

Product Name: NAXIVA-PANAXOL THC 250mg/g
Reference Specification Legacy Number: F-COA-023-DE

Batch Details			
Batch number -Bulk oil	25/073-MT	Manufacturing date	05/2025
Batch number - Finish product	25/074-MT	Expiry date	05/2027

Test	Test Method	Specifications	Result
Identification			
TLC identification	SOP QC-179-MT/ VA1112 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 / VA1044 Ph. Eur. 2.2.5 [◇]	Indicative	0.98
Water content	SOP-175-MT/ VA25322 Karl Fisher Ph. Eur. 2.5.12 [◇]	≤0.5%	<0.2%
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT/ VA45110 Ph. Eur. 2.8.18 [◇]	≤ 2 µg/Kg	< UQL
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	< UQL
Microbiological Quality ¹			
TAMC	MW024-01/ VA52090, Complies to Ph. Eur. 2.6.12 [◇]	≤ 10 ⁴ CFU/mL	<100 CFU/mL
TYMC		≤ 10 ² CFU/mL	<10 CFU/mL
Bile-tolerant gram-negative bacteria	MW024-01/ VA52090, Complies to Ph. Eur. 2.6.31 [◇]	< 10 ² CFU/mL	<10 CFU/mL
E.Coli		Absent in 1mL	Absent in 1mL
Salmonella		Absent in 25 mL	Absent in 25mL
Residual solvent ³			
Ethanol	QC-140-MT/ VA12301 GC-HS-FID	≤ 5000 ppm	NA
Assay - Cannabinoids concentration (%w/w)			
CBN	QC-181-MT DAB [£]	≤ 2.5% m/m	0.9%
CBD		≤ 1.5% m/m (≤ 6% from THC label claim)	0.1%
Δ9-THC		23.75% - 26.25% m/m (95-105 % from label claim)	24.51%

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)	Daniele Grasso	QA Specialist	20-Jun-2025 19:44
Send for Approval	Shani Bonan	QC Manager	22-Jun-2025 13:48
Review	Shani Bonan	QC Manager	22-Jun-2025 13:48
Approve	Shani Bonan	QC Manager	22-Jun-2025 13:48
Approve	Chris Desira	Head of Quality Assurance	23-Jun-2025 08:55
Approve	Irene Zanetti	Qualified Person	23-Jun-2025 09:07
QA Approval	Chris Desira	Head of Quality Assurance	23-Jun-2025 09:09

* Dates are displayed according to the system time zone: (GMT+02:00) Central European Summer Time (Europe/Malta)

Document title	Document type	Document No.	Version
COA for Herbal Substance as raw material for oil (Rich THC) – Dried Flower	Specification	F-SPC-016-MT	02
Effective date: 30/05/2024		Page 1 of 3	

Manuf. Batch No: <u>24311076 MRK1053</u>	Panaxia Malta Batch No: <u>241080-MT</u> (Wet flower Batch No. if applicable: <u>N/A</u>)
PRT NUMBER: <u>RM-000020-MT</u>	Re-test date (to be determined after testing): <u>07 June 2024</u>

1. Specifications:

Test	Test Method*	Specifications	Result
Identification and other tests			
Macroscopic ²	SOP QC-129-MT Complies to Ph. Eur 1433	Brown to green Shredded/clustered inflorescence with characteristic smell with no visual molds ,external pests, stalks or foreign objects	Complies
Microscopic ²	SOP QC-130-MT Complies to Ph. Eur 2.8.23	Features comply	Complies
TLC ²	SOP QC-132-MT Complies to Ph. Eur 2.2.27	Zonal pattern complies	Complies
HPLC PDA-UV spectrum identification ³	SOP QC-145-MT	Complies to standards spectrum	Complies
Foreign matter	SOP QC-111-MT Complies to Ph. Eur EP 2.8.2	≤ 2%	0%.
Water Determination	SOP QC-134-MT Complies to Ph. Eur 2.5.12	≤ 12%	8%.
Pesticide residues- Performed by approved outsource laboratory			
Pesticides	SOP 15000/ SOP 15010 Complies to Ph. Eur 2.8.13,	Comply with the permitted levels for pesticides	Complies
Heavy metals- Performed by approved outsource laboratory			
Arsenic	SOP 77400 Complies to Ph. Eur 2.4.27	≤ 0.2 ppm	< 0.05 < 0.1
Cadmium		≤ 1.0 ppm	< 0.1 < 0.05
Lead		≤ 5.0 ppm	< 0.1
Mercury		≤ 0.1 ppm	< 0.1 < 0.05
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT Complies to 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	≤ 63 µg/Kg	MDL

AUTHORIZATION				QA Authorized Stamp
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:	RA APPROVED BY:	QA AUTHORIZED COPY
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	
<u>[Signature]</u> May 23, 2024	<u>[Signature]</u> May 23, 2024	<u>Chris Dimech</u> May 29, 2024	<u>[Signature]</u> May 29, 2024	

① error mt

05 JUN 2024

INITIALS:

03 JUN 2024

Document title	Document type	Document No.	Version
COA for Herbal Substance as raw material for oil (Rich THC) – Dried Flower	Specification	F-SPC-016-MT	02
Effective date: 30/05/2024		Page 2 of 3	

Microbial contamination - Performed by approved outsource laboratory

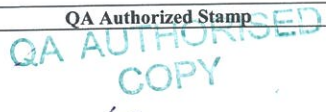
TAMC	VA52105 Complies to Ph. Eur 2.6.12-2.6.13	$\leq 10^7$ CFU/g	30 CFU/g < 100,000 CFU/g
TYMC		$\leq 10^5$ CFU/g	20 CFU/g < 10,000 CFU/g
E. Coli		10^3 (CFU/ g)	< 10 CFU/g
Salmonella		Absence (25g)	Absent in 25g

Active Ingredients

CBDA	QC-107-MT, QC-133-MT	Indicative (%)	0.067
CBGA		Indicative (%)	0.237
CBD		Indicative (%)	MDL
CBG		Indicative (%)	0.257
THCV		Indicative (%)	MDL
CBN		$\leq 1.0\%$	0.057
Δ^9 THC		Indicative (%)	2.437
Δ^8 THC		Indicative (%)	0.547
CBC		Indicative (%)	0.077
THCA		Indicative (%)	18.737
Total Δ^9 THC equivalents		$\geq 5\%$	197
Total CBD equivalents		$\leq 1.0\%$	0.17
Total CBG equivalents		Indicative (%)	0.7
Total Δ^9 THC equivalents: Total CBDequivalents	Ratio	$\geq 20:1$	190:1
Total CBD equivalents+ Total Δ^9 THC equivalents	Sum	$\geq 5\%$	197

1. **UQL** - under quantification limit (UQL<0.055% Δ^9 THC, THCA, CBD, CBDA, CBG, CBGA, and <0.011% for CBN and CBC).
2. **Microscopic/Macroscopic/TLC** – Identity testing should be carried out on all containers.
3. **HPLC PDA-UV spectrum identification**– Identity testing should be carried out on Bulk sample.

① error
mg
05 Jun 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 23, 2024	May 23, 2024	May 29, 2024	May 29, 2024	

INITIALS:

DATE
03 JUN 2024

Document title	Document type	Document No.	Version
COA for Herbal Substance as raw material for oil (Rich THC) – Dried Flower	Specification	F-SPC-016-MT	02
Effective date: 30/05/2024		Page 3 of 3	

2. Packaging and Labeling

2.1 Each package must be labeled, by Seach with at least the following information:

- 2.1.1 Product Name
- 2.1.2 Manufacturer Batch number
- 2.1.3 Net weight
- 2.1.4 Re-test date: Refer to QA-259-MT

3. Storage conditions:

3.1 Store in a cool, dry place at a temperature not exceeding 25°C.

Documented by: <i>Maria Agius</i>	Signature: <i>MB</i>	Date: 05 JUN 2024
<input type="checkbox"/> Version 01: Temporary release: All in-house Testing performed except for Aflatoxins, Ochratoxins, Pesticides and Heavy metals (In-process).		
<input checked="" type="checkbox"/> Version 02: Approved: All in-house and outsourced testing performed.		
<input type="checkbox"/> Version 03 <input type="checkbox"/> N/A : Re-test no. ____: All in-house re-test testing performed as per QC-259-MT.		
QC approved by: <i>Chris Dervin</i>	Signature: <i>[Signature]</i>	Date: 05/06/2024

REVISION HISTORY

Date	Name of corrector	Version no	Details of correction (including Chapter No)	Reason of correction
02/04/2024	Shani Bonan	01	New Document	CCF-MT-2024-23
13/05/2024	Maria Agius	02	Updated temporary approval section to allow for this type of approval prior to sending the samples for external testing.	Final version will include external testing.

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:	QA AUTHORISED COPY
<i>[Signature]</i> May 23, 2024	<i>[Signature]</i> May 23, 2024	<i>Chris Dervin</i> May 29, 2024	<i>[Signature]</i> May 29, 2024	

INITIALS:

DATE:

03 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 Liberty - 17 place des
Refflets - 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 Refflets - CS 30390 -
92097 Paris La Défense Cédex - France

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

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/lq	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



SGD S.A.

Simplified joint stock company with capital of 44 081 866 Euros -
Nanterre Trade and Companies Register N°B552 012 585 - VAT ID :
FR 29 552 012 585

Head Office and Sales Departments : Tour Liberty - 17 place des
Refflets - 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 Refflets - 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 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 FORCETO THE CURRENT ISO 15378 VERSIONTHE 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



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
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92097 Paris La Défense Cédex - France

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

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

Certificate of Conformity

**Invoice To:**

Panaxia Pharmaceutical Malta (Operations) LTD
HHF001A Ħal Far
Birżebbuġa
MALTA
MT26344313

Call: +44 (0) 1482 638380

Melton House Wyke Way Melton
East Yorkshire HU14 3HJ

Email: info@originltd.com

www.originltd.com

Account Ref: PANA003
Certificate No 115312 v1
Customer Order No PO23000457

Date 22/05/2024

Product Code	Product Description	No of Cases	Unit Qty	Qty Despatched
OS1W3-W	1ml White Oral Dosage Syringe - 0.01ml Graduations - Wrapped	20,000.00	1.00	20,000
Your Prod Code: PK000221-MT				
Batch Info:				
	# Batch Quantity Manufacturer Batch Ref			
	1 P0057883 20,000 BRV240313			
OS1W3-W	1ml White Oral Dosage Syringe - 0.01ml Graduations - Wrapped (V4.9)	30,000.00	1.00	30,000
Your Prod Code: PK000221-MT				
Batch Info:				
	# Batch Quantity Manufacturer Batch Ref			
	1 P0057883 30,000 BRV240313			

Deliver To:

Panaxia Pharmaceutical Mali
HHF001A Ħal Far
Birżebbuġa
MALTA

Certificate of Conformity

We confirm that the products detailed herein
have been supplied from a QA approved source
and have been manufactured, inspected and
tested in accordance with the manufacturers

CERTIFICATE OF ANALYSIS

Product: 1ml Dosing Syringe

Product Code: SYPN01-WH - CE

Batch/Lot No.: BRV240313

A.R. No.: FG-24-0698

MFG Date: 08/05/2024

Date: 13/05/2024

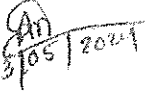
Batch/Lot size: 30,000 NOS

Challan No.: EXP/4/2024-25


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	86.50 mm ± 1.0 mm	85.79 mm - 85.80 mm
4	Outer Diameter	6.50 mm ± 0.3 mm	6.43 mm - 6.58 mm
5	Inner Diameter At Tip	2.40 mm ± 0.2 mm	2.24 mm - 2.42 mm
6	Outer Diameter At Tip	5.10 mm ± 0.2 mm	4.95 mm - 5.10 mm
7	Flange Diameter	18.50 mm ± 0.3 mm	18.46 mm - 18.65 mm
8	Volume Marking	0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml, 0.1ml... up to 1ml ± 10 %	Complies
(b)	Syringe Plunger		
1	Material	High Density Polyethylene ✓	Complies
2	Grade	ACP 6541A ✓	Complies
3	Total Height	92.50 mm ± 1.0 mm	92.38 mm - 92.65 mm
4	Sucking Od	4.85 mm ± 0.2 mm	4.83 mm - 4.97 mm
5	Collar Diameter	15.00 mm ± 0.3 mm	15.05 mm - 15.19 mm
(c)	Pouch		
1	Length Of Pouch	130.00 mm ± 10.0 mm	125 mm - 138 mm
2	Width Of Pouch	30.00 mm ± 5.0 mm	28 mm - 33 mm

Complies with our specification No. -BRV/FG-1903Analyzed by: 

13/05/2024

Approved by: 

13/05/2024

Formal No. FQC/021-06/00

ADDRESS: PLOT NO.15-16, S. NO. 66, NAIKPAD A SAI PRABHAT UDYOG NAGAR-2 WALIY VASAI, PALGHAR, MAHARASHTRA 401208

CERTIFICATE OF ANALYSIS

Product: 1ml Dosing Syringe
Product Code: SYPN01-WH - CE
Batch/Lot No.: BRV240313
A.R. No.: FG-24-0698
MFG Date: 08/05/2024

Date: 10/05/2024
Batch/Lot size: 20,000 NOS
Challan No.: EXP/2/2024-25
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 fillings.	Complies
C	Physical Test		
(a)	Syringe Barrel		
1	Material	Polypropylene	Complies
2	Grade	RP375R	Complies
3	Total Height	86.50 mm \pm 1.0 mm	85.79 mm - 85.80 mm
4	Outer Diameter	6.50 mm \pm 0.3 mm	6.43 mm - 6.58 mm
5	Inner Diameter At Tip	2.40 mm \pm 0.2 mm	2.24 mm - 2.42 mm
6	Outer Diameter At Tip	5.10 mm \pm 0.2 mm	4.95 mm - 5.10 mm
7	Flange Diameter	18.50 mm \pm 0.3 mm	18.46 mm - 18.65 mm
8	Volume Marking	0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml, 0.1ml... up to 1ml \pm 10 %	Complies
(b)	Syringe Plunger		
1	Material	High Density Polyethylene	Complies
2	Grade	ACP 6541A	Complies
3	Total Height	92.50 mm \pm 1.0 mm	92.38 mm - 92.65 mm
4	Sucking Od	4.85 mm \pm 0.2 mm	4.83 mm - 4.97 mm
5	Collar Diameter	15.00 mm \pm 0.3 mm	15.05 mm - 15.19 mm
(c)	Pouch		
1	Length Of Pouch	130.00 mm \pm 10.0 mm	125 mm - 138 mm
2	Width Of Pouch	30.00 mm \pm 5.0 mm	28 mm - 33 mm

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

Analyzed by: *Nishah*
10/05/2024
Format No. FQC/021-06/00

Approved by: *[Signature]*
10/05/2024

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 Pharmaceuticals Art.-Bez.: / article name: DOSIERVERSCHLUSS / dosage closure DOSIERVERSCHLUSSRSV 5,0 OVII / SPRITZEN-EINSATZNW18 W/TR					
Auftr.-Nr. 21124205 Order No.: Ident.-Nr. 6615MA Article no.:		Ihre Auftr.-Nr.: PO21001728 Your order no.: Ihre Ident.-Nr.: CM-2074 Your article no.:		LS-Nr.: 22244775 Packing slip no.: Chargen-Nr.: 127870 Batch no.:	
Herstelldatum:  02/2022 date of manufacture:		Verfallsdatum:  02/2027 shelf life if sterile then		Ursprungsland: Deutschland Country of origin: Germany	
Stückzahl: 30000 Pieces supplied:		Stichprobe: 50 (315) sampling size: quant. (qual)		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-SCHRAUBKAPPSERK 5,0 OVII NW18 W 1. component part: Purell ACP6541A (PEHD) 2. Einzelteil: DOSIERHILFESPRITZEN-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:		HT-MAB PE 9071 weiss /white 2-2,5%			
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	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 Kennzeichnung der Palette / 1 1 1 1 1 1 Gebinde muss der Vorschrift entsprechen / Labelling 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 2 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 2 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 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 2 2 Nicht entfernbare Verunreinigungen innen ≥ 0,3mm ² / Non-removable contamination inside ≥ 0,3mm ²			0,40	0 (3)
2/4	1 1 1 1 Entfernbare 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 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)

Ident.-Nr. Article no.:	6615MA	Ihre Ident.-Nr.: Your article no.:	CM-2074	Chargen-Nr.: Batch no.:	127870	Stichprobe: sampling size:	50 (315) quant. (qual)
Verarbeitungsfehler / Processing Errors							
2/7/15/ 17	❶ 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 Fellreste / Flash, punching errors ❷ Risse, Spalten, Löcher. Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, clefs, holes, parts incompletely injected, seam breaks open ❸ Durchgehende Risse / Wall penetrating cracks ❹ 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	❶ Starke Formnähte u./o Rückstände an den Anspritzpunkten / Marked mould joints and or residues at the injection points ❷ Stark verzogene Teile / Markedly warped items ❸ Deformierung / Deformation ❹ Anspritzpunkt entspricht nicht (seitlich max 0,5mm, zentral max. 0,7mm) / Injection point does not comply (lateral max. 0,5mm, central max. 0,7mm) ❺ Überspritzungen, ❻ Formgrate an Dichtstellen (Over-injection, flash at the sealing points				0,10	0 (1)	+
8/9/12/ 15/19/ 08.1	❶ Anrisse / Incipient cracks Absplitterungen im Dichtungsbereich / Chipping in area of seal ❷ Blasen, Einschlüsse > 1,0mm / Gas bubbles, inclusions > 1mm, ❸ Kühltension außer Toleranz / Cooling stress out of tolerance ❹ Abgeplatzte Stelle(n), Deformierung/en oder Glasspitze(n) am vorderen Teil (Kugel) / Chipped place(s), deformity(ies) or glass spike(s) on tip (ball) ❺ Oberfläche, Kontur uneben / Surface, Shape uneven				0,40	0 (3)	+
6/8/12/ 13	❶ Verformte Behälternisse / Deformed containers ❷ Kratzer (Breite ≥ 0,2mm, Länge ≥ 20mm) / Scratches (width ≥ 0,2mm and length ≥ 20mm) ❸ Fallen, Kerben, Kratzer, Formgrat / Folds, notches, scratches, flash				2,50	3 (12)	+
Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing							
1	❶ 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, ❷ ❸ ❹ Dichtigkeit / test for				0,00	0	+
1/2/3/6	❶ Scheibel Ø, Tropfloch Ø, Biegung außerhalb der Toleranz / Diameter of annular flange, dropper hole, bend out of the tolerance ❷ sonstige Maße, Winkel, Radien außer Toleranz / Other dimensions, angles, radii out of tolerance ❸ Abmessungen a.T. / Dimensions out of tolerance ❹ weitere Maße außer Toleranz / Other dimensions out of tolerance, ❺ Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing				0,10	0 (1)	+
1/3	❶ ❷ Gravur fehlt, falsch u./o. unvollständig. / Engraved text missing, incorrect and/or incomplete, ❸ Druck, Prägung fehlt, falsch u/o unvollständig / Overprinting, embossed text missing, incorrect and/or incomplete ❹ Gewinde fehlt oder ist nur mangelhaft ausgebildet / Thread missing or only inadequately formed ❺ Druckfarbe falsch / Printing color incorrect, ❻ Druckbild fehlt, falsch / Printing image missing or incorrect				0,00	0	+
1/6/7	❶ Gravur für Dosierung unvollständig - Dosierung nicht möglich / Engraved marks for dosage incomplete - Dosage not possible, ❷ Abmessungen entsprechen nicht / Dimensions do not comply, ❸ Text fehlt, falsch oder nicht lesbar / text absent, incorrect or illegible, ❹ Dosierung a.T. / Dosage out of tolerance, ❺ ❻ Farbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion				0,10	0 (1)	+
4	❶ Druckfarbe haftet nicht / Printing does not adhere				0,40	0 (3)	+
Montage / Mounting							
13/15	❶ Kindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, ❷ Außenteil gerissen / External part torn				0,00	0	+
1/2/4/5/ 9/17/19	❶ ❷ ❸ Einzelteil fehlt / Individual parts missing, ❹ Teile durch Montage beschädigt / Parts damaged by mounting, ❺ Teile falsch montiert / Parts incorrect mounted, ❻ Pipette zu tief in Sauger eingesetzt / Pipette set too deep into the test, ❼ 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							
❶ Kunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps ❷ Behälternisse aus Röhrglas / Containers Made of Tubular Glass ❸ Gummiteile / Rubber Parts ❹ Spritzgussteile aus Kunststoff: Verschlüsse; Dichteinlagen und Dosierhilfen (Tropfer etc.) / Injection-moulded Parts Made of Plastic: Closures ❺ 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 obligation to carry out an inspection of goods received.							
Datum: Date:	21.02.2022	Freigabe: release:	ja / yes	Prüfer: I.A.  Approved by  Date: 16.03.2022			

