

Certificate of Conformance

Authorisation of Batch Release for sale in the EU

Product name, dose, dosage form and pack size:	Naxiva Panaxol THC 25mg/ml
Client:	Neuraxpharm Arzneimittel GmbH
Market:	Germany
Batch number:	25009-01
Internal Batch Number:	FP25009-01DE
Quantity	502 kits
Manufacturing Date:	28/11/2025
Expiry date:	09/2027
Active Ingredient Concentration:	THC 2.6% (w/w)
Plant strain/s:	Tchelet

Deviations noted during manufacture:

- No Critical deviations
- Critical deviations were reported and properly investigated and closed

The following document are attached

- *COA Finished Product*
- *Herbal Substance CoA 25/108-MT – Strain Tchelt*
- *Package COA*
 - *10ml amber glass bottles - batch number: 23/337-MT*
 - *10ml amber glass bottles cap- batch number: 25/001-INS*
 - *1ml sterile graduated syringes for patient dosing: - batch number: 25/031-MT, 25/092-MT*
 - *syringe cap- batch number: 24/251-MT*
 - *30ml amber glass bottles - batch number: 24/198-MT, 25/090-MT*
 - *30ml amber glass bottles cap- batch number: 23/142-MT*

Product Name: NAXIVA-PANAXOL THC 25mg/mL
Reference Specification Legacy Number: F-COA-007-DE

<i>Batch Details</i>			
Batch number -Bulk oil	FN 25009-01	Manufacturing date	11/2025
Batch number - Finish product	25009-01	Expiry date	11/2027
MT- Batch number	FP 25009-01 DE		

Test	Test Method	Specifications	Result
Identification			
TLC identification	SOP QC-179-MT/ VA1112 <i>DAB</i> [£]	Zonal pattern of test solution conforms to the zonal pattern of the reference solution	Complies
Organoleptic properties			
Appearance	SOP QC-136-MT Visual inspection <i>DAB</i> [£]	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	Complies
Heavy metals ^{1,2}			
Cadmium	SOP 77405 ICP-MS <i>Ph. Eur. 2.4.27</i> [◇]	≤ 1.0 ppm	< 0.05 ppm
Lead		≤ 5.0 ppm	< 0.1 ppm
Mercury		≤ 0.1 ppm	< 0.05 ppm
Physico-chemicals			
Relative density	SOP-183-MT / VA1044 <i>Ph. Eur. 2.2.5</i> [◇]	Indicative	0.91*
Water content	SOP-175-MT/ VA25322 Karl Fisher <i>Ph. Eur. 2.5.12</i> [◇]	≤0.5%	< 0.2%
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT/ VA45110 <i>Ph. Eur. 2.8.18</i> [◇]	≤ 2 µg/Kg	< LOQ
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	< LOQ
Microbiological Quality ¹			
TAMC	MW024-01/ VA52090,	≤ 10 ⁴ CFU/mL	< 100 CFU/ml
TYMC	<i>Complies to Ph. Eur. 2.6.12</i> [◇]	≤ 10 ² CFU/mL	< 10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01/ VA52090, <i>Complies to Ph. Eur. 2.6.31</i> [◇]	< 10 ² CFU/mL	< 10 CFU/ml
E.Coli		Absent in 1mL	Absent in 1 ml
Salmonella		Absent in 25 mL	Absent in 25 ml
Residual solvent ³			
Ethanol	QC-140-MT/ VA12301 GC-HS-FID	≤ 5000 ppm	NA
Assay - Cannabinoids concentration (%w/w)			
CBN	QC-181-MT <i>DAB</i> [£]	≤ 2.5% m/m	0.0%
CBD		≤ 0.16% m/m (≤ 6% from Δ9-THC label claim)	0.01%



COA - THC25 (THC2.6%) DE

Document Number: SPC-0001223

Document Version: 4.0

Effective Date: 14-Jan-2026

Product Name: NAXIVA-PANAXOL THC 25mg/mL
Reference Specification Legacy Number: F-COA-007-DE

Batch Details			
Batch number -Bulk oil	FN25009-01	Manufacturing date	11/2025
Batch number - Finish product	25009-01	Expiry date	11/2027
MT- Batch number	FP25009-01DE		

Δ9-THC		2.47% - 2.73% m/m (95-105 % from label claim)	2.59%
Vitamin E	QC-149-MT / VA14060	≥ 0.4% m/m	0.5%*
Pesticide Residue ^{1,2}			
Pesticides	SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS Ph. Eur.2.8.13 [‡]	Complies with the limits indicated in Ph. Eur.2.8.13	Complies

Aflatoxins UQL- Under quantification limit; LOQ Aflatoxin B1, B2, G1: 0,5 µg/kg; LOQ Aflatoxin G2: 1,0 µg/kg.

Residual Solvents UDL – Under detection limit. The result of Ethanol that is less than 170ppm is reported UDL.

Residual Solvents UQL – Under quantification limit. The result of Ethanol that is less than 500ppm is reported UQL.

Assay URL – Under reporting level. The concentration of CBN that are less than 0.05% from the label amount of THC and CBD are reported URL (0.001% w/w)

[‡] Current version of monograph

[‡] DAB *Cannabis extractum normatum* monograph

1. Performed by approved outsource laboratory

2. Pesticides and Heavy metals – To be performed every 20th Batch. When skip lot testing is performed both results are reported from the Inflorescence COA.

3. Residual Solvent – To be performed every 20th batch.

Consecutive batch no:	Pesticides and Heavy metals testing required on Finished product:
7	<input type="checkbox"/> Yes; <input checked="" type="checkbox"/> No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: 25/108-MT

<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL		
QC Reviewed by: Jennifer Riano Ortiz	Signature: <i>Jennifer Riano Ortiz</i>	Date: January 14, 2026
Following the review of the manufacturer's COA and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirement, hence this batch is: <input checked="" type="checkbox"/> Approved/ <input type="checkbox"/> Rejected.		
Approved by: Shani Bonan	Signature: <i>[Signature]</i>	Date: January 14, 2026

REVISION HISTORY				
Date	Name of corrector	Version no	Details of correction (including Chapter No)	Reason of correction
12/03/2024	Shani Bonan	01	New Document	CCF-MT-2024-23
11/02/2025	Shani Bonan	02	1. Adding the method's number of QSI 2. Adding Residual solvent - To be performed every 20 th Batch. 3. Remove Ochrotoxin test	1. CC-0000022 2. CC-0000016 3. CC-0000033
17/06/2025	Shani Bonan	03	1. Updated Format of COA	1. CAPA-0000028
07/01/2026	Shani Bonan	04	2. Add a box for Malta batch number	2. CC-0000084

Document State: Effective (Controlled)

CONFIDENTIAL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Shani Bonan	QC Manager	14-Jan-2026 10:40
Send for Approval	Chris Desira	Head of Quality Assurance	14-Jan-2026 10:57
Review	Chris Desira	Head of Quality Assurance	14-Jan-2026 10:57
Approve	Chris Desira	Head of Quality Assurance	14-Jan-2026 12:45
Approve	Shani Bonan	QC Manager	14-Jan-2026 14:39
QA Approval	Ivan Vidmar	Senior QA Specialist	14-Jan-2026 14:40

* Dates are displayed according to the system time zone: (GMT+01:00) Central European Standard Time (Europe/Malta)

Reference Specification Legacy number: F-SPC-007-MT

Panaxia Malta Batch No: FN25009-01	PRT Number: WP000017-MT	Expiry Date: 11/2027
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1. Specifications:

Test	Test Method	Specifications	Result
Identification			
TLC identification	SOP QC-179-MT/ VA1112 <i>DAB</i> [£]	Zonal pattern of test solution conforms to the zonal pattern of the reference solution	Complies
Organoleptic properties			
Appearance	SOP QC-136-MT Visual inspection <i>DAB</i> [£]	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	Complies
Physico-chemicals			
Relative density	SOP-183-MT / VA1044 <i>Ph. Eur. 2.2.5</i> [◇]	Indicative	0.91*
Water content	SOP-175-MT/ VA25322 Karl Fisher <i>Ph. Eur. 2.5.12</i> [◇]	≤0.5%	< 0.2%
Heavy metals ^{1,2}			
Cadmium ^{1,2}	SOP 77405 ICP-MS <i>Ph. Eur. 2.4.27</i> [◇]	≤ 1.0 ppm	< 0.05 ppm
Lead ^{1,2}		≤ 5.0 ppm	< 0.1 ppm
Mercury ^{1,2}		≤ 0.1 ppm	< 0.05 ppm
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT/ VA45110	≤ 2 µg/Kg	< LOQ
Total Aflatoxins (B1, B2, G1, G2)	<i>Ph. Eur. 2.8.18</i> [◇]	≤ 4 µg/Kg	< LOQ
Microbiological Quality ^{1,3}			
TAMC	MW024-01/VA52090 <i>Complies to Ph. Eur. 2.6.12</i> [◇]	≤ 10 ⁴ CFU/mL	< 100 CFU/ml
TYMC		≤ 10 ² CFU/mL	< 10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01/ VA52090 <i>Complies to Ph. Eur. 2.6.31</i> [◇]	< 10 ² CFU/mL	< 10 CFU/ml
E.Coli		Absent in 1 mL	Absent in 1 ml
Salmonella		Absent in 25 mL	Absent in 25 ml
Residual solvent ⁴			
Ethanol	QC-140-MT/ VA12301 GC-HS-FID	≤ 5000 ppm	NA



Assay			
CBN ³	QC-181-MT DAB [£]	≤ 2.5% m/m	0.0%
CBD		≤ 0.16% m/m (≤ 6% from Δ9-THC label claim)	0.01%
Δ9-THC		2.47% - 2.73% m/m (95-105 % from label claim)	2.59%
Vitamin E	QC-149-MT/ VA14060	≥ 0.4% m/m	0.5% *
Pesticide Residue^{1,2}			
Pesticides	SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS Ph. Eur. 2.8.13 [◊]	Complies with the limits indicated in Ph. Eur. 2.8.13	Copmlies

Aflatoxins UQL- Under quantification limit; LOQ Aflatoxin B1, B2, G1: 0,5 µg/kg; LOQ Aflatoxin G2: 1,0 µg/kg

Residual Solvents UDL – Under detection limit. The result of Ethanol that is less than 170ppm is reported UDL.

Residual Solvents UQL – Under quantification limit. The result of Ethanol that is less than 500ppm is reported UQL.

Assay URL – Under reporting level. The concentration of CBN that are less than 0.05% from the label amount of THC and CBD are reported URL (0.001% w/w)

[◊] Current version of monograph

[£] DAB Cannabis extractum normatum monograph

1. Performed by approved outsource laboratory

2. Pesticides and Heavy metals – To be performed every 20th Batch. When skip lot testing is performed both results are reported from the Inflorescence COA.

3. For the France batch the result needs to be also approved to the limit and tests in Appendix-1

4. Residual solvent - To be performed every 20th Batch.

* Result take from batch FN25009-02 according to protocol P-0001516

Consecutive batch no:	Pesticides and Heavy metals testing required on Finished product:
7	<input type="checkbox"/> Yes; <input checked="" type="checkbox"/> No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: 25/108-MT

2. Packaging:

2.1. 30mL of Standardized Extract filled in a 30 mL amber glass pharma grade bottle (PK-000007-MT) with:

2.1.1. **Child Resistant Caps (WP-000037-MT; WP-000043-MT):** a screw cap tamper evident and child safety lock (PK-000013-MT).

2.1.2. **Non-Child Resistant Caps (WP-000016-MT; WP-000034-MT):** a screw cap tamper evident (PK-000008-MT).

3. Shelf life: 24 months

4. Storage conditions: Store in a cool, dry place, protected from light and at a temperature not exceeding 25°C.

PASS **FAIL**

Analysed by: Jennifer Riano Ortiz	Signature: Jennifer Riano Ortiz	Date: January 14, 2026
Following the review of the manufacturer's COA and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirement, hence this batch is: <input checked="" type="checkbox"/> Approved / <input type="checkbox"/> Rejected .		
QC approved by: Shani Bonan	Signature: 	Date: January 14, 2026

Appendix-1-For France market

Test	Test Method	Specifications	Result
Identification			
HPLC PDA-UV Spectrum Identification	SOP QC-181-MT HPLC DAB [£]	UV spectra of THC and CBD peaks on the sample chromatograms conform to that on the standard chromatograms	
Packaging:			
Appearance of the external packaging	SOP QC-347-MT	Intact box and glass bottles, readable labels, no cracks, and visible defects	
Microbiological Quality¹			
Salmonella	MW024-01/VA52090 Complies to Ph. Eur. 2.6.12 / 2.6.13 [◇]	Absent in 10 ml	
S. aureus		Absent in 1 ml	
Assay			
CBN	QC-181-MT DAB [£]	≤ 1.0% _{m/m}	

PASS FAIL

Analysed by:	Signature:	Date:
Following the review of the manufacturer's COA and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirement, hence this batch is: <input type="checkbox"/> Approved/ <input type="checkbox"/> Rejected.		
QC approved by:	Signature:	Date:

REVISION HISTORY				
Date	Name of corrector	Version no	Details of correction (including Chapter No)	Reason of correction
12/03/2024	Shani Bonan	01	New Document	CCF-MT-2024-23
11/02/2025	Shani Bonan	02	1. Adding the method's number of QSI 2. Adding Residual solvent - To be performed every 20 th Batch. 3. Remove Ochratoxin test	1. CC-0000022 2. CC-0000016 3. CC-0000033

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Approve	Shani Bonan	QC Manager	02-Mar-2025 09:10
Approve	Irene Zanetti	Qualified Person	04-Mar-2025 08:13
QA Approval	Chris Desira	Head of Quality Assurance	06-Mar-2025 15:21
Send for Review (Written By)	Shani Bonan	QC Manager	12-Feb-2025 11:13
Review	Chris Desira	Head of Quality Assurance	25-Feb-2025 16:02
Send for Approval	Chris Desira	Head of Quality Assurance	25-Feb-2025 16:03
Approve	Chris Desira	Head of Quality Assurance	25-Feb-2025 16:03

* Dates are displayed according to the system time zone: (GMT+01:00) Central European Standard Time (Europe/Malta)



CERTIFICATE OF ANALYSIS

Product: 1ml Dosing Syringe
 Product Code: SYPN01-WH - CE
 Batch/Lot No.: BRV240943
 A.R. No.: FG-24-1944
 MFG Date: 04/12/2024

Date: 06/12/2024
 Batch/Lot size: 30,000 NOS
 Challan No.: EXP/41/2024-25
 Exp Date: 3 Years from MFG.

Party's Name: Origin Packaging Ltd.

Sr. No.	Tests	Specification	Results
A	Description	1ml Dosing syringe marked at volume of 0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml... up to 1ml with instruction (FOR ORAL USE ONLY) with individual BOPP sealing and CE0123 mark.	Complies
B	Appearance	Should confirm with	Complies
		(I) Colour	
		Barrel: Natural (Markings in Black Ink) Plunger: WHITE (PL00075542)	
		(II) Clarity	
		(III) Free from embedded foreign particles and dust particles.	
		(IV) Free from cuts & Un fillings.	
C	Physical Test		
(a)	Syringe Barrel		
1	Material	Polypropylene	Complies
2	Grade	RP375R	Complies
3	Total Height	86.50mm ± 1.0mm	85.79mm - 85.80mm
4	Outer Diameter	6.50mm ± 0.3mm	6.43mm - 6.58mm
5	Inner Diameter At Tip	2.40mm ± 0.2mm	2.24mm - 2.42mm
6	Outer Diameter At Tip	5.10mm ± 0.2mm	4.95mm - 5.10mm
7	Flange Diameter	18.50mm ± 0.3mm	18.46mm - 18.65mm
8	Volume Marking	0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml, 0.1ml... up to 1ml ± 5 %	Complies
(b)	Syringe Plunger		
1	Material	High Density Polyethylene	Complies
2	Grade	ACP 6541A	Complies
3	Total Height	92.50mm ± 1.0mm	92.38mm - 92.65mm
4	Sucking Od	4.85mm ± 0.2mm	4.83mm - 4.97mm
5	Collar Diameter	15.00mm ± 0.3mm	15.05mm - 15.19mm
(c)	Pouch		
1	Length Of Pouch	130.00mm ± 10.0mm	125mm - 138mm
2	Width Of Pouch	30.00mm ± 5.0mm	28mm - 33mm

Complies with our specification No. -BRV/FG-1903

Analyzed by:

Anurika
06/12/2024

Approved by:

gjh
06/12/2024

Format No. FQC/021-06/00

Bharat Rubber Works Pvt. Ltd.
 T-13, 3rd Floor, Pinnacle Business Park,
 Mahakali Caves Road, Andheri East,
 Mumbai - 400093. Maharashtra
 CIN NO. U25190MH2007PTC174074

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BHARAT RUBBER WORKS

Healthcare Packaging Solutions

CERTIFICATE OF ANALYSIS

Product: 1ml Dosing Syringe

Product Code: SYPN01-WH - CE

Batch/Lot No.: BRV250075

A.R. No.: FG-25-0172

MFG Date: 27/01/2025

Date: 31/01/2025

Batch/Lot size: 50,000 NOS

Challan No.: EXP/52/2024-25

Exp Date: 3 Years from MFG.

Party's Name: ORIGIN PACKAGING LTD

Sr. No.	Tests	Specification	Results
A	Description	1ml Dosing syringe marked at volume of 0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml.... up to 1ml with instruction (FOR ORAL USE ONLY) with individual BOPP sealing and CE0123 mark.	Complies
B	Appearance	Should confirm with (I) Colour Barrel: Natural (Markings in Black Ink) Plunger: WHITE (PL00075542) (II) Clarity (III) Free from embedded foreign particles and dust particles. (IV) Free from cuts & Un filings.	Complies
C	Physical Test		
(a)	Syringe Barrel		
1	Material	Polypropylene	Complies
2	Grade	RP375R	Complies
3	Total Height	86.50mm ± 1.0mm	85.70mm - 85.96mm
4	Outer Diameter	6.50mm ± 0.3mm	6.46mm - 6.62mm
5	Inner Dimeter At Tip	2.40mm ± 0.2mm	2.27mm - 2.45mm
6	Outer Dimeter At Tip	5.10mm ± 0.2mm	4.93mm - 5.12mm
7	Flange Diameter	18.50mm ± 0.3mm	18.49mm - 18.66mm
8	Volume Marking	0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml, 0.1ml.... up to 1ml + 5 %	Complies
(b)	Syringe Plunger		
1	Material	High Density Polyethylene	Complies
2	Grade	ACP 6541A	Complies
3	Total Height	92.50mm ± 1.0mm	92.20mm - 92.61mm
4	Sucking Od	4.85mm ± 0.2mm	4.80mm - 4.93mm
5	Collar Diameter	15.00mm ± 0.3mm	15.01mm - 15.16mm
(c)	Pouch		
1	Length Of Pouch	130.00mm ± 10.0mm	124mm - 137mm
2	Width Of Pouch	30.00mm ± 5.0mm	26mm - 31mm

Complies with our specification No. -BRV/FG-1903

Analyzed by:




Party
31/01/2025

Approved by:

[Signature]
31/01/2025

Format No. FQC/021-06/00

Bharat Rubber Works Pvt. Ltd.
T-13, 3rd Floor, Pinnacle Business Park,
Mahakali Caves Road, Andheri East,
Mumbai - 400093. Maharashtra
CIN NO. U25190MH2007PTC174074

 www.bharatrubberworks.com
 +91 22 6859 2401/424
 marketing@brworksindia.com

Article number	PRT Number	Manufacturer	Item
0254307020	PK-000007-MT	SGD Pharma	30mL, type 3 amber glass bottles

Article number	PRT Number	Panaxia's Supplier	Item
34030	PK-000007-MT	Zscheile & Klinger	30mL dropper bottles, DIN 18, type 3 amber glass

Manuf. Batch No:	Panaxia Batch No:	Manuf. Expiry Date:
N 241562	2510910-MT	24-01-2031

1.0 Specifications:

Test	Test Method*	Specifications	Results (average)
Specifications and Description:			
Glass Quality	Supplier COA	Arsenic	<0.100 ppm 0.001
		Hydro-resist-powder/1g	<0.850 mL 0.520
		Hydrolytic resistance (HCL)	<6.100 mL 4.850
		Spectral transmission	<10.000% 2.520
		Annealing	<18.000 Conforms
Glass Measurements	Supplier COA	Minor thread diameter	15.680 - 15.980 mm 15.820
		Mini internal bore	>9.500 mm 11.550
		Neck finish height 2	10.800 - 11.200 mm ^{the 25-06-2025} 11.010 11.010
		Maxi external neck	<18.000 mm 17.750
		Opening diameter	10.450 - 10.750 mm 10.740
		Neck finish diameter	17.700 - 18.000 mm 17.780
		Bead diameter	19.800 - 20.200 mm 19.950
		Neck finish height	13.500 - 13.900 mm 13.570
Glass characteristics	Supplier COA	Capacity	34.300 - 36.700 mL 35.525
		Vertical load	>200.000 Kg/cm 400.000
		Thermal shock	>42.000 Conforms
Color	Supplier COA	Brown (amber glass)	Complies
Length (L)	Measure Length using Calibrated Ruler	78.50 - 80.10 mm	78.50
Body Diameter (D)	Measure Length using Calibrated Caliper	31.900 - 32.900 mm	32.15
Appearance (bottom)	Check if designated mark is present on bottom side	30 mL mark	Complies

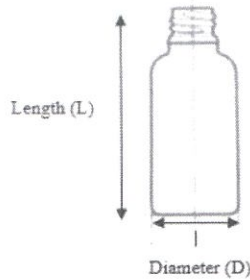


Figure 1: Physical Description

2.0 Packaging and Labeling

- 2.1 Each package must be labeled, by the manufacturer, with at least the following information:
 - 2.1.1 Supplier name and address
 - 2.1.2 Quantity per bag
 - 2.1.3 Supplier article number and description
 - 2.1.4 Supplier batch number
 - 2.1.5 Packed on

2.2 Expiry date: 6 years from manufacturing date (Specified on SGD supplemented documentation)

3.0 Storage conditions:

- 3.1 Store in a cool dry location at a temperature lower than 30°C.

Sample Number	Length (mm)			Body Diameter (mm)			
	1	2	3	1	2	3	4
1	78.50	11	78.50	1	32.13	11	32.19
2	78.50	12	78.50	2	32.21	12	32.01
3	78.50	13	78.50	3	32.14	13	32.07
4	78.50	14	78.50	4	32.20	14	32.27
5	78.50	15	78.50	5	32.04	15	31.98
6	78.50	16	78.50	6	32.23	16	32.29
7	78.50	17	78.50	7	32.20	17	32.37
8	78.50	18	78.50	8	32.17	18	31.93
9	78.50		N.A.	9	32.08		N.A.
10	78.50		N.A.	10	32.27		N.A.

Equipment/Instrument used:	Equipment/Instrument ID:
Calibrated Caliper	CAL - 01 - MT
Calibrated Ruler	RUL - 01 - MT

PASS FAIL

Analysed by: <i>Jennifer Reano Ortiz</i>	Signature: <i>[Signature]</i>	Date: <i>25.06.2025</i>
Following the review of the manufacturer's COA and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirement, hence this batch is : <input checked="" type="checkbox"/> Approved/ <input type="checkbox"/> Rejected.		
QC approved by: <i>ROSANNA DEMOLA</i>	Signature: <i>[Signature]</i>	Date: <i>26/06/2025</i>

Document title	PRT Number	Document type	Document No.	Version
COA Screw closure for 30 ml	PK-000081-MT	COA	F-SPC-113-113-MT	02
Effective date: 13/02/2025			Page 3 of 4	

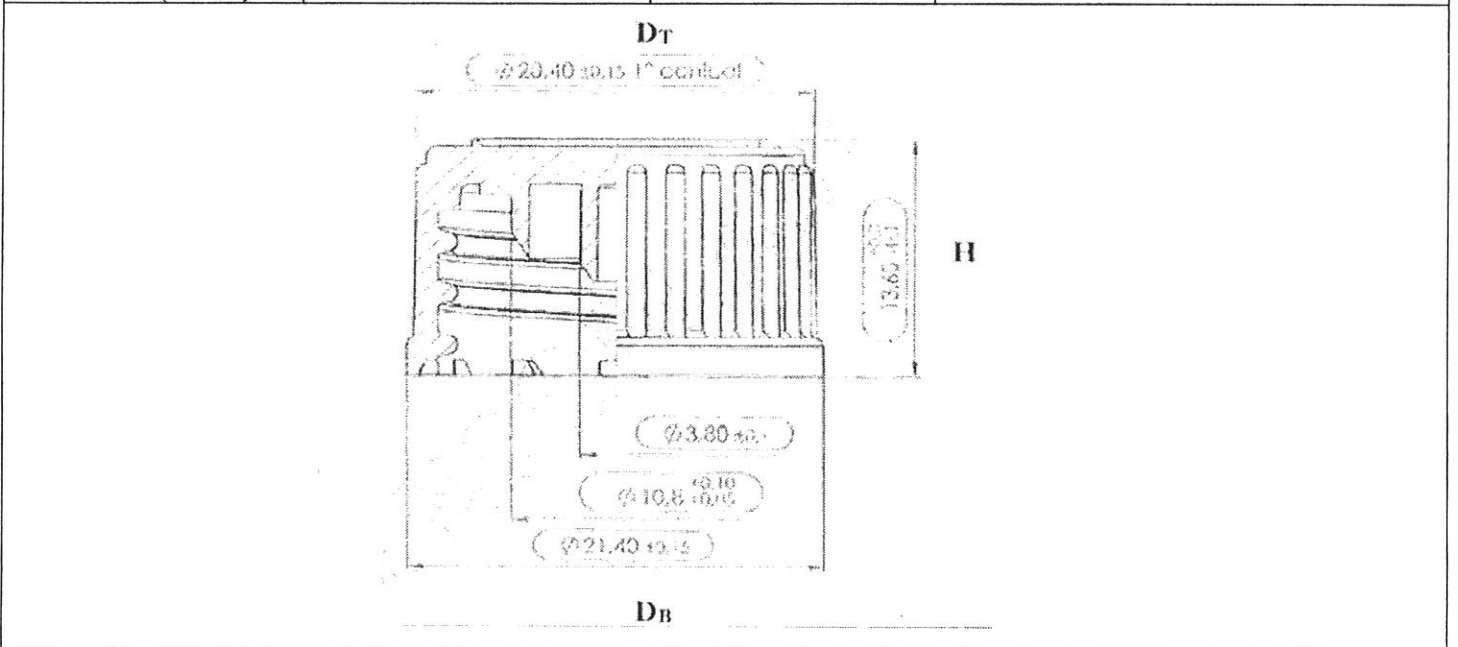
Article number	Manufacturer	Item
004	Sensoplast Packmitteltechnik GmbH	Screw caps with bore seal for spatula and brush DIN 168 GL-18

Article number	Manufacturer	Item
004	Y.S Ashkenazi Netzer Sereni, Israel	Screw caps with bore seal for spatula and brush DIN 168 GL-18 for 30 ml glass bottle

Manuf. Batch No: <u>559872/1-1</u>	Panaxia Batch No: <u>25/001-INS</u>	Manuf. Expiry Date: <u>27/01/2029</u>
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1. Specifications:

Test	Test Method*	Specifications	Results (average)
Specifications and Description:			
Geometrical Conformity	Supplier COA	in compliance with technical drawing	NA
Colour	In compliance with technical drawing and delivery note	Black <i>white</i>	NA
Functional Conformity	Supplier COA	warranted	NA
Height	Measure using Calibrated Ruler	13.50 - 13.90 mm	13.53
Diameter (top)	Measure using Calibrated Caliper	20.25 - 20.55 mm	20.49
Diameter (bottom)		21.25 — 21.55 mm	21.27



MASTER

<i>Document title</i> COA Screw closure for 30 ml	<i>PRT Number</i> PK-000081-MT	<i>Document type</i> COA	<i>Document No.</i> F-SPC-113-113-MT	<i>Version</i> 02
Effective date: 13/02/2025			Page 4 of 4	

Sample Number	Height(H) (mm)	Diameter (D_T) (mm)	Diameter (D_B) (mm)
1	13.52	20.54	21.26
2	13.52	20.25	21.27
3	13.52	20.50	21.26
4	13.53	20.41	21.40
5	13.54	20.55	21.25
6	13.55	20.52	21.32
7	13.55	20.50	21.25
8	13.55	20.55	21.25
9	13.56	20.55	21.26
10	13.52	20.55	21.27
Average	13.53	20.49	21.27

Equipment/Instrument used:	Equipment/Instrument ID:
Calibrated Caliper	MCSU 270
Calibrated Ruler	GMP 1

2. **Packaging and Labelling:** Each package must be labeled by the manufacturer, with at least the following information:
- Supplier name and address.
 - Quantity per bag.
 - Supplier article number and description
 - Supplier batch number and packed on.

Expiry Date: 5 years from manufacturing date (Specified on material COA)

3. **Storage Conditions:** There are no special requirements to temperature or humidity. However, high fluctuations in temperature have to be avoided, so that no condensation could be caused. A temperature above 40°C should be avoided to prevent distortion.

PASS **FAIL**

Following the review of the manufacturer's COC and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirement, hence this batch is: **Approved/** **Rejected.**

QC Checked by: Wc Stella Maldonado	Signature: Wc Stella m	Date: 14/02/2025
QC Reviewed by: ARMSTRONG RAGHUL	Signature: CRA	Date: 14/02/2025

REVISION HISTORY

Date	Name of corrector	Version no	Details of correction (including Chapter No)	Reason of correction
16/03/2021	Alaa Suwan	01	New Document	N/A
28/09/2021	Jonathan Borg	02	Transferred details from Procedure to Specification. Added Table for Individual Samples. Changed title from Specification to COA.	Obsoleted QC 328MT. General Update.



Hubert De Backer nv

Customer ... : PANAXIA PHARMACEUTICAL MALTA (OPERATIONS) L

F.a.o. : QUALITY DEPARTMENT

Temse, 22/11/2024

CERTIFICATE OF CONFORMITY

This delivery contains the following articles :

Article Number	Quantity	Description + Item customer	Your ref.
T2133	39225	CAP 560 PP 099 WHITE PK000005-MT	PO24000369 dd. 09/09/2024
			Our ref./Batch no
			24-1148/00

Approved by : Jimmy De Bergé
Dispatch department

We certify that the above components have been subject to in-process control and, if applicable, other testing. They comply with the agreed specification and were manufactured using the agreed materials, according a certified quality management system to ISO 9001:2015, EN ISO 13485:2016 and EN ISO 15378:2017.

Released by : Gianina Sarman
QA department

This document is created electronically and is valid without signature.

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IBAN: BE18 413-9042251-65 | SWIFT: KRED BEBB | BTW BE 0441 075 925 | RPR Dendermonde



24/08-MT

SGD S.A.
Simplified joint stock company with capital of 44 081 866 Euros -
Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D :
FR 29 552 012 585
Head Office and Sales Departments : Tour Liberty - 17 place des
Reflots - 92097 Paris La Défense Cédex - France. Phone:+33(0)1 40
90 36 00 - Fax:+33(0)1 40 90 36 01
Postal address : Tour Liberty - 17 place des Reflets - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 30.09.2024

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery address

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO24000326	from 27.08.2024	
Customer's product code	GI000201-MT		
Delivery	81563419	Quantity Delivered	19.404 PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML	
SGD Drawing N	69676i	Type III AMBER GLASS	
Treatment	None		
Run Number	N 241345	Manufacturing Date	14.06.2024 to 26.06.2024
Quantity per Pallet	9.702	Production Site	SUCY EN BRIE France

Glass quality

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
ARSENIC	ppm	N/A	0,100	0,001	0,001	0,001	0,000
Hydro-resist-powder/1g	ml	N/A	0,850	0,520	0,520	0,520	0,000
Hydrolytic resistance (HCl)	ml	N/A	6,100	5,500	5,740	5,640	0,120
Spectral transmission	%	N/A	10,000	0,940	0,940	0,940	0,000
Annealing	N/A	N/A	18,000	Conforms			

Glass measurements

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Body diameter	mm	31,900	32,900	32,120	32,310	32,224	0,032
Mini Internal bore	mm	9,500	N/A	11,000	11,730	11,376	0,160
Neck finish height 2	mm	10,800	11,200	10,970	11,090	11,015	0,031
Maxi External neck	mm	N/A	18,000	17,690	17,950	17,780	0,058
Minor thread diameter	mm	15,680	15,980	15,790	15,900	15,855	0,025
Opening diameter	mm	10,450	10,750	10,600	10,750	10,698	0,037
Total height	mm	78,500	80,100	79,170	79,570	79,417	0,099
Neck finish diameter	mm	17,700	18,000	17,730	17,890	17,810	0,036
Bead diameter	mm	19,800	20,200	19,840	20,050	19,989	0,044
Neck finish height	mm	13,500	13,900	13,500	13,620	13,570	0,025



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CERTIFICATE OF QUALITY

The 30.09.2024

Customer PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO24000326	from	27.08.2024
Customer's product code	GI000201-MT		
Delivery.	81563419	Quantity Delivered	19.404 PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML	
SGD Drawing N	69676I	Type III AMBER GLASS	
Treatment	None		
Run Number	N 241345	Manufacturing Date	14.06.2024 to 26.06.2024
Quantity per Pallet	9.702	Production Site	SUCY EN BRIE France

We, SGD S.A., hereby certify that the above referred bottles have been tested and are in conformity with :

THE SPECIFICATIONS IN FORCE

TO THE CURRENT ISO 15378 VERSION

THE HYDROLYTIC RESISTANCE

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force
- Hydrolytic Resistance testing - Grain - is done at least once per year.

ARSENIC

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force
- Arsenic tests are carried out once per year by Furnace

SPECTRAL TRANSMISSION

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force



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CERTIFICATE OF QUALITY

The 30.09.2024

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery address

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO24000326	from	27.08.2024
Customer's product code	GI000201-MT		
Delivery	81563419	Quantity Delivered	19.404 PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML	
SGD Drawing N	69676f	Type III AMBER GLASS	
Treatment	None		
Run Number	N 241345	Manufacturing Date	14.06.2024 to 26.06.2024
Quantity per Pallet	9.702	Production Site	SUCY EN BRIE France

Glass characteristics

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Weight	g	N/A	N/A	40,000	41,600	40,926	0,410
Capacity	ml	34,300	36,700	34,900	35,800	35,417	0,189
Vertical load	kg/cm	200,000	N/A	400,000	400,000	400,000	0,000
Thermal shock	kg/cm	200,000	400,000	Conforms			

Quality Manager

Aline BAILLET



SGD S.A.
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Postal address : Tour Liberty - 17 place des Reffets - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 09.11.2023

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery address

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO23000277	from	04.09.2023
Customer's product code	PRT-GI000201-MT		
Delivery	81535153	Quantity Delivered	34.320 PCE
SGD Product Code	52490 04 001	TROPFFLASCHE 10 ML	
SGD Drawing N	68713G	type 3 AMBER GLASS	
Treatment	None		
Run Number	N 231232	Manufacturing Date	28.04.2023 to 09.05.2023
Quantity per Pallet	17.160	Production Site	SUCY EN BRIE France

We, SGD S.A., hereby certify that the above referred bottles have been tested and are in conformity with :

THE SPECIFICATIONS IN FORCE

TO THE CURRENT ISO 15378 VERSION

THE HYDROLYTIC RESISTANCE

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force
- Hydrolytic Resistance testing - Grain - is done at least once per year.

ARSENIC

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force
- Arsenic tests are carried out once per year by Fumace

SPECTRAL TRANSMISSION

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force



SGD S.A.
Simplified joint stock company with capital of 44 051 866 Euro -
Nanterre Trade and Companies Register N°B552 012 565 - VAT ID :
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CERTIFICATE OF QUALITY

The 09.11.2023

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery address

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO23000277	from	04.09.2023
Customer's product code	PRT-GI000201-MT		
Delivery	81535153	Quantity Delivered	34.320 PCE
SGD Product Code	52490 04 001	TROPFFLASCHE 10 ML	
SGD Drawing N	68713G	type 3 AMBER GLASS	
Treatment	None		
Run Number	N 231232	Manufacturing Date	28.04.2023 to 09.05.2023
Quantity per Pallet	17.160	Production Site	SUCY EN BRIE France

Glass quality

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
ARSENIC	ppm	N/A	0,100	0,003	0,003	0,003	0,000
Hydro-resist-powder/1g	ml	N/A	0,850	0,560	0,570	0,570	0,000
Hydrolytic resistance (HCL)	ml	N/A	8,100	7,600	7,820	7,710	0,110
Spectral transmission	%	N/A	10,000	1,630	1,630	1,630	0,000
Annealing	N/A	N/A	18,000	Conforms			

Glass measurements

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Body diameter	mm	25,000	25,800	25,300	25,470	25,400	0,041
Mini Internal bore	mm	9,500	N/A	11,170	11,830	11,484	0,149
Neck finish height 2	mm	10,800	11,200	10,860	11,140	10,984	0,061
Maxi External neck	mm	N/A	18,000	17,730	17,970	17,856	0,048
Minor thread diameter	mm	15,680	15,980	15,690	15,820	15,765	0,030
Opening diameter	mm	10,450	10,750	10,610	10,750	10,696	0,035
Total height	mm	57,400	58,600	57,880	58,250	58,094	0,081
Neck finish diameter	mm	17,700	18,000	17,700	17,800	17,740	0,025
Bead diameter	mm	19,800	20,200	19,900	20,040	19,985	0,026
Neck finish height	mm	13,500	13,900	13,520	13,710	13,610	0,042



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CERTIFICATE OF QUALITY

The 09.11.2023

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO23000277	from	04.09.2023
Customer's product code	PRT-GI000201-MT		
Delivery	81535153	Quantity Delivered	34.320 PCE
SGD Product Code	52490 04 001	TROPFFLASCHE 10 ML	
SGD Drawing N	68713G	type 3 AMBER GLASS	
Treatment	None		
Run Number	N 231232	Manufacturing Date	28.04.2023 to 09.05.2023
Quantity per Pallet	17.160	Production Site	SUCY EN BRIE France




Glass characteristics

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
<i>Weight</i>	g	N/A	N/A	24,500	25,500	25,000	0,247
<i>Capacity</i>	ml	13,000	15,000	13,500	14,100	13,826	0,140
<i>Vertical load</i>	kg/cm	200,000	N/A	400,000	400,000	400,000	0,000
<i>Thermal shock</i>	N/A	42,000	N/A	Conforms			

Quality Manager

Laurent MILLET



PZ-FBL Band/Vol. 18,19,20,22,34 <small>aktuelle Ausgabe / current Ed.</small>		Prüfzertifikat nach Fehlerbewertungsliste (Editio Cantor Verlag) Test Certificate acc. to Defect Evaluation List		 Remy & Geiser GmbH Werk I / Plant I Remy & Geiser Str. 1 98553 Hinternah	
Kunde: / customer: Panaxia Pharmaceuticals Art.-Bez.: / article name: DOSIERVERSCHLUSS / dosage closure DOSIERVERSCHLUSSRSV 5,0 OVII / SPRITZEN-EINSATZNW18 W/TR		Auftr.-Nr. 21124205 <small>Order No.:</small> Ident.-Nr. 6615MA <small>Article no.:</small> Herstelldatum:  02/2022 <small>date of manufacture:</small>		Ihre Auftr.-Nr.: PO21001728 <small>Your order no.:</small> Ihre Ident.-Nr.: CM-2074 <small>Your article no.:</small> Verfallsdatum:  02/2027 <small>shelf life if sterile then</small>	
Stückzahl: 30000 <small>Pieces supplied:</small> Stichprobe: 50 (315) <small>sampling size:</small> quant. (qual) Zchn.-Nr.: 03006608-01 <small>drawing no.:</small>		LS-Nr.: 22244775 <small>Packing slip no.:</small> Chargen-Nr.: 127870 <small>Batch no.:</small> Ursprungsland: Deutschland <small>Country of origin: Germany</small>			
Angaben zur Lagerung: Es bestehen keine besonderen Anforderungen an Temperatur und Luftfeuchtigkeit. Jedoch sind häufige, große Temperaturschwankungen zu vermeiden damit sich kein Kondenswasser bildet. Ferner sollte die Einwirkung von Temperaturen über 45°C vermieden werden um Verformungen auszuschließen. <small>Storage conditions: There are no special requirements to temperature or humidity. However, high fluctuations in temperature have to be avoided, so that no condensation could be caused. Furthermore, a temperature above 45°C should be avoided, to prevent distortion.</small>					
Materialzusammensetzung: <small>polymer used:</small>		Einfärbung: <small>colouring agents:</small>			
1. Einzelteil: RANDTROPFER-SCHRAUBKAPERSK 5,0 OVII NW18 W <small>1. component part: Purell ACP6541A (PEHD)</small>		HT-MAB PE 9071 weiss /white 2-2,5%			
2. Einzelteil: DOSIERHILFESPRITZEN-EINSATZ NW18 TR <small>2. component part: Purell 1840H (PELD)</small>					
3. Einzelteil: #NV <small>3. component part: #NV</small>		#NV			
4. Einzelteil: #NV <small>4. component part: #NV</small>		#NV			
5. Einzelteil: 0 <small>5. component part:</small>					
Stichprobenumfang nach Fehlerbewertungsliste (Quantitative Prüfung) <small>Sampling inspection to defect evaluation list (quantitative tests)</small>		Entscheidung: + entspricht <small>Decision: + accepted</small>		Prüfvermerk: QK <small>insp. Remark:</small>	
Fehler-Nr. <small>Attr.-no.</small>		Fehler/Einzelmerkmal <small>Defect/Individual characteristics</small>		AQL	max. Fehler Defects
		Anlieferung, Kennzeichnung, Verpackung / Delivery, labelling, packing			Entscheidung Decision
Die Fehlermerkmale beziehen sich hier nicht auf das Packmittel selbst, sondern auf Paletten und Packeinheiten (Gebinde). Für die Prüfung dieser Fehlermerkmale ist kein Stichprobenverfahren anwendbar. Die Vergabe bezüglich dieser Merkmale ist eine fehlerfreie Lieferung. Fehlerklasse 1 bedeutet in diesem Zusammenhang, dass das Packmittel in der vorliegenden Anlieferform nicht einsetzbar ist. Lässt sich die Ware mit geringem Aufwand durch Nachbesserung in einen verwendbaren Zustand bringen, so ist dies durchzuführen. <small>The defect characteristics refer not to the packaging material itself but to the pallets and packaging units (containers). No random sampling method is applicable for the testing of these defect characteristics. The requirement for these defect characteristics is a shipment without defects. In this context Defect Class 1 means that the packaging material is not utilizable in the form supplied. If the goods can be brought into a utilizable state at little expense by means of reworking this is to be performed.</small>					
1	1 1 1 1 Palette und/oder Außenverpackung entspricht nicht der Vorschrift, beschädigt, verschmutzt (Packmittelspezifikation) / pallet and/or outer packaging does not meet packaging specification, damaged, soiled	0,00	0		+
2/3	2 2 2 2 Packschema falsch / Packaging scheme incorrect	0,00	0		+
1/3/4/5	1 1 1 1 1 1 Kennzeichnung der Palette / 1 1 1 1 1 1 Gebinde muss der Vorschrift entsprechen / Labeling of the Pallet / Container must comply with the specification	0,00	0		+
5/6/7	1 1 1 1 Einzelverpackung (Sterilverpackung) beschädigt, verschmutzt, unvollständig / Individual packs (Sterile Packing), damaged, soiled, incomplete	0,00	0		+
8/9	2 2 2 2 Lieferantenstichprobe / Begleitpapiere, Qualitätsdokumente, Prüfzertifikat falsch / fehlen / Suppliers random sample / Accompanying documents, quality documents, test certificate incorrect / missing	0,00	0		+
Untermischung / Intermixing					
1	1 1 1 1 1 1 Untermischung / Intermixing	0,00	0		+
Ausgangsmaterial / Starting material					
1/2	1 1 1 1 Das Material (EP Edition 9.4 - 3.1.3; 3.1.4) (EP Edition 9.5 - 3.1.5; 3.1.6) / Die Einfärbung muss der Vorschrift entsprechen / The material / The colour must comply with the specification	0,00	0		+
1/2/3/4/5	2 2 Grundglas, Wasserbeständigkeit der Innenoberfläche/gemäß Glasgießmethode. Lichtdurchlässigkeit, Farbe entspricht nicht der Vorschrift / Base glass, Water resistant of internal surface /acc.glass grain method, Light transmission of base glass. Color of base glass does not meet specification	0,00	0		+
10	2 2 Zusammenhaftende bzw. klebrige Gummiteile / rubber parts adhering to one another or sticking	0,40	0 (3)		+
Sauberkeit / Cleanliness					
1/5/6/7	1 1 1 1 Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, 1 1 1 1 Grenzwerte für Partikel überschritten / Agreed limits for particles exceeded	0,00	0		+
1/3/8	1 1 1 1 Fremdeinschlüsse-Aussehen stark beeinträchtigt, > 1mmØ oder Anhäufung 2 mehrere fest anhaftende Fremdkörper, Flecken ≥ 0,2mm ² / lose Partikel / Foreign bodies enclosed appearance markedly impaired, > 1mm Ø / Brandstellen flächenförmig / Burn-marks >2mm diameter	0,10	0 (1)		+
2/4	1 1 Im Material eingeschlossene Fremdkörper / Brandstellen punktförmig 0,5- 2mm Ø / Foreign bodies incorporated in the material / Scorch dots 0,5- 2mm Ø	0,40	0 (3)		+
1	2 2 Nicht entfernbare Verunreinigungen innen ≥ 0,3mm ² / Non-removable contamination inside ≥ 0,3mm ²	0,40	0 (3)		+
2/4	1 1 Entfernbbare Verunreinigungen innen ≥ 0,3mm ² außen ≥ 0,5mm ² / Removable contamination inside ≥ 0,3mm ² , outside ≥ 0,5mm ²	1,00	0		+
3/4/7/9/10	2 2 Brandstellen / Scorched spots 1 1 1 1 Fremdeinschlüsse-Aussehen wenig beeinträchtigt < 1mm Ø / Foreign bodies enclosed- appearance less impaired, < 1mm Ø, Lose Materialreste / Loose material residues	2,50	3 (12)		+

Verarbeitungsfehler / Processing Errors				
2/7/15/ 17	ⓈNicht ausgeformte Gummiteile, Risse, Riefen, Kerben, Löcher, Dichtigkeit (Funktion) beeinträchtigt / Incompletely formed rubber parts, tears, grooves, notches, holes, seal and or function impaired / Formgrad, Stanzfehler anhaftende Fallreste / Flash, punching errors ⓈRisse, Spalten, Löcher. Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, clefs, holes, parts incompletely injected, seam breaks open ⓈDurchgehende Risse / Wall penetrating cracks ⓈKanal verstopft keine Dosierung möglich / Duct blocked dosage impossible, im Bereich des Abtropfrandes und der dichtenden Flächen geraut-Dichtigkeit nicht gegeben / Roughness in the area of the dropping rim and of the sealing areas-seal not possible	0,00	0	+
1/3/4/9/ 13	ⓈStarke Formnähte u./o Rückstände an den Anspritzpunkten / Marked mould joints and or residues at the injection points Stark verzogene Teile / Markedly warped items ⓈDeformierung / Deformation ⓈAnspritzpunkt entspricht nicht (seitlich max 0,5mm, zentral max. 0,7mm) / Injection point does not comply (lateral max. 0,5mm, central max. 0,7mm) Überspritzungen, ⓈFormgrate an Dichtstellen (Over-injection, flash at the sealing points	0,10	0 (1)	+
8/9/12/ 15/19/ 08.1	ⓈAnrisse / Incipient cracks Absplittierungen im Dichtungsbereich / Chipping in area of seal Blasen, Einschlüsse > 1,0mm / Gas bubbles, inclusions > 1mm, Kühlspannung außer Toleranz / Cooling stress out of tolerance Abgeplatzte Stelle(n), Deformierung/en oder Glasspitze(n) am vorderen Teil (Kugel) / Clipped place(s), deformity(ies) or glass spike(s) on tip (ball) ⓈOberfläche, Kontur uneben / Surface, Shape uneven	0,40	0 (3)	+
6/8/12/ 13	Ⓢverformte Behältnisse / Deformed containers Kratzer (Breite ≥ 0,2mm, Länge ≥ 20mm) / Scratches (width ≥ 0,2mm and length ≥ 20mm) ⓈFallen, Kerben, Kratzer, Formgrad / Folds, notches, scratches, flash	2,50	3 (12)	+

Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing				
1	ⓈKanal Ø a.T. / Duct diameter out of tolerance, Dosierung/Tropfgeschwindigkeit muss der Vorschrift (Prüfvorschrift nach Vereinbarung) entsprechen / Dosage/dropping speed must comply with the specification (testing procedure according to agreement, Verbindungsstege abgerissen- anzahlmäßig mehr als die Hälfte der Stege / Connecting strip torn off- numerically more than half of the studs, ⓈDichtigkeit / test for	0,00	0	+
1/2/3/6	ⓈScheibel Ø, Tropffloch Ø, Biegung außerhalb der Toleranz / Diameter of annular flange, dropper hole, bend out of the tolerance Ⓢsonstige Maße, Winkel, Radien außer Toleranz / Other dimensions, angles, radii out of tolerance ⓈAbmessungen a.T. / Dimensions out of tolerance Ⓢweitere Maße außer Toleranz / Other dimensions out of tolerance, Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing	0,10	0 (1)	+
1/3	ⓈGravur fehlt, falsch u./o. unvollständig. / Engraved text missing, incorrect and/or incomplete. Druck, Prägung fehlt, falsch u/o unvollständig / Overprinting, embossed text missing, incorrect and/or incomplete Gewinde fehlt oder ist nur mangelhaft ausgebildet / Thread missing or only inadequately formed ⓈDruckfarbe falsch / Printing color incorrect, Druckbild fehlt, falsch / Printing image missing or incorrect	0,00	0	+
1/6/7	ⓈGravur für Dosierung unvollständig - Dosierung nicht möglich / Engraved marks for dosage incomplete - Dosage not possible. Abmessungen entsprechen nicht / Dimensions do not comply, Text fehlt, falsch oder nicht lesbar / text absent, incorrect or illegible, Dosierung a.T. / Dosage out of tolerance, ⓈFarbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion	0,10	0 (1)	+
4	ⓈDruckfarbe haftet nicht / Printing does not adhere	0,40	0 (3)	+

Montage / Mounting				
13/15	ⓈKindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, Außenteil gerissen / External part torn	0,00	0	+
1/2/4/5/ 9/17/19	ⓈEinzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts damaged by mounting, Teile falsch montiert / Parts incorrect mounted, ⓈPipette zu tief in Sauger eingesetzt / Pipette set too deep into the teat, Tropfeinsatz durch Montage beschädigt / Dropper insert damaged by mounting	0,10	0 (1)	+

* falls zutreffend die dazugehörige Fehlerbewertungsliste * if applicable the relevant Defect Evaluation List (1) Skip-Lot verfahren: skip-batch Process
 ⓈKunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps ⓈBehältnisse aus Röhrglas / Containers Made of Tubular Glass ⓈGummiteile / Rubber Parts ⓈSpritzgussteile aus Kunststoff: Verschlüsse; Dichteinlagen und Dosierhilfen (Tropfer etc.) / Injection-moulded Parts Made of Plastic: Closures ⓈApplikatoren und Messeinrichtungen aus Kunststoff / Applicators and Measuring Devices Made of Plastic

Hiermit bestätigen wir, dass die Qualität des oben bezeichneten Produktes nach den gültigen Prüfnormen ("Sterilität entsprechend ISO 11135 bzw. 11137 in der jeweiligen aktuellen Ausgabe) gemäß Spezifikation (Ausführungsvorschrift, technischer Zeichnung) sowie der jeweils gültigen Fehlerbewertungsliste hergestellt, verpackt, *sterilisiert und geprüft wurden und die dabei zulässigen Grenzwerte nicht überschritten wurden. Soweit für das obige Produkt abweichende Vereinbarungen zwischen Hersteller bzw. Lieferant und Verwender (Kunden) bestehen, werden diese zugrunde gelegt. We hereby confirm that the quality of the products described above has been produced, packed, *sterilized, inspected and tested in accordance with the valid inspection and testing standards ("Sterility conforming ISO 11135 or 11137 in its current version) according to the specification (documented procedure, technical drawing) and the Defect Evaluation List and did not exceed the permissible limits. Where alternative agreement for the above product exist between the customer and the manufacturer and/or supplier, the relevant values have been based on these.

*falls zutreffend / if applicable
 Vereinbarte Artikelspezifikationen beinhalten die Unbedenklichkeit der Materialien nach Verordnung (EU) Nr. 10/2011, 1935/2004, RL94/62/EG, 1907/2006, 1223/2009, deren Herstellung nach 2023/2006 und deren aktuellen Ergänzungen. Gleichzeitig wird die Konformität nach ISO 13485 (aktuelle Ausgabe) und RL 93/42/EWG (Verordnung 2017/745) bestätigt
 Agreed article Specifications includes the compliance of the materials with EU-regulations 10/2011/EC, 1935/2004/EC, guidelines 94/62/EC, 1907/2006/EC, 1223/2009/EC, whose manufacturing based on 2023/2006/EC and the current amendments. At the same time, conformity with ISO 13485 (current edition) and RL 93/42 / EEC (Regulation 2017/745) is confirmed.

Für Folgeschäden beim Kunden (unerwartete Unterbrechung an Abfüllanlage, Prüfaufwand, Rückruf usw.), wird keine Haftung übernommen solange die Vorgaben gemäß Fehlerbewertungsliste eingehalten sind. For secondary failures by the customer (secondary failures bottling plant, additional tests, product recall etc.) to assume no liability as long as the standard in accord with Defect Evaluation List are adhered to.

Vorstehende Angaben entbinden nicht von der Durchführung einer Wareneingangskontrolle
 The above particulars do not release the customer from the of obligation to carry out an inspection of goods received.

Datum: 21.02.2022 Freigabe: ja / yes Prüfer: I.A.
 Date: release: Approved by: [Signature]

