



		Panaxia Pharmaceutical Malta (Operations) Ltd. HHF001A Hal Far, B'Buga BBG 3000, Malta		
Document title	PRT no.	Document type	Document No.	Version
Release COA for Standardized Cannabis Extract THC 5.21% <i>m/m</i> (Germany) - Naxiva Panaxol-THC 50 mg/ <i>ml</i> , 30 ml	FG-000002-MT	COA	F-COA-010-DE	01
Effective date: 21/05/2024			Page 1 of 3	

Batch Details			
Batch number -Bulk oil	24/169-MT	Manufacturing date	27/08/2024
Batch number - Finish product	24/228-MT	Expiry date	07/2026

Test	Test Method	Specifications	Result
Identification			
TLC identification	SOP QC-179-MT DAB [£]	Zonal pattern of test solution conforms to the zonal pattern of the reference solution	Complies
Organoleptic properties			
Appearance	SOP QC-136-MT Visual inspection DAB [£]	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	Complies
Heavy metals ^{1,2}			
Cadmium	SOP 77405 ICP-MS Ph. Eur. 2.4.27 [◇]	≤ 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 Ph. Eur. 2.2.5 [◇]	Indicative	0.95
Water content	SOP-175-MT Karl Fisher Ph. Eur. 2.5.12 [◇]	≤0.5%	< 0.2%
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT HPLC Ph. Eur. 2.8.18 [◇]	≤ 2 µg/Kg	ND
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	ND
Ochratoxin A	SOP QC-322-MT HPLC Ph. Eur. 2.8.22 [◇]	≤377 µg/Kg	UDL
Microbiological Quality ¹			
TAMC	MW024-01	≤ 10 ⁴ CFU/mL	< 10 CFU/ml
TYMC	Complies to Ph. Eur. 2.6.12 [◇]	≤ 10 ² CFU/mL	< 10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01 Complies to Ph. Eur 2.6.31 [◇]	< 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			
Ethanol	QC-140-MT GC-HS-FID	≤ 5000 ppm	NA*
Assay - Cannabinoids concentration (%w/w)			
CBN	QC-181-MT DAB [£]	≤ 2.5% m/m	0.1%
CBD		≤ 0.31% m/m (≤ 6% from Δ9-THC label claim)	URL
Δ9-THC		4.95% - 5.47% m/m (95-105 % from label claim)	5.18%

AUTHORIZATION				QA Authorized Stamp
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:	RA APPROVED BY:	
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	
 May 21, 2024	 May 21, 2024	Chris Decker May 21, 2024	 May 21, 2024	

		Panaxia Pharmaceutical Malta (Operations) Ltd. HHF001A Hal Far, B'Buga BBG 3000, Malta			
<i>Document title</i>		<i>PRT no.</i>	<i>Document type</i>	<i>Document No.</i>	<i>Version</i>
Release COA for Standardized Cannabis Extract THC 5.21% m/m (Germany) - Naxiva Panaxol-THC 50 mg/ml, 30 ml		FG-000002-MT	COA	F-COA-010-DE	01
Effective date: 21/05/2024				Page 2 of 3	



Batch Details			
Batch number -Bulk oil	24/169-MT	Manufacturing date	27/08/2024
Batch number - Finish product	24/228-MT	Expiry date	07/2026




Vitamin E	QC-149-MT	≥ 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 ND - Not Detected. The results of Aflatoxins that are not detected are reported as ND.
Ochratoxins UDL – Under detection limit. The result of Ochratoxin A that is less than 0.5µg/kg is reported UDL.
Ochratoxins UQL – Under quantification limit. The result of Ochratoxin A that is less than 2.5µg/kg is reported UQL.
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 CBD and CBN that are less than 0.05% from the label amount of THC are reported URL (0.003%)
[⊖] 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.

Consecutive batch number:	Pesticides and Heavy metals testing required on Finished product:
02	<input type="checkbox"/> Yes; <input checked="" type="checkbox"/> No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: 24/080-MT

*Residual solvents skip lot testing as per approved ASID001/2019 (20th variation)




<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL		
Approved by: Shani Bonan	Signature: 	Date: October 31, 2024
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 Reviewed by: Chris Desira	Signature: 	Date: October 31, 2024

AUTHORIZATION				QA Authorized Stamp
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:	RA APPROVED BY:	
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	
 May 21, 2024	 May 21, 2024	Chris Desira May 21, 2024	 May 21, 2024	

		Panaxia Pharmaceutical Malta (Operations) Ltd. HHF001A Hal Far, B'Buga BBG 3000, Malta			
<i>Document title</i>		<i>PRT no.</i>	<i>Document type</i>	<i>Document No.</i>	<i>Version</i>
Release COA for Standardized Cannabis Extract THC 5.21% m /m (Germany) - Naxiva Panaxol-THC 50 mg/ml, 30 ml		FG-000002-MT	COA	F-COA-010-DE	01
Effective date: 21/05/2024				Page 3 of 3	

Batch Details			
Batch number -Bulk oil	24/169-MT	Manufacturing date	27/08/2024
Batch number - Finish product	24/228-MT	Expiry date	07/2026

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

AUTHORIZATION				QA Authorized Stamp
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:	RA APPROVED BY:	
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	
 May 21, 2024	 May 21, 2024	Chris Debon May 21, 2024	 May 21, 2024	

Document title	PRT Number	Document type	Document No.	Version
COA for 1mL Oral Dosage Syringe (Origin)	PK-000224-MT	COA	F-SPC-113-291-MT	02
Effective date: 12/06/2024			Page 1 of 2	

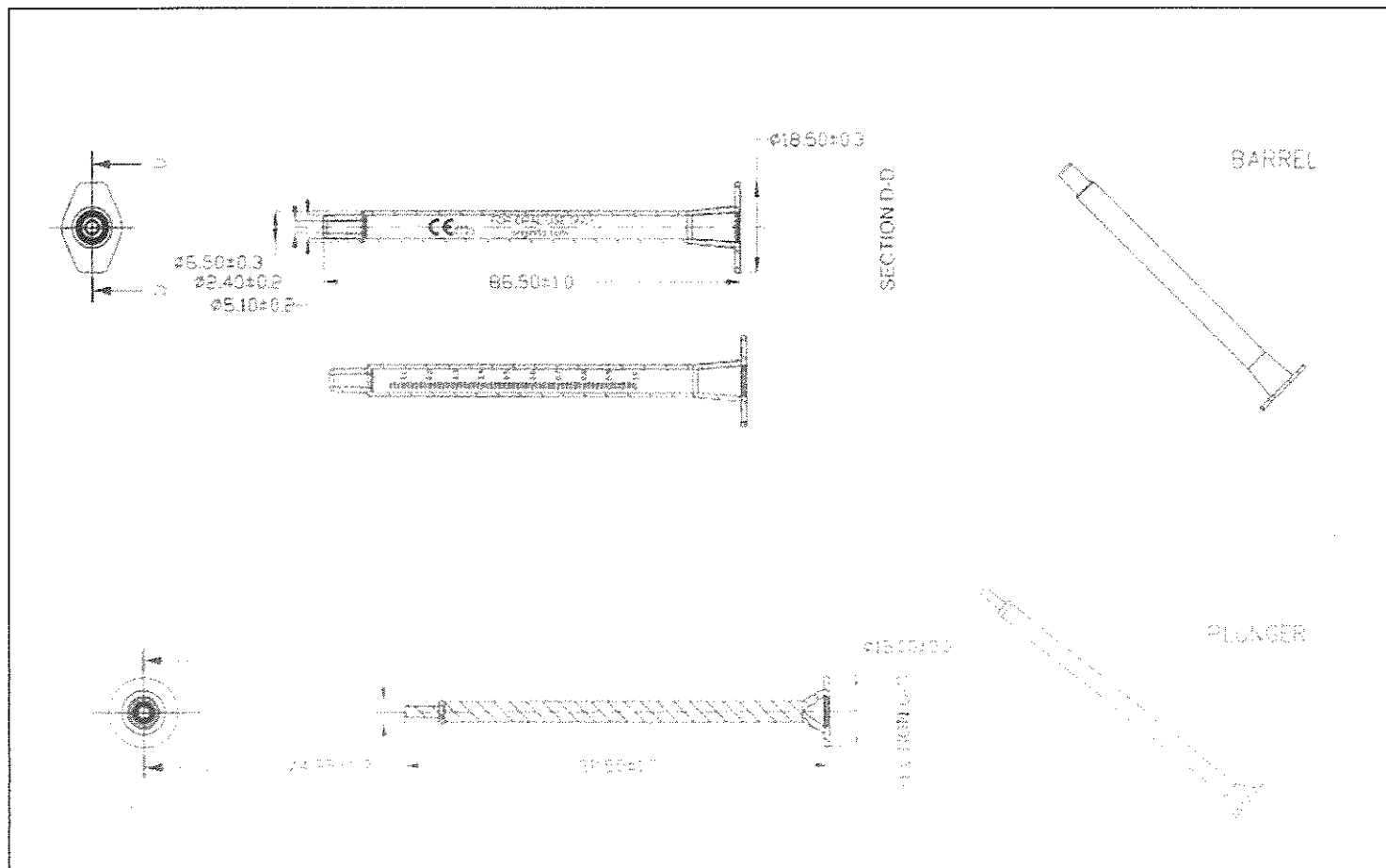
Product Code	Manufacturer/Supplier	Item
BRV240313/OS1W3-W	Bharat Rubber/Origin	1mL Oral Dosage Syringe

Manuf. Batch No:	Panaxia Batch No:	Manuf. Expiry Date:
BRV 240313	24/104-117	07/05/2024 to 08/05/2024

14 JUN 2024

1.0 Specifications:

Test	Test Method*	Barrel		Plunger	
Specifications and Description:		Specifications:	Results (average)	Specifications:	Results (average)
Material	Supplier COA	PP Purell RP375R	Complies	HDPE Purell ACP 6541A	Complies
Color	Supplier COA	Natural (Markings in black ink)	Complies	White (PL00075542)	Complies
Length (L)	Measure using Calibrated Ruler	85.5 – 87.5mm	86.1	91.5 – 93.5mm	93.3
External Diameter (D)	Measure using Calibrated Caliper	6.5±0.3mm	6.7	4.85mm±0.2mm	4.81



Equipment/Instrument used:	Equipment/Instrument ID:
Calibrated Ruler	CAL-01-MT
Calibrated Caliper	RUL-02-MT

QA AUTHORISED COPY

AUTHORIZATION		
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:
[Signature] 12 JUN 2024	[Signature] 12/06/2024	[Signature] 12/06/2024

INITIALS: 12 JUN 2024

Document title	PRT Number	Document type	Document No.	Version
COA for 1mL Oral Dosage Syringe (Origin)	PK-000224-MT	COA	F-SPC-113-291-MT	02
Effective date: 12/06/2024			Page 2 of 2	

Sample Number	Length (mm)		External Diameter (mm)		Net Weight (g)
1	86.0	93.5	4.70	6.69	
2	86.0	93.0	4.84	6.67	
3	86.5	93.5	4.88	6.63	
4	86.0	93.0	4.81	6.64	
5	barrel	plunger	barrel	plunger	
6					
7					
8					
9					
10					
Average	86.1	93.3	4.81	6.66 = 6.7	

NA DV 12 JUN 2024

2.0 Packaging and Labeling

2.1 Each box must be labeled, by the manufacturer, with at least the following information:

- 2.1.1 Supplier name and address
- 2.1.2 Supplier lot number (=order number)
- 2.1.3 Quantity
- 2.1.4 Supplier article number and description
- 2.1.5 For products marked with CE 0120:
 - 2.1.5.1 Shelf life
 - 2.1.5.2 The CE 0120 mark
 - 2.1.5.3 Symbol with storage instructions

2.2 Expiry date: 3 years from manufacturing date (Specified on material COA)

3.0 Storage conditions:

3.1 Store in a cool dry location.

☒ PASS ☐ FAIL

Analysed by: DV	Signature: Denise Vella	Date: 12 JUN 2024
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 <input checked="" type="checkbox"/> Approved/ <input type="checkbox"/> Rejected.		
QC approved by: Jelena Markovic	Signature: [Signature]	Date: 14 JUN 2024

REVISION HISTORY

Date	Name of corrector	Version no	Details of correction (including Chapter No)	Reason of correction
20/05/2024	Chris Desira	01	New Document	CCF-MT2023-46
12/06/2024	Maria Agius	02	1. Updated product code and manufacturer/Supplier section to include reference to both manufacturer's and supplier's code 2. Updated colour of barrel and plunger to align with manufacturer's COA	1. Manufacturer COA does not include reference to supplier's product code. 2. Changes due to co-qualified grades of raw materials as communicated with Supplier.

AUTHORIZATION

ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:
[Signature] 12 JUN 2024	[Signature] 12/06/2024	[Signature] 12/06/2024

QA AUTHORISED
COPY

INITIALS 12 JUN 2024



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 CB16 - 17 place des
Reflets - 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 CB 16 - 17 place des Reflets - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 23.05.2023

Customer

PANAXIA PHARMACEUTICAL INDUSTRIES / 39371

71201

LOD

IL

Delivery adress

PANAXIA PHARMACEUTICAL INDUSTRIES / 39371001

LOD

IL

Customer's order PO23000121

from 25.04.2023

Customer's product code CM-2048

Delivery	81521342	Quantity Delivered	9.702	PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML		
SGD Drawing N 69676I	Treatment	None	type 3	AMBER GLASS
Run Number	N 231206	Manufacturing Date	03.04.2023	to 11.04.2023
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

..I..



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CERTIFICATE OF QUALITY

The 23.05.2023

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71201 LOD

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Delivery address

PANAXIA PHARMACEUTICAL INDUSTRIES / 39371001

LOD

IL

Customer's order PO23000121

from 25.04.2023

Customer's product code CM-2048

Delivery 81521342

Quantity Delivered

9.702 PCE

SGD Product Code 02543 07 020

TROPFFL. 30 ML

SGD Drawing N 69676I Treatment

None type 3 AMBER GLASS

Run Number N 231206

Manufacturing Date 03.04.2023 to 11.04.2023

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		0,100	0,050	0,050	0,050	0,000
Hydro-resist-powder/1g	ml		0,850	0,590	0,590	0,590	0,000
Hydrolytic resistance (HCl)	ml		6,100	4,640	4,940	4,790	0,150
Spectral transmission	%		10,000	1,630	1,630	1,630	0,000
Annealing			18,000	Conforms			

Glass measurements

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Body diameter	mm	31,900	32,900	32,120	32,270	32,206	0,034
Mini Internal bore	mm	9,500		10,930	11,820	11,483	0,186
Minor thread diameter	mm	15,680	15,980	15,760	15,870	15,815	0,026
Neck finish height 2	mm	10,800	11,200	10,970	11,090	10,999	0,032
Maxi External neck	mm		18,000	17,710	17,960	17,830	0,055
Opening diameter	mm	10,450	10,750	10,570	10,740	10,660	0,049
Body diameter	mm	31,900	32,900				
Total height	mm	78,500	80,100	79,250	79,850	79,475	0,108
Neck finish diameter	mm	17,700	18,000	17,710	17,810	17,745	0,026
Bead diameter	mm	19,800	20,200	19,900	20,070	20,002	0,039
Neck finish height	mm	13,500	13,900	13,530	13,700	13,610	0,040

..I..



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CERTIFICATE OF QUALITY

The 23.05.2023

Customer**PANAXIA PHARMACEUTICAL INDUSTRIES / 39371**

71201

LOD

IL

Delivery adress**PANAXIA PHARMACEUTICAL INDUSTRIES / 39371001**

LOD

IL

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from 25.04.2023

Customer's product code CM-2048


Delivery	81521342	Quantity Delivered	9.702	PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML		
SGD Drawing N 69676I	Treatment	None	type 3 AMBER GLASS	
Run Number	N 231206	Manufacturing Date	03.04.2023 to	11.04.2023
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			40,600	42,000	41,208	0,331
Capacity	ml	34,300	36,700	34,900	35,900	35,420	0,223
Vertical load	kg/cm	200,000		400,000	400,000	400,000	0,000
Thermal shock		42,000		Conforms			

Quality Manager

Laurent MILLET

PZ-FBL Band/Vol. 18,19,20,22,34 aktuelle Ausgabe / current Ed.		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 Pharmaceutical Art.-Bez. / article name: DOSIERVERSCHLUSS / dosage closure DOSIERVERSCHLUSSRSV 5,0 OVII / SPRITZEN-EINSATZNW18 W/TR					
Auftr.-Nr. 22126354 Order No.:		Ihre Auftr.-Nr.: PO22000312 Your order no.:		LS-Nr.: 22248155 Packing slip no.:	
Ident.-Nr. 6615MA Article no.:		Ihre Ident.-Nr.: CM-2074 Your article no.:		Stückzahl: 15000 Pieces supplied:	
Herstelldatum: 11/2020 date of manufacture:		Verfallsdatum: 11/2025 shelf life:		Stichprobe: 50 (315) sampling size: quant. (qual)	
Sterilisationsdatum: entfällt date of sterilization:		Ursprungsland: Deutschland Country of origin: Germany		Zchn-Nr.: 03006608-01 drawing no.:	
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. 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.					
Materialzusammensetzung: polymer used: 1. Einzelteil: RANDTROPFER-SCHRAUBKAPPSK 5,0 OVII NW18 W 1. component part: Purell ACP6541A (PEHD) 2. Einzelteil: DOSIERFILSPRITZEN-EINSATZ NW18 TR 2. component part: Purell 1840H (PELD) 3. Einzelteil: #NV 3. component part: #NV 4. Einzelteil: #NV 4. component part: #NV 5. Einzelteil: 0 5. component part:					
Einfärbung: colouring agents: REMAFIN-EP-WEISS PL00075542-ZT					
Stichprobenumfang nach Fehlerbewertungsliste (Quantitative Prüfung) Sampling inspection to defect Evaluation list (quantitative (tests))		Entscheidung: + entspricht Decision: + accepted		Prüfvermerk: QK Insp. Remark:	
Fehler-Nr. Attr.-no.		Fehler/Einzelmerkmal Defect/Individual characteristics		AQL	max.Fehler Defects
				Entscheidung Decision	
Anlieferung, Kennzeichnung, Verpackung / Delivery, labelling, packing					
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. 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.					
1	12345 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	23 Packschema falsch / Packaging scheme incorrect			0,00	0
1/3/4/5	12345 Kennzeichnung der Palette / 12345 Gebinde muss der Vorschrift entsprechen / Labelling of the Pallet / Container must comply with the specification			0,00	0
5/6/7	12345 Einzelverpackung (Sterilverpackung) beschädigt, verschmutzt, unvollständig / individual packs (Sterile Packing), damaged, soiled, incomplete			0,00	0
8/9	23 Lieferantenstichprobe / Begleitpapiere, Qualitätsdokumente, Prüfzertifikat falsch / fehlen / Suppliers random sample / Accompanying documents, quality documents, test certificate incorrect / missing			0,00	0
Untermischung / Intermixing					
1	12345 Untermischung / Intermixing			0,00	0
Ausgangsmaterial / Starting material					
1/2	123 Das Material (EP Edition 10 - 3.1.3; 3.1.4) (EP Edition 10 - 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 Grundglas, Wasserbeständigkeit der Innenoberfläche/gemäß Glasgrießmethode, 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 zusammenhaftende bzw. klebrige Gummiteile / rubber parts adhering to one another or sticking			0,40	0 (3)
Sauberkeit / Cleanliness					
1/5/6/7	123 Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, 12345 Grenzwerte für Partikel überschritten / Agreed limits for particles exceeded			0,00	0
1/3/8	123 Fremdeinschlüsse-Aussehen stark beeinträchtigt, > 1mmØ oder Anhäufung 2 mehrere fest anhaftende Fremdkörper, Flecken ≥ 0,2mm2 / lose Partikel/ Foreign bodies enclosed appearance markedly impaired, > 1mm Ø / Brandstellen flächenförmig / Burn-marks >2mm diameter			0,10	0 (1)
2/4	12 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 Nicht entfernbare Verunreinigungen innen ≥ 0,3mm² / Non-removable contamination inside ≥ 0,3mm²			0,40	0 (3)
2/4	12 entfernbare Verunreinigungen innen ≥ 0,3mm² außen ≥ 0,5mm2 / Removable contamination inside ≥ 0,3mm², outside ≥ 0,5mm²			1,00	0
3/4/7/9/10	2 Brandstellen / Scorched spots 123 Fremdeinschlüsse-Aussehen wenig beeinträchtigt < 1mm Ø / Foreign bodies enclosed- appearance less impaired, < 1mm Ø, Lose Materialreste / Loose material residues			2,50	3 (12)

Ident.-Nr. Article no.:	6615MA	Ihre Ident.-Nr.: Your article no.:	CM-2074	Chargen-Nr.: Batch no.:	111585	Stichprobe: sampling size:	50 (315) quant. (qual)
Verarbeitungsfehler / Processing Errors							
2/7/15/ 17	③ Nicht ausgeformte Gummiteile, Risse, Riefen, Kerben, Löcher, Dichtigkeit (Funktion) beeinträchtigt / Incompletely formed rubber parts, tears, grooves, notches, holes, seal and or function impaired / Formgrat, Stanzfehler anhaftende Felleste / Flash, punching errors ④ Risse, Spalten, Löcher, Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, cleats, holes, parts incompletely injected, seam breaks open ② Durchgehende Risse / Wall penetrating cracks ③ 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	⑤ Starke Formnähte u./o Rückstände an den Anspritzpunkten / Marked mould joints and or residues at the injection points Stark verzogene Teile / Markedly warped items ④ Deformierung / Deformation ③ 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, ⑥ Formgrate an Dichtstellen (Over-injection, flash at the sealing points				0,10	0 (1)	+
8/9/12/ 15/19/ 08.1	② Anrisse / Incipient cracks Absplittungen 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) / Cipped place(s), deformity(ies) or glass spike(s) on tip (ball) ① Oberfläche, Kontur uneben / Surface, Shape uneven				0,40	0 (3)	+
6/8/12/ 13	② verformte Behältnisse / Deformed containers Kratzer (Breite ≥ 0,2mm, Länge ≥ 20mm) / Scratches (width ≥ 0,2mm and length ≥ 20mm) ⑤ Falten, Kerben, Kratzer, Formgrat / Folds, notches, scratches, flash				2,50	3 (12)	+
Abmessungen; Gravur; Druck; Dimensions; Engraved text; Printing							
1	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, ② ③ Dichtigkeit / test for				0,00	0	+
1/2/3/6	② Scheibel Ø, Tropfloch Ø, Biegung außerhalb der Toleranz / Diameter of annular flange, dropper hole, bend out of the tolerance ① sonstige Maße, Winkel, Radien außer Toleranz / Other dimensions, angles, radii out of tolerance ③ Abmessungen a.T. / Dimensions out of tolerance ④ weitere Maße außer Toleranz / Other dimensions out of tolerance, Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing				0,10	0 (1)	+
1/3	① ④ 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 ② Druckfarbe falsch / Printing color incorrect, Druckbild fehlt, falsch / Printing image missing or incorrect				0,00	0	+
1/6/7	⑤ 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, ① ④ Farbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion				0,10	0 (1)	+
4	② Druckfarbe haftet nicht / Printing does not adhere				0,40	0 (3)	+
Montage / Mounting							
13/15	① 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	① ⑤ Einzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts damaged by mounting, Teile falsch montiert / Parts incorrect mounted, ① Pipette zu tief in Sauger eingesetzt / Pipette set too deep into the test, 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							
① Kunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps ② Behältnisse aus Röhrglas / Containers Made of Tubular Glass ③ Gummiteile / Rubber Parts ④ Spritzgussteile aus Kunststoff: Verschlüsse; Dichteinlagen und Dosierhilfen (Tropfer etc.) / Injection-moulded Parts Made of Plastic: Closures ⑤ 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, guideline 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 obligation to carry out an inspection of goods received.							
Datum: Date:	31.08.2022	Freigabe: release:	Ja / yes	Prüfer: i.A.	