Pour (bulk) density[a]	: 0.892 g/cm^3 (Granular)
Molecular weight	: 61.83 g/mol
Melting point	: 450°C
Boiling point	: 1860°C
Heat capacity	: 24.7 J/g°C
Thermal conductivity	: 0.407 W/mK
Specific surface area	: <1 m^2/g
Diffusion coefficient	: 1.1x10^{-5} cm^2/s
Surface tension	: 63.83 mN/m (1.0% aqueous solution by weight)
Colorimetry test	: 94.52 (average L value)

[a] Applies to a representative sample.

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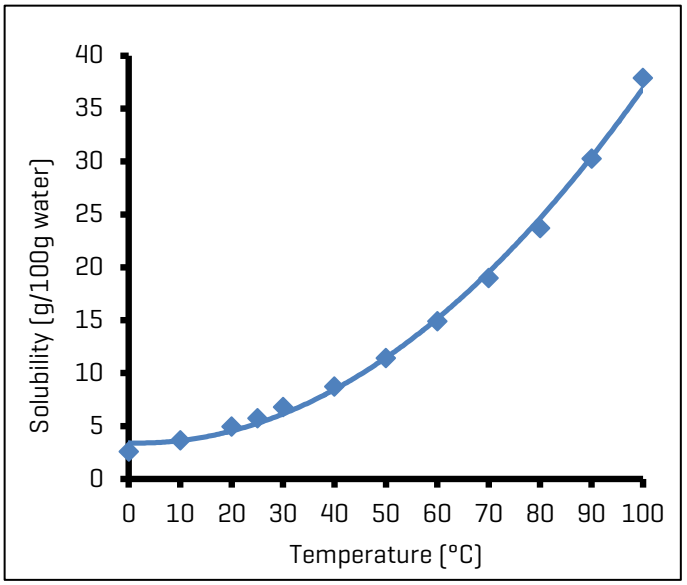
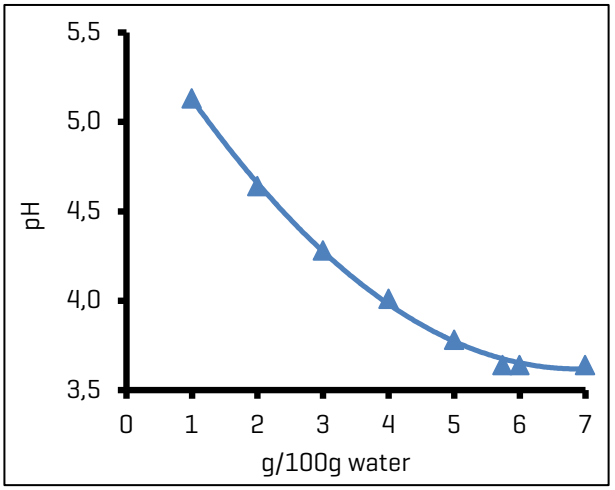
For more information:
Technology Development Department
EYS FRM-ETİ-00 17 /23/9/2014-02
Rev. 2021/01

Solubility[b,c]:



Temperature (°C)	Solubility (g/100g water)
0	2.59
10	3.64
20	4.94
25	5.74
30	6.78
40	8.73
50	11.41
60	14.90
70	18.97
80	23.70
90	30.26
100	37.90

Solution pH values:



Solution (g/100g water)	pH (±0.03 / 25°C)
1	5.13
2	4.64
3	4.28
4	4.01
5	3.78
5.74[c]	3.64
6	3.64
7	3.64

[b] Factors affecting the dissolution rate, such as the particle size of material to be dissolved, the mixing speed of the solution are effective on the time to reach the saturation point. The values on the table should be evaluated by taking this into account.

[c] Saturation value of boric acid at 25°C in 100g water is 5.74g.

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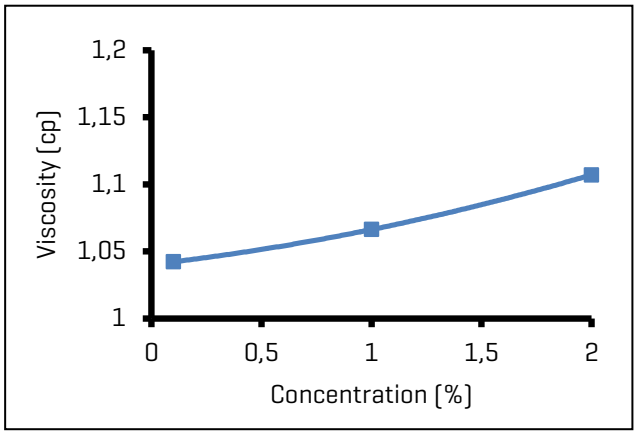
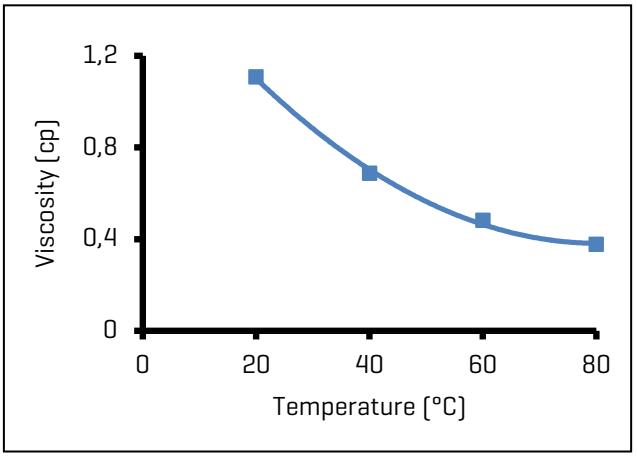
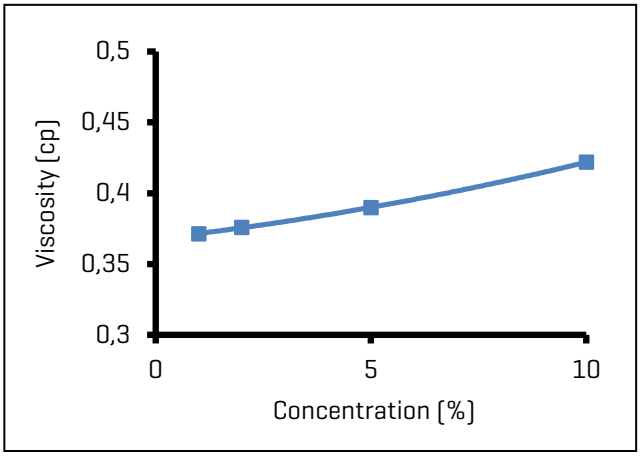
Solution viscosity values:



Temp. (°C)	Conc. (%)	Viscosity (cp)
20	0.1	1.04
20	1	1.07
20	2	1.11



Temp. (°C)	Conc. (%)	Viscosity (cp)
20	2	1.11
40	2	0.69
60	2	0.48
80	2	0.38



Temp. (°C)	Conc. (%)	Viscosity (cp)
80	1	0.37
80	2	0.38
80	5	0.39
80	10	0.42

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Chemical Content:

Component	Content				
	Granular			Powder	
	Normal Sulphate	Low Sulphate	Ultra Low Sulphate	Ultra Low Sulphate	Normal Sulphate
Equivalent H_3BO_3	99.92-101.07%	99.92-101.07%	99.92-101.07%	99.92-101.07%	99.92-100.89%
B_2O_3	56.25-56.90%	56.25-56.90%	56.25-56.90%	56.25-56.90%	56.25-56.80%
B	17.47 - 17.67%	17.47 - 17.67%	17.47 - 17.67%	17.47 - 17.67%	17.47 - 17.64%
Water-soluble B	17.47 - 17.67%	17.47 - 17.67%	17.47 - 17.67%	17.47 - 17.67%	17.47 - 17.64%
SO_4	300 ppm max	130 ppm max	12 ppm max	12 ppm max	300 ppm max
Cl	5 ppm max	5 ppm max	3 ppm max	3 ppm max	5 ppm max
Fe	4 ppm max	4 ppm max	3 ppm max	3 ppm max	4 ppm max

Heavy metal content:

Component	Content (mg/kg)
As	0.450 max
Cd	<0.005
Pb	<0.010
Cr	<0.005
Hg	<0.010

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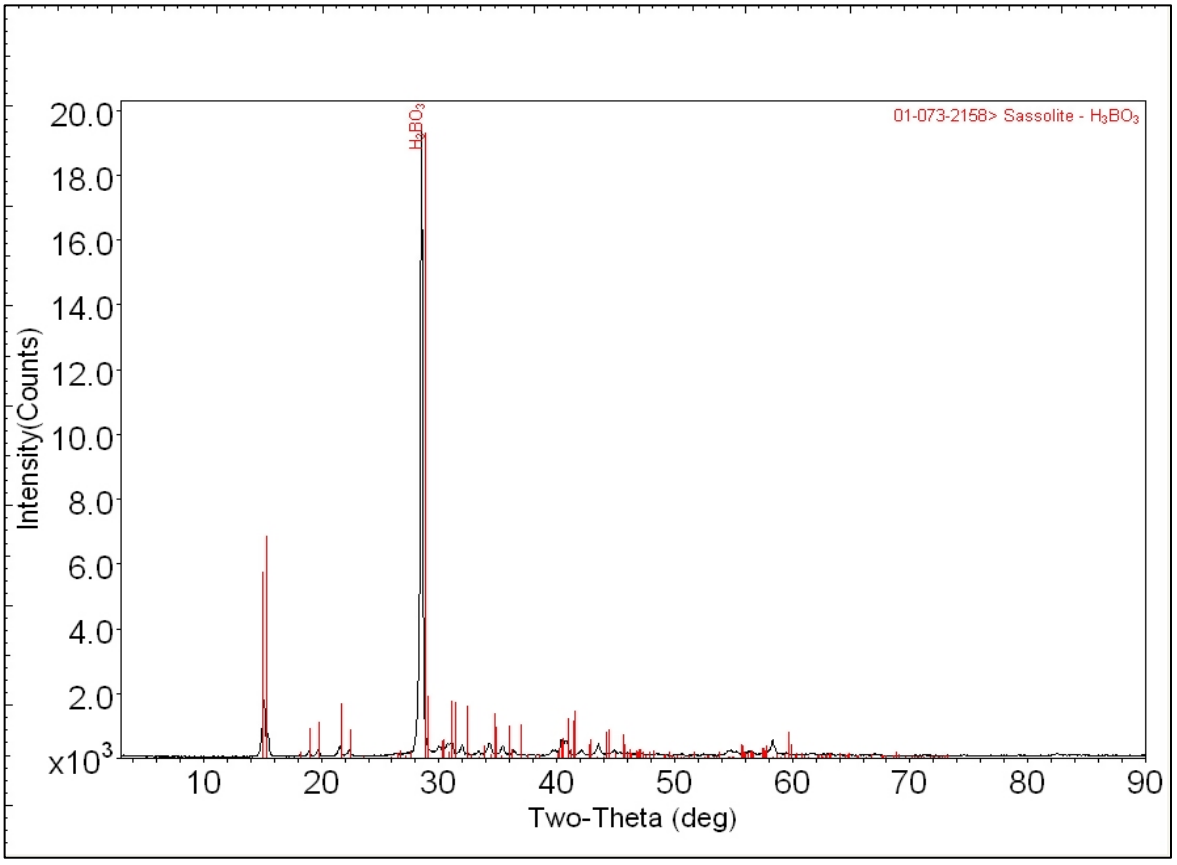
Particle size:

Size	Content				
	Granular, Normal sulphate	Granular, Low sulphate	Granular, Ultra Low sulphate	Powder	Powder, Ultra Low sulphate
+1.000mm	4% max	4% max	4% max	0% max	0% max
-0.063mm	4% max	4% max	4% max	-	
-0.125mm	-	-	-	45% max	45% max

X-Ray Diffraction Analysis:



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LABORATORIOS ARGENOL

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CERTIFICATE OF ANALYSIS

PRODUCT:	**COLLOIDAL SILVER**
BATCH NUMBER:	**C25-0081**

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	≥ 1,5 ml NaOH 0,1N	2,3	Ph.Eur 11
Silver Ions	No precipitate	CORRECT	Ph.Eur 11
Sensitivity to electrolytes	No opalescence	CORRECT	Ph.Eur 11
Water insoluble substances	≤ 1,0 %	<0,1	Ph.Eur 11
Loss on drying 80°C	≤ 8,0 %	0,9	Ph.Eur 11
Silver content	70,0 - 80,0 %	72,8	Ph.Eur 11

MANUFACTURING DATE: 29/01/2025

RETEST DATE: 29/01/2027

RELEASE DATE: 20/02/2025

20/02/2025

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Teresa Barrena

QUALITY ASSURANCE

检 验 报 告 单

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

品 名 Name of product	结晶磺胺 4-aminobenzene sulfonamide	报告日期 Report Date	2024 年 10 月 16 日 Oct.16, 2024
批 号 Lot NO.	240812	生产日期 Manufacture Date	2024 年 8 月 August, 2024
数 量 Net weight	46kg	有效期至 Retest Date	2027 年 8 月 August , 2027
ANALYTICAL ITEMS	SPECIFICATION		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℃～166.0℃		165.2℃～165.7℃
Acidity	NMT. 0.2ml		0.05ml
Clarity of solution	Should be clear		Conforms
Related substances	Any single impurity NMT0.5%		0.11%
	Total impurities NMT1.0%		0.16%
	Purity NLT 99.0%		99.84%
Heavy metals	NMT 20ppm		Conforms
干燥失重 Loss on drying	不得过0.5% Not more than 0.5%		0.05%
Sulfated ash	NMT 0.1%		0.05%
Microbiological limits	TAMC<1000cfu/g TYMC<100cfu/g		Conforms
含量 Assay	含$C_6H_8N_2O_2S$应不小于99.0% NLT 99.0% of $C_6H_8N_2O_2S$		99.8%
检验依据 According to	EP11		
结 论 Conclusion	合格 Complies		

检验者：王美芳 复核者：严银凤 负责人：缪彩珍

Analyst: Checker: Supervisor:

NO.159 Dongguan Road,Tuncun ,Tongli Town， Wujiang District,Suzhou,Jiangsu,China 215216
TEL：+86-512-63371371 FAX: +86-512-63371236

江苏天和制药有限公司
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.00.228.1.0

品名 PRODUCT: **Sulfacetamide Sodium**	报告编号 CERTIFICATE NO: 0002
批号 BATCH NO: S01-2312039	报告日期 CERTIFICATE DATE: 2024.10.12
批量 BATCH SIZE: 500kg	生产日期 DATE OF MANUFACTURE: 2023.12.18
有效日期 EXPIRY DATE: N/A	复测期 RETEST DATE: 2027.12.

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)	9.0
Related substances		EP(2.2.29)	
Impurity A	≤0.2%		0.03%
Single unspecified impurities	≤0.10%		0.03%
Total impurities	≤0.5%		0.08%
Sulfates	≤200ppm	EP(2.4.13)	<200ppm
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	≤0.5%		0.01%
Microbial clearance		In house	
TAMC	$\leq 10^2$cfu/g		1cfu/g
TYMC	$\leq 10^1$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)
2024. 10. 12	2024.10.13	2024.10.14

TECHNICAL DATA SHEET

Product Name	**COCOA BUTTER**
Botanical Name	Theobroma cacao
Product Code	PBO6004
CAS #	8002-31-1
INCI Name	Theobroma Cacao (Cocoa) Seed Butter

Part Used	Beans
Extraction Method	Cold Pressed
Quality	100% Pure and Natural

PROPERTIES	SPECIFICATIONS
Appearance	Cream to pale yellow colored semi-solid butter
Odour	Rich characteristic cocoa aroma
Melting Point (°C)	32° - 36°
Moisture (%)	Maximum 0.2
Saponification Value (mgKOH/g)	188 - 198
Peroxide Value (meq O_2/kg)	Maximum 4.0
Iodine Value (g I_2/100g)	32 - 45
Free Fatty Acids (% oleic)	Less than 1.75
Acid Value (mgKOH/g)	Less than 3.5
Solubility	Soluble in cosmetic esters and fixed oils; Insoluble in water

FATTY ACID COMPOSITION:

FATTY ACID	C-CHAIN	SPECIFICATIONS (%)
Palmitic Acid	C16:0	21.00 – 29.00
Stearic Acid	C18:0	31.00 – 39.00
Oleic Acid	C18:1 (n-9)	31.00 – 38.00
Linoleic Acid	C18:2 (n-6)	1.50 – 5.00

STABILITY AND STORAGE:

Keep in tightly closed container in a cool and dry place, protected from sunlight. When stored for more than 24 months, quality should be checked before use.

As it is electronically generated document, hence no signature required.

LABORATORIOS ARGENOL

API
PRODUCT LIST

SILVER BASED ANTIMICROBIALS

✓ Due to their antimicrobial properties, our products are used against a broad spectrum of bacteria, preventing infections and the growth of microorganisms that proliferate around us including bacteria, moulds and fungi.

TANNIC ACID DERIVATIVES

✓ It is used as an astringent in gastrointestinal treatments.

	PRODUCT NAME	CAS NUMBER	MAIN THERAPEUTIC INDICATION	CEP/DMF
SILVER COLLOIDS	Colloidal Silver EP	[9007-35-6]	Antimicrobial/Antiseptic Preservative	ASMF/US DMF
	Colloidal Silver Solution	[9007-35-6]	Antimicrobial/Antiseptic Preservative	ASMF/US DMF
	Silver Vitellinate	[9015-51-4]	Antimicrobial/Antiseptic Preservative	ASMF/US DMF
	Silver Proteinate	[9008-42-8]	Antimicrobial/Antiseptic Preservative	ASMF/US DMF
SILVER SALTS	Silver Sulfadiazine	[22199-08-2]	Antimicrobial	ASMF/US DMF
	Silver Sulfate	[10294-26-5]	Antimicrobial	ASMF/US DMF
	Silver Nitrate	[7761-88-8]	Antiseptic/Cauterizing Sclerosing	ASMF/US DMF
	Silver Citrate	[126-45-4]	Antimicrobial	ASMF/US DMF
SILVER ZEOLITES	Silver Zeolite	[130328-18-6]	Antimicrobial	ASMF/US DMF
	Silver Copper Zeolite	[130328-19-7]	Antimicrobial	ASMF/US DMF
METALLIC SILVER	Metallic Silver Powder	[7440-22-4]	Antimicrobial	ASMF/US DMF
TANNIC ACID DERIVATIVES	Albumin Tannate	[9006-52-4]	Antidiarrheal / Astringent	ASMF/US DMF
	Bovine Gelatin Tannate	[9000-70-8]	Antidiarrheal / Astringent Antibacterial / Anti-inflammatory	ASMF/US DMF
	Porcine Gelatin Tannate	[9000-70-8]	Antidiarrheal / Astringent Antibacterial / Anti-inflammatory	ASMF/US DMF

API SOURCING

API supply based on over **80 years of experience.**

Global network of established partnerships over 60 countries.

FACILITIES & CERTIFICATIONS

GMP Certification issued by the Spanish Agency of Medicine and Healthcare Products.

European Production: 2 Manufacturing plants (22.000 m^2 in total) located in Spain.

CONTACT US

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Certificate of Analysis

furacilin2

COA No.: P-3-20200400I

Product Name: Nitrofurazone EP8.0

BATCH NUMBER	JD-BP-3-20201105	TEST DATE	November 23, 20
BATCH SIZE	1000Kg	MANUFACTURE DATE	November 19, 20
QUANTITY	50Kg	RETEST DATE	November 17, 23

ANALYSIS	SPECIFICATION	RESULT
Appearance (Visual)	Yellow or brownish-yellow crystalline powder	Yellow crystalline powder
Identification A (EP)	The ratio of the absorbance measured at the maximum at 375 nm to that measured at the maximum at 260 nm is 1.15 to 1.30.	Conforms
Identification B (EP)	Examine by infrared absorption spectrophotometry, comparing with the spectrum obtained with nitrofural CRS.	Conforms
Identification C (EP)	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	Conforms
Identification D (EP)	A violet-red colour is produced.	Conforms
pH (EP)	5.0 to 7.0	6.0
Loss on drying (EP)	Not more than 0.5%	0.1%
Sulphated ash (EP)	Not more than 0.1%	0.04%
Related substances (HPLC) (EP)		
1,2-bis[(5-nitrofuran-2-yl) methylidene] diazane	Not more than 0.5%	<0.05%
(5-nitrofuran-2-yl)methylene diacetate	Not more than 0.5%	0.09%
Any unspecified impurity	Not more than 0.10%	<0.05%
Total impurities	Not more than 1.0%	0.12%
Assay (UV) (EP)	97.0 to 103.0% of $C_6H_6N_4O_4$ Calculated on the dried basis	99.1%
Residual Acetic Acid	Not more than 1000ppm	720ppm

Conclusion: This batch of product complies with above specification.

济南金达药化有限公司 質量檢驗專用章

Prepared by QA: Wang Hunjun Signed/ Date: 王慧君/2020.12.03

Reviewed by QA: Sun Yingwen Signed/ Date: 孙英文/2020.12.03

We hereby certify that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control, at the above-mentioned site(s) in full compliance with Guidelines in ICH Q7. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Qualified Person: Wang Shuai Signed/ Date: 王帅/2020.12.03

BOLLETTINO DI ANALISI

SPETT.LE
BRENNTAG S.R.L.
STR.DRUMUL GARII NR.2 BIS
077040 CHIAJNA JUD.ILFOV-ROMANIA

CODICE PRODOTTO: 157809
NOME PRODOTTO: GLICERINA 99,7% VEG.EP'E422'
DATA ANALISI: 22-09-2024
DEL: 21-09-2021 LOTTO:
2021TZ008974
DDT: 2021 G1 29995
DATA SCADENZA: 21-09-2026
DATA PRODUZIONE: 21-09-2024

DESCRIZIONE

C3H8O3
Liquido viscoso,limpido e incolore.

APPLICAZIONE

Limitatamente al prodotto confezionato in fusti, codice commerciale 157809, segnaliamo che in conformità al Regolamento 2018/213 esso non può essere utilizzato nei seguenti settori:
formule per lattanti, formule di proseguimento, alimenti a base di cereali, alimenti per la prima infanzia, alimenti a fini medici speciali creati per soddisfare le esigenze nutrizionali dei lattanti e dei bambini nella prima infanzia,
bevande a base di latte e prodotti analoghi specificamente destinati ai bambini nella prima infanzia.

DATI ANALITICI

C/I	DESCRIZIONE ANALISI	NOTE	MAX MIN TIP	VALORE	TOLLERANZA	U.M.	METODO ANALITICO	RISULTATO
C	IDENTIFICAZIONE	A,B: conforme						CONFORME
C	TITOLO SUL SECCO		MINIMO	99,70				99,90
C	UMIDITÀ		MASSIMO	0,5000		%		0,0800
C	COLORE APHA		MASSIMO	10			CQ10	3
C	CENERI SOLFORICHE		MASSIMO	100		ppm		<100
C	CLORURI		MASSIMO	10		ppm		<10
C	METALLI PESANTI		MASSIMO	5		ppm		<5
C	PIOMBO		MASSIMO	2,00		ppm		<0,05
C	ARSENICO		MASSIMO	3,00		ppm		<0,02
C	CADMIO		MASSIMO	1,00		ppm		<0,02
C	Indice di rifrazione			1,4725	+/- 0,0015	°		1,4737
C	CONTENUTO IN ESTERI	ml HCl 0,1M	MINIMO	8,00				9,40
C	COMPOSTI ALOGENATI		MASSIMO	35		ppm		<35
C	CONTENUTO IN ZUCCHERI	conforme						CONFORME
C	IMPUREZZE	A (Dietilenglicole)	MASSIMO	0,1		%		<0,1
C	IMPUREZZE	B (Etilenglicole)	MASSIMO	0,1		%		<0,1
C	IMPUREZZE	C (Propilenglicole)	MASSIMO	0,1		%		<0,1
C	IMPUREZZE	con RT<RT glicerolo	MASSIMO	0,1		%		<0,1
C	IMPUREZZE TOTALI	con RT>RT glicerolo	MASSIMO	0,5		%		<0,1
C	DENSITA' , a 20°C			1,2629	+/- 0,0004			1,2630

C/I = CONTROLLATO / INFORMATIVO

CONFORMITA'

Additivo alimentare conforme ai requisiti del Regolamento UE 231/2012.
Il prodotto è conforme ai limiti della Farmacopea
Il prodotto è analizzato dal produttore secondo i metodi di legge.

DICHIARAZIONI

Il prodotto non viene trattato con radiazioni ionizzanti.
Prodotto esente da solventi residui citati nella CPMP/ICH/283/95.
Il prodotto è esente da rischio BSE/TSE.

BRENNTAG s.p.a.
Sede Legale e amministrativa
Milanofiori Strada 6, Pal. A/13
20057 Assago(MI)
Tel. 02 48333.0. (ric. aut.)
Telefax 02 48333.330

Cap. Soc. € 18.300.000,00 i.v.
R.E.A. MI 472696
Registro Imprese di Milano
e C.F. n. 00835510157
Part. IVA IT 00835510157

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Pomigliano D' Arco (NA) - Via G. Luraghi, snc
Tel. 081 3291502 Fax 081 8841768
Cepagatti (PE) – S.P di Bonifica, 34/36
Tel. 085 970001 Fax 085 9700588
Palo del Colle (BA) – S.P. per Bitetto
Tel. 080 9911038 Fax 080 624373

BOLLETTINO DI ANALISI

Il prodotto non contiene e non deriva da OGM, pertanto non necessita di etichettatura specifica ai sensi dei Regolamenti 1829/2003/CE e 1830/2003/CE.
Il prodotto è esente da glutine.
Il prodotto non contiene lattice.

ULTERIORI INFORMAZIONI

Il prodotto deriva da olio di palma.
Il prodotto non deriva da Jatropha plant.
Il prodotto è certificato Kosher.

BRENNTAG s.p.a.
Sede Legale e amministrativa
Milanofiori Strada 6, Pal. A/13
20057 Assago(MI)
Tel. 02 48333.0. (ric. aut.)
Telefax 02 48333.330

Cap. Soc. € 18.300.000,00 i.v.
R.E.A. MI 472696
Registro Imprese di Milano
e C.F. n. 00835510157
Part. IVA IT 00835510157

Uffici Commerciali:

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Trezzano s/n (MI) - Via Boccaccio, 3
Tel.02 48333.0 (r.a.) - Fax 02 48333.327
Ossona (MI) - Via Toscanini, 6
Tel.02 9032281 - Fax 02 90322814
Filago (BG) - Via Delle Industrie, 9
Tel.035 409611 - Fax 035 594761
Bentivoglio (BO) - Via Galliera, 6/2
Tel. 051 6035511 - Fax 051 767488
Lugo (RA) - Via Piratello, 68
Tel. 0545 27100 - Fax 0545 33739

Padova (PD) - Via Nuova Zelanda, 10
Tel. 049 9201496 - Fax 049 9201498
Alpo di Villafranca (VR) - Via Dosdegà,65
Tel.02 898311 - Fax 02 89831115
Orbassano (TO) - Via Bertone, 6
Tel.011 9626511 - Fax 011 9650291
Anagni (FR) – Via Fratta Rotonda Vado Largo, 6
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Società con socio unico, Società soggetta all'attività di direzione e coordinamento da parte della Brenntag AG

Laboratorio QC – Sito di Trezzano sul Naviglio (MI)
Francesco Scarpino

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

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

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	2124040314	Quantity 数 量	1000Kg		
Mfg Site 生产场地	10-1	Packing Specification 规 格	25Kg/drum		
Mfg Date 生产日期	2024.04.22	Expiry Date 有效期	2027.04.21		
Certificate No. 报告编号	2124040314R2	Report Date 报告日期	2024.05.28		
Storage condition 储存条件	Protected from light 遮光保存				

Contents 项 目	Specification:EP11.0+Customer's Specification 标 准：EP11.0+客户标准	Results of analysis 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
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%	0.08%
Sulfates 硫酸盐	≤0.1%	<0.1%
Heavy metals 重金属	≤0.002%	<0.002%
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%	99.3%
Solubility 溶解性	Very soluble in water, slightly soluble in ethanol (96 percent), practically insoluble in methylene chloride	Conform 符合
Endotoxin 细菌内毒素	≤0.14EU/mg	<0.14EU/mg
Residual solvent 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%	0.006%
Microbial limit 微生物限度	(1) TAMC≤10^3cfu/g 需氧菌总数≤10^3cfu/g	<1×10^2cfu/g
	(2) TYMC≤10^2cfu/g 霉菌、酵母菌总数≤10^2cfu/g	<1×10^1cfu/g
	(3) E.Coli: Not detectable 大肠埃希菌：不得检出	Not detected 未检出

Conclusion: Conforming to EP11.0+Customer's Specification.

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

DIRECTOR OF QC DEPT（负责人） CHECKER（复核人） REPORTER（报告人）

CAI YUEJUN（蔡跃军） FANG KAIKAI（方凯凯） ZHANG SHUTING（张淑婷）

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

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	20250313	数量 QUANTITY	150KGS
包装 PACKING	25KG/桶 25KG/ Bucket	报告编号 LOT NO	20250313
生产日期 PRODUCTION DATE	Mar.13, 2025	有效期 EXPIRY DATE	Mar.12, 2029
检验标准 STANDARD	EP10.0		
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℃-155.5℃ Conform Conform	
酸度 ACIDITY	PH5.0-6.5	PH=5.8	
溶液外观 Appearance of solution	Clear and colourless	Conform	
干燥失重 LOSS ON DRYING	≤0.5%	0.05%	
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%	99.8%	
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 EP10.0		
主管 MANAGER	2025.04.10	报告人 REPORTER	2025.04.10

BRAND NAME: **COCOA BUTTER**

1. IDENTIFICATION OF PRODUCT AND COMPANY

Identification of product:
Brand name: COCOA BUTTER

Identification of company:

NEDERLAND, S.A.
Ctra. De la Vila, nº 48
08840 – VILADECANS

Tel.: +34. 93 637.34.72
Fax.: +34. 93 637.28.86

Recommended use of the chemical and restrictions on use

Recommended Use	Ingredient for Food or Cosmetics.
Uses advised against	No information available

2. HAZARDS IDENTIFICATION

Classification
OSHA Regulatory Status
This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label elements
Emergency Overview

Appearance: tan colored fat
Physical state: Solid
Odor: strong chocolate odor

Hazards not otherwise classified (HNOC) Not applicable

Other Information Not applicable

3. COMPOSITION / INFORMATION OF COMPONENTS

COCOA BUTTER

Dangerous components: None

The product contains no substances which at their given concentration, are considered to be hazardous to health.

4. FIRST AIDS MESURES

Description of first aid measures

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact	Wash skin with soap and water.
Inhalation	Remove to fresh air.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.

5. PROTECTION MEASURES FOR FIRE EXTINCTION

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media	CAUTION: Use of water spray when fighting fire may be inefficient.
Specific hazards arising from the chemical	No information available.

Explosion data

Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. MEASURES TO TAKE IN CASE OF ACCIDENTAL SPILLAGE

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation, especially in confined areas.

Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment	Steps to be Taken in Case Material is Released or Spilled: Dike and contain the spill with inert material (ie: sand, earth,sawdust) and transfer liquid and solid diking material to separate containers for recovery or disposal. Wash floor area with hotwater solution. Remove contaminated clothing and wash before reuse. Wash affected skin areas with

	soap and water. Keepspills out of all sewers and bodies of water.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. MANIPULATION AND STORAGE

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place, under the hygienic-sanitary suitable precautions.
Incompatible materials	None known based on information supplied.

8. LIMITS OF EXHIBITION AND MEASURES OF PERSONAL PROTECTION

Control parameters

Exposure Guidelines	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Controls	Showers Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin and body protection	Suitable protective clothing.
Respiratory protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
General Hygiene Considerations	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties	
Physical state	Solid
Appearance	Tan coloured fat
Colour	Light yellow
Odour	Cocoa. Typical
Odour threshold	Characteristic of cocoa

Property	Values
pH	No information available
Melting point / freezing point	30-36 °C
Boiling point / boiling range	>120 ºC
Flash point	>250 ºC
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Relative density	No information available
Water solubility	Insoluble
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	>300 ºC
Decomposition temperature	No information available
Kinematic viscosity	No information available
Dynamic viscosity	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information	
Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available
Volatility	No information available

10. STABILITY AND REACTIVITY

Reactivity	No data available
Chemical stability	Stable under recommended storage conditions.
Possibility of Hazardous Reactions	None under normal processing.
Conditions to avoid	Extremes of temperature and direct sunlight.

Incompatible materials	None known based on information supplied.
Hazardous Decomposition Products	None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure: NOT TOXIC

Product Information

Inhalation	No data available
Eye contact	No data available
Skin contact	Not irritant.
Ingestion	No data available

Information on toxicological effects

Symptoms	No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

Numerical measures of toxicity - Product Information

12. ECOLOGICAL INFORMATION

Ecotoxicity

Persistence and degradability	No information available.
Bioaccumulation	No information available.
Other adverse effects	No information available

13. ELIMINATION OF RESIDUES

Waste treatment methods

Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Do not reuse container.

14. INFORMATION RELATIVE TO THE TRANSPORT

Not dangerous product according to the criteria of the regulation of the transport.

DOT	Not regulated
ICAO (air)	Not regulated
IMDG	Not regulated

15. DISPOSITIONS (REGULATIONS) OF LEGAL CHARACTER

Labelling according to the CEE Boards: Not dangerous product

Indication of dangerousness: Not applicable

Phrases R: Not applicable

Phrases S: Not applicable

International Inventories * Complies

* TSCA (United States Toxic Substances Control Act Section 8(b) Inventory), DSL/NDSL (Canadian Domestic Substances List/Non-Domestic Substances List), EINECS/ELINCS (European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances), ENCS (Japan Existing and New Chemical Substances), IECSC (China Inventory of Existing Chemical Substances), KECL (Korean Existing and Evaluated Chemical Substances), PICCS (Philippines Inventory of Chemicals and Chemical Substances), AICS (Australian Inventory of Chemical Substances)

US Regulations

Federal

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

State

California Proposition 65	This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations
U.S. EPA Label Information
EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

NFPA	Health hazards 0	Flammability 0	Instability 0	Physical and Chemical Properties
HMIS	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

SYNNAT PHARMA PRIVATE LIMITED
Plot No.60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District-531019,
Andhra Pradesh, India.
Website: www.synnatpharma.com

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

CERTIFICATE OF ANALYSIS

Product Name :	PAPAVERINE HYDROCHLORIDE Ph.Eur	Report Date :	17.04.2025
Batch / Lot No. :	64020125	Mfg. Date :	Jan-2025
Quantity :	50.00 Kg	Expiry/~~Retest~~ Date :	Nov-2029

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 (^{0}C)	Between 146°C and 149°C		148.5°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.		3.20, 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 %.		0.12%, Complies
Sulphated ash (% w/w)	Maximum 0.1 %.		0.02%, Complies
Assay (% w/w)	Between 99.0 % and 101.0 % (dried substance).		100.2%, Complies

SYNNAT PHARMA PRIVATE LIMITED
Plot No.60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District-531019,
Andhra Pradesh, India.
Website: www.synnatpharma.com

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

CERTIFICATE OF ANALYSIS

Product Name :	PAPAVERINE HYDROCHLORIDE Ph.Eur	Report Date :	17.04.2025
Batch / Lot No. :	64020125	Mfg. Date :	Jan-2025
Quantity :	50.00 Kg	Expiry/~~Retest~~ Date :	Nov-2029

Test Parameter	Specification			Result
ADDITIONAL TESTS				
Residual solvents (by GC-HS)	Chloroform	Not more than 60 ppm.		*ND, Complies
	Toluene	Not more than 100 ppm.		11 ppm, Complies
	Mesitylene	Not more than 70 ppm.		*BQL, Complies
Microbial analysis	Total bacterial count		Not more than 100 cfu/gm	10 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

SYNNAT PHARMA PVT. LTD. Anakapalli

Prepared by : Soury Date : 20/05/25

Reviewed by : Date : 20/05/25

Approved by: Rao Date : 20/05/2025

Hansen & Rosenthal GmbH & Co. KG

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	mm²/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

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

Headquarters:
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Am Sandtorkai 64
20457 Hamburg, Germany
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Mineral oil and vaseline plant:
Tudapetrol Mineralölerzeugnisse
Nils Hansen GmbH & Co. KG*
Halskestraße 30-34
22113 Hamburg, Germany
Phone +49 40 781108-0
Fax +49 40 781108-199

Refinery Salzbergen:
H&R ChemPharm GmbH*, **
Neuenkirchener Straße 8
48499 Salzbergen, Germany
Phone +49 5976 945-0
Fax +49 5976 945-624

Refinery Hamburg:
H&R Ölwerke Schindler GmbH*, **
Neuhöfer Brückenstr. 127-152
21107 Hamburg, Germany
Phone +49 40 32523-0
Fax +49 40 32523-285

197 21.06.2023

Certificate of Analysis

Potassium Chloride 99.9 % KCl

Ph. Eur., USP

Macco Organiques, s.r.o.
Zahradni 1938 46c
CZ-792 01 Bruntal

2022-12-20
Werk Werra, Standort WI
Nicole Kolz
Quality Control
08620/79-2050
nicole.kolz@k-plus-s.com

Manufacturer:	K+S Minerals and Agriculture GmbH	K+S Batch No.:	3422600922
K+S Order No:	7100260142	Manufact. Date:	2022-12-09
Delivery / Item No.:	7200773992 / 000010	Retest date:	2025-12-08
Quantity:	24 TO		
Loading date:	2022-12-19	K+S Specification:	77761 2-39 (K29)
Cust. Order No.:	20/2022/220256		

General information:
Manufacturer's address: Bertha-von-Suttner-Str. 7, 34131 Kassel, Germany
Manufacturing site's address: In der Aue 1, 36266 Heringen, Germany
Appearance: White or almost white, crystalline powder or colourless crystals.
Residual solvents: Meets ICH guideline CHMP/ICH/82260/2008 and test < 467 > of the United States Pharmacopoeia.
Solubility: Freely soluble in water; practically insoluble in anhydrous ethanol.

Parameter	Method of Analysis	Result	Specification
Appearance of Solution	Ph. Eur.	corresponds	o.K.
Acidity/Alkalinity	volumetry	corresponds	o.K.
Bromide *)	ICP-AES (Br and I in KCl)	corresponds	<= 1000 mg/kg
Sulphate	ICP-AES (KCl)	11 mg/kg	<= 300 mg/kg
Aluminium	ICP-AES (KCl)	<0.1 mg/kg	<= 1 mg/kg
Iron	ICP-AES (KCl)	<0.1 mg/kg	<= 20 mg/kg
Alkaline-Earth Metals as Ca	ICP-AES (KCl)	12 mg/kg	<= 200 mg/kg
Sodium	ICP-AES (KCl)	67 mg/kg	<= 1000 mg/kg
Loss on drying (3h, 105°C) *)	gravimetry	0.01 %	<= 1.0 %
Identity Reaction	ICP-AES (KCl)	corresponds	o.K.
Iodide acc. Ph.Eur. *)	ICP-AES (Br and I in KCl)	corresponds	o.K.
Iodide acc. USP *)	ICP-AES (Br and I in KCl)	<2 mg/kg	<= 50 mg/kg
Lead	ICP-AES (KCl)	<0.5 mg/kg	<= 0.5 mg/kg
Thallium	ICP-AES (KCl)	<0.5 mg/kg	<= 0.8 mg/kg
Assay (Dried Basis)	calculated	100.0 %	99.0 ... 100.5 %

*) not tested on each batch

Electronically released by Nicole Kolz on 2022-12-12

LABORATORIOS ARGENOL

www.laboratorios-argenol.com

LABORATORIOS ARGENOL S.L.
Autovía de Logroño Km 7,400. Pol. Europa 2, Nave 1
50011 Zaragoza (Spain)
Tel. +34 976 336 266 - Fax. +34 976 533 659
lab-argenol@laboratorios-argenol.com

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

LABORATORIOS ARGENOL
Autovía de Logroño, Km. 7,400
Polígono Europa 2, nave 1
500[illegible] ZARAGOZA
Telét: 976 336 266 Fax: 976 53 36 59

TERESA BARRENA
QUALITY ASSURANCE

WEIFANG SHENGTAI MEDICINE CO., LTD.

202, FANGSHAN ROAD, CHANGLE COUNTY, WEIFANG CITY, SHANDONG PROVINCE, CHINA

CERTIFICATE OF ANALYSIS 检验报告单

Product Name 产品名称	☑Dextrose Anhydrous 无水葡萄糖 ☐Dextrose Monohydrate 一水葡萄糖	Grade 级别	☐ Pharma Grade 药品级 ☑ Injection Grade 注射级
Batch No. 批号	20241001	Order No. 订单序号	02
Packing 包装规格	25 kg/bag 25 千克/袋	Quantity 数量	152000kg
Manufacture Date 生产日期	October 1，2024 2024 年 10 月 1 日	Expiry Date 有效期	September 30，2026 2026 年 9 月 30 日
Inspection Date 检验日期	October 2，2024 2024 年 10 月 2 日	Reporting Date 报告日期	October 9，2024 2024 年 10 月 9 日
Standard 检验依据	☑BP 2022 ☑EP 10.0 and ChP 2020 requirements ☑BP 2022 ☑EP 10.0 标准及中国药典 2020 标准		

Items 指标	**Standard 标准**	**Results 结果**	**Conclusion 结论**
Appearance 表观	White or almost white, crystalline powder 白色或近白色结晶性粉末	White crystalline powder	conform
Solubility 溶解度	Freely soluble in water, very slightly soluble in ethanol(96 percent)易溶于水，极微溶于乙醇(96%)	Freely soluble in water, very slightly soluble in ethanol(96 percent)	conform
Identification 鉴别	A. Specific Optical Rotation 比旋度+52.5°～+53.3°	+53.0°	conform
	B. The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a).供试品溶液色谱图主峰在保留时间、大小上与标准溶液(a)色谱图主峰相似。	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a).	conform
	C. The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a). 供试品溶液色谱图中主斑点的位置，颜色、大小与标准溶液(a)色谱图中主斑点的位置、颜色、大小相似。	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a).	conform
	D. A red precipitate is formed. 形成红色沉淀物	A red precipitate is formed	conform
	E. Water 水分 ☐7.5%-9.5% ☑≤1.0%	0.15%	conform
Appearance of Solution 溶液颜色和澄清度	The solution is clear and not more intensely coloured than reference solution BY_7 溶液澄清且浅于参考溶液 BY_7	The solution is clear and not more intensely coloured than reference solution BY7	conform
Content 含量	97.5%-102.0%	100.2%	conform
Conductivity 电导率	≤20μS·cm-1	1.6μS·cm-1	conform
Related Substances 相关物质	Maltose and Isomaltos 麦芽糖和异麦芽糖杂质总和≤0.4%	0.07%	conform
	Maltotriose 麦芽三糖杂质≤0.2%	0.01%	conform
	Fructose 果糖杂质≤0.15%	0%	conform
	Unspecified 未知杂质≤0.10%	0.01%	conform
	Total Impurities 总杂质≤0.5%	0.08%	conform
Dextrin 糊精	The substance dissolves completely 样品完全溶解	The substance dissolves completely	conform
Soluble Starch, Sulfite 可溶性淀粉，亚硫酸盐	≤15ppm	<15ppm	conform
Aerobic Plate Count 需氧菌总数	≤1000cfu/g	<10cfu/g	conform
Moulds and Yeasts 霉菌和酵母菌总数	≤100cfu/g	<10cfu/g	conform
Escherichia Coli 大肠杆菌	Negative/g	Not detected	conform
Bacterial Endotoxin 细菌内毒素限值	<1.25EU/g	<0.3EU/g	conform

Conclusion: The products meet the requirements of ☑BP 2022 ☑EP 10.0 and ChP 2020 requirements.

结论: 产品符合☑BP 2022 ☑EP 10.0 标准及中国药典 2020 标准。

Analyst 检验人: Reviewer 复核人: Approver 审批人:

CERTIFICATE OF QUALITY FOR SODIUM BICARBONATE EP/USP- EXTRA FINE GRADE

COMPANY	ASTRON CHEMICALS SA				
OUR ORDER NO.	3010129147	**ITEM NO**	3195SB00950		
CUSTOMER REF.	2400661 / EST2024/066				
QUANTITY	19.000	**PACKAGE**	42 X 25 KG PAPER SACKS		
BATCH NUMBERS	0000104063	0000104365	0000105589		
PACK DATES	10-FEB-2025	11-FEB-2025	18-FEB-2024		
RETEST DATE	365 Days from pack date				

CUSTOMER INFO	

This certificate confirms that the above product complies with the following limits:

CHEMICAL COMPOSITION

			Limit	
Identification	Gives reactions characteristic of sodium salts and of bicarbonates			
Normal Carbonate			passes test	
Mercury*	Hg	mg/kg	0.1	max
Sodium Bicarbonate	$NaHCO_3$	%	99.0-100.5	
Loss on Drying	Weight Loss	%	0.25	max
Ammonium	NH_4	mg/kg	20	max
Arsenic	As	mg/kg	2	max
Calcium	Ca	mg/kg	100	max
Chloride	Cl	mg/kg	150	max
Lead	Pb	mg/kg	2	max
Iron	Fe	mg/kg	20	max
Sulphate/Limit of sulphur compounds	SO_4	mg/kg	150	max
pH of a freshly prepared 5% Solution			8.6	max
Residual solvents (USP)	Meets the requirements			
Insoluble Substances	1g dissolves completely in 20 ml. of water to give a clear solution			

PARTICLE SIZE

	Microns	% by Weight*	
Retained on	250	0.2	max
Retained on	125	2.0	max
Retained on	63	25.0	max

* Limits expressed as non-cumulative values

Signed: .....

(M.D. on behalf of Tata Chemicals Europe)

Date 20-MAR-2024

Ref SSRB001E

TATA CHEMICALS EUROPE LIMITED
Winnington Lane, Northwich, Cheshire CW8 4GW, United Kingdom
Tel +44 (0) 1606 724000 Fax +44(0) 1606 781353 www.tatachemicals.com
VAT Reg No. GB 593653895 Private Limited Company, Registered in England. Registered No. 2607081

SALINEN AUSTRIA

CERTIFICATE OF ANALYSIS

Laboratory Salinen Austria AG

PHARMASAL HD

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

Lot number: C85291024
Retest date: 29.10.2027
Production date: 29.10.2024 - 02.11.2024

		Specification	Unit	Result	Unit
Identification	Na+	positive		conforms	-
Identification	Cl-	positive		conforms	-
Assay	NaCl	99,9 - 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, amt. 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: 12.11.2024

Salinen Austria AG
Labor
Steinkogelstraße 30
4802 Ebensee
Tel. +43 6132 / 200-0

LANOLINE STELLUX AI 10/40

Nom CTFA ou INCI	Lanolin
Composition	Fatty acid and fatty alcohol esters, obtained by the refining of wool grease.
Quality	Euro. Pharm III and current USP
CAS #	Lanolin : 8006-54-0- BHT : 128-37-0
EINECS #	Lanolin : 232-348-6- BHT : 204-881-4

Dropping point (°C)	38-44
Melting point (°C)	36-42
Acidity (%) (FFA)	0.50 max
Acid value (mg KOH/g)	1 max
Loss on drying (1h @105°C) (%)	0.5 max
Sulfated ash (%)	0.15 max
Saponification value (mg KOH/g)	90-105
Iodine value (Wijs)	28-38
Water-soluble acids/alkalies	conform
Water-soluble oxidants	conform
Peroxide value (meq)	20 max
Water absorption (%)	200 mini
Paraffins (%)	1 max
Chlorides (ppm)	150 max
BHT content (ppm)	200 max
Pesticides content (ppm)*	40 max
Color (Gardner) à 80°C	10 max.

* Organo-chlorinated, organo- phosphorated et pyrethroid pesticides

S.A.. au capital de 1 950 000 euros
Zoning industriel – Rue des Garennes 9B – B-7700 Mouscron. BELGIUM
Phone # (32) 5656 1843 – Fax # (32) 5656 1848 – stella@stella.fr
R.C. Tournai 60.577 – VAT # BE 425 151 097

检 验 报 告 单

CERTIFICATE OF ANALYSIS

品　　名 Name of product	磺胺噻唑钠 Sulfathiazole Sodium	报告日期 Report Date	2025年03月14日 March 14, 2025
批　　号 Lot NO.	250201	生产日期 Manufacture Date	2025 年 02 月 February, 2025
数　　量 Net weight	250kg	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℃		200℃～201℃
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	22.0-27.0%		25.0%
微生物限度 Microbial limit	需氧菌总数 Total number of aerobic bacteria	不得过10^3cfu/g Not more than 10^3cfu/g	＜10
	霉菌和酵母菌总数 Total number of mold and yeast	不得过10^2cfu/g Not more than 10^2cfu/g	＜10
含　　量 Assay	以干品计，含 $C_9H_8N_3NaO_2S_2$ 应不小于 99.0%且不大于 101.0% NLT 99.0% and NMT 101.0% of $C_9H_8N_3NaO_2S_2$,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　　复核者：王美芳　　负责人：缪彩珍
Analyst:　　Checker:　　Supervisor:

NO.159 Dongguan Road,Tuncun ,Tongli Town，Wujiang District,Suzhou,Jiangsu,China 215216
TEL：+86-512-63371371　　FAX: +86-512-63371236

TALC ANALYSIS CERTIFICATE

IMIFABI

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
P. aeruginosa	-	USP **	Absent	Absent in 10 g
E. coli	-	USP **	Absent	Absent in 10 g
S. entérica	-	USP **	Absent	Absent in 10 g
S. aureus ssp	-	USP **	Absent	Absent in 10 g
C. albicans	-	USP **	Absent	Absent in 10 g
Clostridium spp.	-	USP **	Absent	Absent in 10 g

NOTE

1. Representative results for batch (25,000 tons)
2. Whiteness (L*) - Minolta CM600D Illum. C; Obs. 2°
3. Expiration date: 60 months (provided it is kept on the established conditions and in its original packaging).
4. Invoice:
5. Nº DCB: 08264
6. Nº of CAS registry: 14807-96-6
7. ** Current version
8. 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

IMIFABI

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

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.° - 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

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

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.° - 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

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.

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.° - 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

Certificate of Analysis

Mat.-No	1000670	Batch-No	0000207121
Product	Menthol Ph. Eur.	No. of Analysis	40000237328
Company No	102417		
Company	Brenntag SRL		

Characteristic	Value	Unit	Lower Limit	Upper Limit
Appearance (sensorical)	Corresponds	Acicular crystals or shining prism		
Colour (sensorical)	Corresponds	colourless or white		
Optical rotation (at 20°C)	-49,6	°	-51,0	-48,0
Solubility in Ethanol 96%	Corresponds			
Solubility set values	Corresponds	(2,5 g in 25 ml) clear and colourless soluble		
Identity	corresponds Ph.Eur.			
Melting point	42	°C	41	44
Residue on evaporation	0,01	%		0,05
Acidic or alkaline substances	corresponds Ph.Eur.			
Chromatographic Profile	corresponds			
Isopulegol	0,15	A%		0,30
Menthol	99,5	A%	99,0	
Neomenthol	0,07	A%		0,30
Related substances	1,00	A%		1,00

Observations/ Remarks: corresponds to Ph.Eur , USP

Date of manufacture 08.05.2023 Date of retest 06.05.2028

Created WE
Date 01.08.2024

This document was generated by computer and carries no signature.

384/4
Düllberg Konzentra GmbH & Co. KG
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Komplementär Verwaltungsgesellschaft
Düllberg Konzentra m.b.H.Hamburg
Registergericht: HamburgHR B 37513
Steuernummer: 49 /615 /00287

Kommanditgesellschaft: Sitz Hamburg
Registergericht: Hamburg HR A 47413
Geschäftsführer: Manfred Düllberg
Christian Düllberg

Deutsche Bank AG
BLZ 200 700 00/Kto 49 00007
IBAN:DE51200700000490000700
BIC: DEUTDEHH

SCL Italia
Larderello Group

CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : **1057/24** Issue Date: **October 04, 2024**

Lot. n°: **C020224010**

Manufacturing date: **July 31, 2024**
Expiry date: **July 31, 2027**

SODIUM TETRABORATE DECAHYDRATE EP

The product is an accordance with the European Pharmacopeia 11.0 for sodium tetraborate decahydrate

Analysis:

Characteristics		Units		Test Results	Specific Min.	Specific Max.	Analytical chemistry procedure employed
Description			:	**Powder, white granules**			
Identification			:	**Positive**			European Pharmacopoeià
Appearance of the solution			:	**According to Ph. Eur.**			European Pharmacopoeià
pH of 4 % solution			:	**9,3**	9,0	9,6	pH-Meter
Ammonium	NH_4	ppm	<	**10**	-	10	European Pharmacopoeià
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	$Na_2B_4O_7 \cdot 10H_2O$	%	:	**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
M[redacted]oli
[redacted]
[redacted]

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CERTIFICATO DI ANALISI - CERTIFICATE OF ANALYSIS

Prodotto - Product 011166_006 ZOLFO PRECIPITATO PH. EUR. - SULFUR PRECIPITATED PH. EUR. - SULFUR

Conformità - Compliance EP

Lotto - Batch Number R2433325

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: 17/01/2025 **Data rititolazione - Retest date:** 31/12/2029 **Data di analisi - Analysis date:**17/01/2025

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	SOLUBILITY	Practically insoluble in water
	Solubile in disolfuro di carbonio		Soluble in carbon disulfide
	Leggermente solubile in oli vegetali		Sligtly 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.	PHARMACOPOEIA	Complies with Ph. Eur.
DICHIARATE DAL FORNITORE	USP ed. vigente	SUPPLIER'S DECLARATION	USP curr. ed.

INFORMAZIONI GENERALI		GENERAL NOTICES	
SINONIMI	Zolfo magistero	OTHER NAMES	Milk of Sulphur
NATURA DEL PRODOTTO	Sintetica	PRODUCT SOURCE	Synthetic origin
TIPO DI PRODOTTO	Conforme a Farmacopea	TYPE OF PRODUCT	Complies with Pharmacopoeia
	Prodotto per uso esterno		Product for external use
ALLERGENI	Esente da lattice	ALLERGENS	Latex free
	Non contiene allergeni cosmetici (Reg. 1223/2009/CE)		The product doesn't contain any cosmetic allergen ingredients (Reg. 1223/2009/EC)
PESTICIDI	Assenti	PESTICIDES	None
MICOTOSSINE	Assenti	MYCOTOXINS	Negative
SOLVENTI RESIDUI	Nessun solvente organico viene impiegato nel processo produttivo	RESIDUAL SOLVENTS	No organic solvents are used in the manifacturing process
CONTAMINANTI	Esente da diossina	CONTAMINANTS	Dioxin-free
CONSERVAZIONE	Conservare in contenitori ben chiusi in luogo fresco e asciutto	STORAGE	Store in tightly closed containers in a cool, dry place
	Conservare lontano da fonti di ignizione e calore		Keep away from sources of ignition and heat
PROPRIETÀ	Coadiuvante nel trattamento di stati di cheratosi e di infiammazione	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 - PIO5676410722 - Cap. Soc. € 360,000,00 i.v.

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CERTIFICATO DI ANALISI - CERTIFICATE OF ANALYSIS

Prodotto - Product **011166_006 ZOLFO PRECIPITATO PH. EUR. - SULFUR PRECIPITATED PH. EUR. - SULFUR**

Conformità - Compliance **EP**

Lotto - Batch Number **R2433325**

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: **17/01/2025** **Data rititolazione - Retest date:** **31/12/2029** **Data di analisi - Analysis date:17/01/2025**

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
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Certificate of Analysis

LANXESS
Energizing Chemistry

SC BRENNTAG SRL
Vasilica Calin
Str. Garii 1
077040 Comuna Chiajna

E-mail: vasilica.calin@brenntag.com

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

Date: 07.06.2024

Material No.	Material Description
62609761	PUROX® B FOOD/PHARMA ULTRA PURE GRADE BENZOIC ACID IN 25 KG BAG (55 BAGS PER PALLET)

Customer Product No.
491170

Customer Order Data

Order No.	Your Order No.	Ship-to Party
4000348088/000010	4570111378	4000283592 DSV Air & Sea GmbH

Delivery Data

Delivery No.	Delivered Quantity	Planned Delivery Date	Vehicle ID
5000612938/000010	2.750,000 KG	11.06.2024	IS12SWT

Batch	Delivered Quantity	Date Of Manufacture	Best Before	Production Plant
24231	2.750,000 KG	03.06.2024	03.06.2026	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

LANXESS
Energizing Chemistry

Batch	Material Description	Delivery No.	Planned Delivery Date
24231	PUROX® B FOOD/PHARMA ULTRA PURE GRADE BENZOIC ACID IN 25 KG BAG (55 BAGS PER PALLET)	5000612938/000010	11.06.2024

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
24231	PUROX® B FOOD/PHARMA ULTRA PURE GRADE BENZOIC ACID IN 25 KG BAG (55 BAGS PER PALLET)	5000612938/000010	11.06.2024

Inspection Method / Characteristic	Result	Specification	Unit
13) AM 011 Sulphated Ash: max. 0.01%2)3)			
14) AM 009 Oxidizable Substances: max. 0.2 ml 0.02 mol KMnO4/g2)3)			
15) AM 011 Residue on Ignition: max. 0.05%2)3)			
16) AM 010 Carbonizable Substances (matching fluid): max. Q2)3)			
17) AM 012: Turbidity (20% solution in ethanol): max. 4.0 NTU2)3)			
18) AM 013 Solidification point : 121.5 – 122.5°C2)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

Macco Organiques, s.r.o.
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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
Assay	97.0 - 103.0 per cent	101.5 %
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'

SKW STICKSTOFFWERKE PIESTERITZ GMBH

Analytical department
Producer Test Certificate 3.1
according to EN 10 204

Customer	Brenntag GmbH		
SKWP order no.	20534229	Customer order no.	4501560548
For queries	Quality management Tel. + 49(0) 34 91 - 68 43 43 / 68 20 75		
Product name	**Urea, crystalline pure**		
Charge	**V 006-2023**	Quantity	18,000 TO
Packaging period	09.01.2023 - 11.01.2023		
Best before end	01.2026		

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	℃	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, 16.01.2023

Dr. Geisler
Abteilung Analytik

SCL Italia
Larderello Group

CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : **1353/24**

Issue Date: **December 18, 2024**

Lot. n°: **C010424032**

Manufacturing date: **December 09, 2024**
Expiry date: **December 09, 2029**

BORIC ACID EP

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

Analysis:

Characteristics		Units		Test Results	Specific Min.	Specific Max.	Analytical chemistry procedure employed
Description			:	**Powder, white granules**			
Identification			:	**Positive**			European Pharmacopoeià
Appearance of the solution			:	**According to Ph. Eur.**			European Pharmacopoeià
Solubility in alcohol			:	**According to Ph. Eur.**			European Pharmacopoeià
Organic matter			:	**According to Ph. Eur.**			European Pharmacopoeià
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_3BO_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
M[redacted]ipoli

Laboratorios Imperiales, S.A. de C.V.
Calle 13-Este, No. 606, CIVAC Jiutepec Morelos, CP: 62578
Tel: (+52) 777 3191410, 777 321 66 71

Contact Information:
Claudio Bezanilla Salcedo
Title: CEO
Mail: cbezanilla@limsafc.com.mx
Tel: (+52) 55 1941 2141

LIMSA

ANNEX OF STANDARD OPERATING PROCEDURE FOR CERTIFICATE OF ANALYSIS ELABORATION.

FORMAT FOR CERTIFICATE OF ANALYSIS.

Code: ANX1-PNO-DAC-021

CoA/S

Product: Bismuth Tribromophenate.	Internal product code: 412
Sample weight: 400 g	Batch number: PTQ-3551/23
Delivery weight: 200.00 Kg	Analysis number: 3551/23
Manufacturing date: 28-JUN-22	Internal batch number: H-72/23
Retest date: 28-JUN-28	CAS No: 5175-83-7
Reference: US Dispensatory 25th, Medicamenta III 1963, BP 1949, USP	

Test	Specification	Result
Description	Light yellow, amorphous powder with a faint characteristic odor.	Meets
Identification Bismuth ion (Bi^{+3}) Tribromophenol	 Positive for Bi^{+3} Positive for tribromophenol	 Positive Positive
Substance not precipitated by NH_4OH	≤ 0.50%	0.03%
Free 2, 4, 6-Tribromophenol	≤ 3.3%	1.09%
Arsenic	0.0002	< 0.0002
Cooper	To pass test	Pass test
Silver	To pass test	Pass test
Lead	To pass test	Pass test
Sulphate	To pass test	Pass test
Nitrates	To pass test	Pass test
Loss on drying	Not specified	0.3%
Assay of Bismuth(as Bi)	40.0-49.0	46.92%

Storage and packaging conditions.

Package	Double polyethylene plastic bag, packed in cardboard fiber drum.	Storage	Less than 25°C protect from direct sunlight exposure.
Marks	According to ND	Shelf life	6 years.

Analyzed by:	Issued by:	Approved by:
J. Martinez, JM. Bahena, B. Treviño	Xochitl Yutziri Benitez Nava C.P. D.G.P. 4719879 Head of Quality Control	p.a. Claudio Bezanilla Martinez. C.P.D.G.P. 187941 Sanitary Responsible N o. ARM-0577-2002
Date: 16-NOV-23	Date: 17-NOV-23	Date: 17-NOV-23