

Certificate of Conformance

Authorisation of Batch Release for sale in the EU

Product name, dose, dosage form and pack size:	Naxiva Panaxol THC 10mg/ml CBD 10 mg/ml
Client:	Neuraxpharm Arzneimittel GmbH
Market:	Germany
Batch number:	24/225-MT
Quantity	300 KITS
Manufacturing Date:	16/10/2024
Expiry date:	07/2026
Active Ingredient Concentration:	THC 1.04% (w/w) (10mg/ml) CBD 1.04% (w/w) (10mg/ml)
Plant strain/s:	Charlotte Angel & Master Kosh

Deviations noted during manufacture:

- ☒ No Critical/Major deviations
☐ Critical/Major deviations were reported and properly investigated and closed

The following document are attached-

- *Certificate of analysis*
- *Herbal substance COA*
 - *Herbal substance batch Number: 24/173-MT Herbal substance Strain: Charlotte Angel*
 - *Herbal substance batch Number: 24/168-MT Herbal substance Strain: Master Kosh*
- *Package COA*
 - *10ml amber glass bottles - batch number: 23/337-MT, 23/088-MT*
 - *10ml amber glass bottles cap- batch number: 24/007-MT*
 - *1ml sterile graduated syringes for patient dosing: batch number: 23/085-MT, 24/104-MT*
 - *syringe cap - batch number: 24/003-MT*
 - *30ml amber glass bottles - batch number: 24/043-MT, 24/198-MT*
 - *30ml amber glass bottles cap- batch number: 22/183-MT*

I hereby certify that all the manufacturing stages of this batch have been carried out in full compliance with EU GMP and the technical agreement in force. The herbal substance used for the production of the batch had not been irradiated during the growing of the product process. The batch is released for sale by the undersigned Qualified Person in accordance with EC directive 2001/83.

Qualified Person:

Signature & Date

Steve Zambet 04 Dec 2024

Name

Reference Specification Legacy Number: F-COA-001-DE

Batch Details			
Batch number -Bulk oil	24/208-MT	Manufacturing date	16/10/2024
Batch number - Finish product	24/225-MT	Expiry date	07/2026

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	0.95
Water content	SOP-175-MT/ VA25322 Karl Fisher Ph. Eur. 2.5.12 [◇]	≤0.5%	0.1%
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT/ VA45110 HPLC Ph. Eur. 2.8.18 [◇]	≤ 2 µg/Kg	UQL
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	UQL
Ochratoxin A	SOP QC-322-MT /VA45118 HPLC Ph. Eur. 2.8.22 [◇]	≤151 µg/kg	UQL
Microbiological Quality ¹			
TAMC	MW024-01/VA52090	≤ 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/VA52090	< 10 ² CFU/mL	< 10 CFU/ml
E.Coli	Complies to Ph. Eur. 2.6.31 [◇]	Absent in 1mL	Absent in 1 ml
Salmonella		Absent in 25 mL	Absent in 25 ml
Residual solvent			
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	0.03%
CBD		0.99% - 1.09% m/m (95-105 % from label claim)	1.02%
Δ9-THC		0.99% - 1.09% m/m (95-105 % from label claim)	1.03%
Vitamin E	QC-149-MT / VA14060	≥ 0.4% m/m	0.5%
Pesticide Residue ^{1,2}			

Reference Specification Legacy Number: F-COA-001-DE

Batch Details			
Batch number -Bulk oil	24/208-MT	Manufacturing date	16/10/2024
Batch number - Finish product	24/225-MT	Expiry date	07/2026

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
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Aflatoxins UQL- Under quantification limit; LOQ Aflatoxin B1, B2, G1: 0,5 µg/kg; LOQ Aflatoxin G2: 1,0 µg/kg.
Ochratoxins UQL – Under quantification limit. The result of Ochratoxin A that is less than 0.5 µg/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 CBN that are less than 0.05% from the label amount of THC and CBD are reported URL (0.0005% 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:
	☐ Yes; ☒ No, results reported from Inflorescence COA/s batch no/s used during manufacturing: 24/173-MT, 24/168-MT

☒ PASS ☐ FAIL		
Approved by: Shani Bonan	Signature: 	Date: December 4, 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: ☒ Approved/ ☐ Rejected.		
QC Reviewed by: Chris Desira	Signature: 	Date: December 4, 2024

REVISION HISTORY				
Date	Name of corrector	Version no	Details of correction (including Chapter No)	Reason of correction
20.03.2024	Shani Bonan	01	New Document	CCF-MT-2024-23
3/12/2024	Shani Bonan	02	1. Included Residual Solvent skip-lot testing 2. Adding the method's number of QSI 3. Update the shelf life to 244 month	1. CC-0000016 2. CC-0000022 3. Update

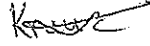
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Shani Bonan	QC Manager	03-Dec-2024 17:27
Review	Chris Desira	Head of Quality Assurance	03-Dec-2024 19:21
Send for Approval	Chris Desira	Head of Quality Assurance	03-Dec-2024 19:22
Approve	Chris Desira	Head of Quality Assurance	03-Dec-2024 19:22
Approve	Shani Bonan	QC Manager	03-Dec-2024 19:36
Approve	Irene Zanetti	Qualified Person	04-Dec-2024 07:33
QA Approval	Ivan Vidmar	Senior QA Specialist	04-Dec-2024 07:47

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

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.:		Chargen-Nr.: 111585 Batch no.:	
Herstelldatum: date of manufacture: 11/2020		Verfallsdatum: shelf life: 11/2025		Ursprungsland: Deutschland Country of origin: Germany	
Sterilisationsdatum: date of sterilization: entfällt				Stückzahl: 15000 Pieces supplied: Stichprobe: 50 (315) sampling size: quant. (qual)	
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	12345 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	12345 Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, 12345 Grenzwerte für Partikel überschritten / Agreed limits for particles exceeded			0,00	0
1/3/8	12345 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	12345 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	23 Nicht entfernbare Verunreinigungen innen ≥ 0,3mm² / Non-removable contamination inside ≥ 0,3mm²			0,40	0 (3)
2/4	12345 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 12345 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 Füllreste / 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, ⑤ 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.	


Hubert De Backer nv

Customer PANAXIA PHARMACEUTICAL MALTA

F.a.o. QUALITY DEPARTMENT

Temse, 30/01/2023

CERTIFICATE OF CONFORMITY

This delivery contains the following articles :

Article Number	Quantity	Description + Item customer	Your ref.
FP0000 . T2024 .. T2023	50000	FLOWPACK	PO22000749 dd. 22/09/2022
		ORAL APPLICATOR PLUNGER 1 ML	Our ref./Batch no
		550 HDPE	22-1711/00
		099 WHITE	
		ORAL APPLICATOR BARREL 1 ML	
		560 PP	
		250 NATURAL	
		163 RED 0,1-0,2-0,3-0,4-0,5-0,6-0	

CM-2053

 Approved by : Marijn Todts
 Dispatch department

1

Use-by date: 12/2026

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 : Nathalie Van Assche
 QA department

This document is created electronically and is valid without signature.

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 IBAN: BE16 410 3042251 36 | SWIFT: BRED BE55 | BTW BE 0441 076 925 | BFR Dendermonde



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 :9 552 012 585

Head Office and Sales Departments : Tour CB16 - 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 CB 16 - 17 place des Refflets - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 21.07.2022

Customer

PANAXIA PHARMACEUTICAL INDUSTRIES / 39371

71201

LOD

IL

Delivery address

PANAXIA PHARMACEUTICAL INDUSTRIES / 39371001

LOD

IL

Customer's order PO22000396

from 12.05.2022

Customer's product code CM-2052

Delivery	81491445	Quantity Delivered	17.160	PCE
SGD Product Code	52490 04 001	TROPFFLASCH 10 ML		
SGD Drawing N 68713G	Treatment	None	type 3 AMBER GLASS	
Run Number	N 221273	Manufacturing Date	02.05.2022 to	09.05.2022
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		0,100	0,050	0,050	0,050	0,000
Hydro-resist-powder/1g	ml		0,250	0,590	0,590	0,590	0,000
Hydrolytic resistance (HCl)	ml		9,100	6,400	7,000	6,730	0,310
Spectral transmission	%		10,000	0,920	0,920	0,920	0,000
Annealing			18,000	Conforms			

Glass measurements

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Minor thread diameter	mm	15,680	15,980	15,730	15,850	15,794	0,030
Opening diameter	mm	19,450	19,750	19,520	19,720	19,611	0,046
Body diameter	mm	25,000	25,800	25,260	25,540	25,375	0,041
Mini Internal bore	mm	9,500		10,960	11,800	11,385	0,179
Neck finish height 2	mm	10,800	11,200	10,940	11,170	10,991	0,073
Maxi External neck	mm		18,000	17,730	17,930	17,815	0,045
Total height	mm	57,400	58,600	57,650	58,230	58,015	0,119
Neck finish diameter	mm	17,700	18,000	17,700	17,900	17,741	0,021
Bead diameter	mm	19,200	20,200	19,840	20,050	19,993	0,041
Neck finish height	mm	13,500	13,900	13,510	13,740	13,644	0,052



SGD S.A.
Simplified joint stock company with capital of 44 081 866 Euros -
Nanterro 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
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 CB 16 - 17 place des Reflots - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 21.07.2022

Customer

PANAXIA PHARMACEUTICAL INDUSTRIES / 39371

71201 LOD IL

Delivery address

PANAXIA PHARMACEUTICAL INDUSTRIES / 39371001

LOD IL

Customer's order PO22000396

from 12.05.2022

Customer's product code CM-2052

Delivery 81491445

Quantity Delivered 17,160 PCE

SGD Product Code 52490 04 001

TROPFFLASCHE 10 ML

SGD Drawing N 68713G Treatment

None type 3 AMBER GLASS

Run Number N 221273

Manufacturing Date 02.05.2022 to 09.05.2022

Quantity per Pallet 17.160

Production Site SUCY EN BRIE France

Glass characteristics

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Weight	g			12,600	15,000	14,321	0,315
Capacity	ml	13,000	15,000	13,800	14,600	14,209	0,304
Vertical load	kg/cm	200,000		400,000	400,000	400,000	0,000
Thermal shock		42,000		Conforms			

Quality Manager

Laurent MILLET

LM

Approved By QA	
Signature: <i>Stef</i>	
Date: <i>22.08.22</i>	

22.08.22
L.P. 22.08.22



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
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 Liberty - 17 place des Reflets - 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 44 061 866 Euros -
Nanterre Trade and Companies Register N°B552 012 565 - VAT ID :
FR 29 552 012 565
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 30360 -
92097 Paris La Défense Cédex - France

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 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



SGD S.A.

Simplified joint stock company with capital of 44 081 866 Euros -
Nanterre Trade and Companies Register N°B552 012 525 - VAT ID :
FR 29 552 012 525

Head Office and Sales Departments : Tour Liberty - 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 Liberty - 17 place des Reflets - 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 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
Weight	g	N/A	N/A	24,500	25,500	25,000	0,247
Capacity	ml	13,000	15,000	13,500	14,100	13,826	0,140
Vertical load	kg/cm	200,000	N/A	400,000	400,000	400,000	0,000
Thermal shock	N/A	42,000	N/A	Conforms			

Quality Manager

Laurent MILLET



Hubert De Backer nv

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

F.a.o.: QUALITY DEPARTMENT

Temse, 2/04/2024

CERTIFICATE OF CONFORMITY

This delivery contains the following articles :

Article Number	Quantity	Description + Item customer	Your ref.
T2133	25000	CAP 560 PP 099 WHITE PK000005-MT	PO24000111 dd. 20/03/2024
			Our ref./Batch no
			24-0432/00

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.

Laagstraat 59 | 9140 Temse | Belgium | T +32(0)3 776 34 94 | F +32(0)3 777 71 94 | hdb@hdb.be | www.hdb.be
IBAN: BE18 413-9042251-65 | SWIFT: KRED BEBB | BTW BE 0441 075 925 | RPR Dendermonde

FRM-KD-118.02

COMPANY / UNTERNEHMEN:
DATE / DATUM: 14/12/23

Remy & Geiser GmbH

Ein Unternehmen der Bormioli Pharma Group
Sitz: Remy & Geiser Straße 1 98553 Schleusingen (OT Hinternah), Germany

DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

ARTICLE / Art.-Code	8840MA-AR240001
DELIVERY NOTE / Lieferschein Nr	23004312
CUSTOMER ARTICLE ID / Kunde Art.-Code	
DESCRIPTION / Art.-Bez.	KINDERGESICHERTER VERSCHLUSS KG KPV OVII 6,0 /SPRITZEN- EINSATZ TYP II NW18 W/W/TR
BATCH / Chargen-Nr	H23015_22204693
PRODUCTION DATE / Herstellungsdatum	06/12/23
SHELF LIFE / Verfalldatum	09/01/2028
PLANT ADDRESS / Adresse der Produktionsstätte	WERK IV REMY & GEISER STRASSE 1 98553 SCHLEUSINGEN DE GERMANY
CUSTOMER / Kunde	Panaxia Pharmaceutical Industries
ORDER NUMBER / Auftr.-Nr.	20077278
CUSTOMER ORDER NUMBER / Kunde Auftr.-Nr.	PO23000265
QUANTITY DELIVERED (kpcs) / Stückzahl (kpcs)	64 KP

We declare that the goods referred to the lot indicated above, received with the supply indicated in the aforementioned delivery note and attached to this document, have been tested and resulted to be IN ACCORDANCE with the product technical specifications and Defect Evaluation List by Editio Cantor Verlag Aulendorf, in the respective valid version – please refer to tables related to the supplied items category in the following pages.

Sampling plan: ISO 2859-1; level II; normal inspection

The control method and quality level of the supply, unless different specifications agreed with the Customer, are those defined in our Quality System.

The above particulars do not release the customer from the obligation to carry out an inspection of the received goods.

Kindly note that we cannot guarantee the suitability of the used material.

In order to ensure that your packaging system works safely, we recommend you perform tests with the corresponding liquid.

According to its formulation, the materials used to manufacture the supplied item comply with the following provisions:

- Regulations applicable to articles intended for contact with food:
 - Reg. 10/2011 EU and following amendments
 - Reg. 1895/2005/EC; Reg. 1935/2004/EC; Reg. 2023/2006/EC
- REACH regulation 1907/2006/EC
- Reg. 1223/2009/EC and following amendments
- Reg. 2023/2006/EC and following amendments
- Dir 94/62/EC: relative to the content of heavy metals
- Class I Medical Devices DoC: refer to product specification.

COMPONENT	COMPONENT DESCRIPTION
LI 1731M-AR240001	KINDERGESICHERTES EINZELTEIL KG ÜK NW18 W
LI 4509M-AR240001	KINDERGESICHERTES EINZELTEIL KG KSK OVII TYP V; VI; VII 6,0 N
LI 8805A-AR240001	DOSIERHILFE SPRITZEN-EINSATZ TYP II NW18 TR

MATERIAL	COMPONENT	MATERIAL DESCRIPTION
30147	1731M-AR240001	PURELL ACP 6541 A

B0658	1731M-AR240001	FARBKONZENTRAT WEISS REMAFIN-EP-WEISS PL00075542-ZT ähnlich RAL 9016 2%ig
B0658	4509M-AR240001	FARBKONZENTRAT WEISS REMAFIN-EP-WEISS PL00075542-ZT ähnlich RAL 9016 2%ig
B0147	4509M-AR240001	PURELL ACP 6541 A
B0143	8805A-AR240001	PURELL PE1840H NATUR

Plant Quality Manager/ Qualitätsmanager für den Produktionsstandort

Benny Mueller

PRÜFZERTIFIKAT NACH FEHLERBEWERTUNGSLISTE (EDITIO CANTOR VERLAG) 18, 19, 20, 22, 34 aktuelle Ausgabe
Test Certificate acc. to Defect Evaluation List (Editio Cantor Verlag) Vol. 18, 19, 20, 22, 34 in current edition

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 deformation.

Fehler-Nr. Attr.-no.	Fehler/Einzelmerkmal Defect/Individual characteristics	AQL	Entscheidung Result
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.			
18.01.01 19.01.01 20.01.01 22.01.01	(1)(3)(4)(5)(6) Palette und/oder Außenverpackung entspricht nicht der Vorschrift, beschädigt, verschmutzt (Packmittelspezifikation) / pallet and/or outer packaging does not meet packaging specification, damaged, soiled	-	+
19.01.04 20.01.02 03	(1)(3)(4)(5)(6) Packschema falsch / Packaging scheme incorrect	-	+
18.01.03/04 19.01.06 20.01.06 22.01.03/04	(1)(3)(4)(5)(6) Kennzeichnung der Palette / (1)(3)(4)(5)(6) Gebinde muss der Vorschrift entsprechen / Labelling of the Pallet / Container must comply with the specification	-	+
18.01.05/07 19.01.09/10 20.01.08 22.01.05/06	(1)(3)(4)(5)(6) Einzelverpackung (Sterilverpackung) beschädigt, verschmutzt, unvollständig / Individual packs (Sterile Packing), damaged, soiled, incomplete	-	+
20.01.09/10	(1)(3)(4)(5)(6) Lieferantenstichprobe / Begleitpapiere, Qualitätsdokumente, Prüfzertifikat falsch / fehlen / Suppliers random sample / Accompanying documents, quality documents, test certificate incorrect / missing	-	+
Untermischung / Intermixing			
18.03.01 19.02.01/02 20.02.01 22.03.01	(1)(3)(4)(5)(6) Untermischung / Intermixing	-	+
Ausgangsmaterial / Starting material			
1.1.1/2 18.02.01/02 19.03.05 22.02.01/02	(1)(3)(4)(5)(6) 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	-	+
20.04.10	(3)(6) Zusammenhaftende bzw. klebrige Gummiteile / rubber parts adhering to one another or sticking	0,40	+
Sauberkeit / Cleanliness			
1.4.1 18.04.01/05/06 20.07.02 22.04.01/05/06	(1)(3)(4)(5)(6) Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, (1)(3)(4) Grenzwerte für Partikel überschritten / Agreed limits for particles exceeded	-	+
14.04.08 22.04.01 03	(1)(4)(5)(6) Fremdeinschlüsse-Aussehen stark beeinträchtigt, > 1mmØ oder Anhäufung (3) 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	+
18.04.02 22.04.04	(1)(4)(6) Im Material eingeschlossene Fremdkörper / Brandstellen punktförmig 0,5- 2mm Ø / Foreign bodies incorporated in the material / Scorch dots 0,5- 2mm Ø	0,40	+
14.04.09 22.01.04	(5) Brandstellen / Scorched spots (1)(4)(5)(6) Fremdeinschlüsse-Aussehen wenig beeinträchtigt < 1mm Ø / Foreign bodies enclosed- appearance less impaired, < 1mm Ø, Lose Materialreste / Loose material residues	2,50	+
Verarbeitungsfehler / Processing Errors			
1.5.5 22.05.07	(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 Fellreste / Flash, punching errors (4)(5) Risse, Spalten, Löcher, Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, clefts, holes, parts incompletely injected, seam breaks open (4) 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	-	+

Fehler-Nr. Attr.-no.	Fehler/Einzelmerkmal Defect/Individual characteristics	AQL	Entscheidung Result
Verarbeitungsfehler / Processing Errors			
5.5.1 22.05.06/03/09	(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 (1)(4) Anspritzpunkt entspricht nicht (seitlich max 0,5mm, zentral max. 0,7 mm) / Injection point does not comply (lateral max. 0,5mm, central max. 0,7mm) Überspritzungen, (4) Formgrate an Dichtstellen (Over-injection, flash at the sealing points	0,10	+
18.05.12 22.05.08/09	(1) Oberfläche, Kontur uneben / Surface, Shape uneven	0,40	+
19.03.13 22.05.12	(4)(5)(6) Falten, Kerben, Kratzer, Formgrat / Folds, notches, scratches, flash	2,50	+
Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing			
9.9.1 22.06.01	(4) 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, (3)(4) Dichtigkeit / test for leaks, Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing	-	+
18.06.03.01 20.09.01 22.06.01.01	(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	0,10	+
18.07.01 19.18.05 22.07.01	(1)(4)(6) 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 (4)(6) Druckfarbe falsch / Printing color incorrect, Druckbild fehlt, falsch / Printing image missing or incorrect	-	+
07.07.01 18.07.07 19.18.06 22.07.01/03	(5)(6) 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)(6) Farbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion	-	+
Montage / Mounting			
22.08.13/15	(4)(6) Kindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, Außenteil gerissen / External part torn	-	+
18.08.01/03/04 22.08.05/17/18	(1)(4)(5)(6) Einzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts damaged by mounting, Teile falsch montiert / Parts incorrect mounted, (4)(6) Pipette zu tief in Sauger eingesetzt / Pipette set too deep into the teat, Tropfeinsatz durch Montage beschädigt / Dropper insert damaged by mounting	0,10	+
Fertigungsfehler Pipetten / Manufacturing defects Pipettes			
19.08.01	(6) Abgeplatzte Stelle/n, Deformierung/en, oder Glasspitze/n am vorderen Teil (Kugel) / Chipped area(s), deformation or glass spike/s on the tip	0,25	+

* falls zutreffend die dazugehörige Fehlerbewertungsliste * if applicable the relevant Defect Evaluation List

+:Passed - Non passed

(1) Kunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps • (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 (6) Pipetten Monturen/Glass Pipette Dropper

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

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



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

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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 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

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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 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

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

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-1903

Analyzed 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 WALIV 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



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
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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

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

