

Certificate of Conformance

Authorisation of Batch Release for sale in the EU

| | |
|--|-------------------------------|
| Product name, dose, dosage form and pack size: | Naxiva Panaxol CBD 25mg/ml |
| Client: | Neuraxpharm Arzneimittel GmbH |
| Market: | Germany |
| Batch number: | 25008-00 |
| Internal Batch Number: | FP25008-00DE |
| Quantity | 428 kits |
| Manufacturing Date: | 24/11/2025 |
| Expiry date: | 09/2027 |
| Active Ingredient Concentration: | CBD 2.6% (w/w) |
| Plant strain/s: | Charlotte Angel |

Deviations noted during manufacture:

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

The following document are attached

- *COA Finished Product*
- *Herbal Substance CoA 25/087-MT – Strain Charlotte Angel*
- *Package COA*
 - *10ml amber glass bottles - batch number: 23/337-MT*
 - *10ml amber glass bottles cap- batch number: 25/001-INS*
 - *1ml sterile graduated syringes for patient dosing: - batch number: 25/031-MT*
 - *syringe cap- batch number: 24/251-MT*
 - *30ml amber glass bottles - batch number: 24/198-MT*
 - *30ml amber glass bottles cap- batch number: 23/142-MT*

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country. 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: Grace Laveh 18 Jan 2026
Signature & Date Name

Product Name: NAXIVA-PANAXOL CBD 25mg/mL
Reference Specification Legacy number: F-COA-009-DE

| <i>Batch Details</i> | | | |
|--------------------------------------|----------------|---------------------------|---------|
| Batch number -Bulk oil | FN 25008-00 | Manufacturing date | 11/2025 |
| Batch number - Finish product | 25008-00 | Expiry date | 11/2027 |
| MT- Batch number | FP 25008-000DE | | |

| Test | Test Method | Specifications | Result |
|--|---|--|-----------------|
| Identification | | | |
| TLC identification | SOP QC-179-MT/ VA1112 <i>DAB</i> [£] | Zonal pattern of test solution conforms to the zonal pattern of the reference solution | Complies |
| Organoleptic properties | | | |
| Appearance | SOP QC-136-MT Visual inspection <i>DAB</i> [£] | Homogenous greenish or yellow to brown liquid, no significant precipitate observed | Complies |
| Heavy metals^{1,2} | | | |
| Cadmium | SOP 77405 ICP-MS <i>Ph. Eur. 2.4.27</i> [◇] | ≤ 1.0 ppm | 0.05 ppm |
| Lead | | ≤ 5.0 ppm | 0.1 ppm |
| Mercury | | ≤ 0.1 ppm | < 0.05 ppm |
| Physico-chemicals | | | |
| Relative density | SOP-183-MT / VA1044 <i>Ph. Eur. 2.2.5</i> [◇] | Indicative | 0.91 |
| Water content | SOP-175-MT/ VA25322 Karl Fisher <i>Ph. Eur. 2.5.12</i> [◇] | ≤0.5% | < 0.2% |
| Toxins- Mycotoxins | | | |
| Aflatoxin B1 | SOP QC-131-MT /VA45110 <i>Ph. Eur. 2.8.18</i> [◇] | ≤ 2 µg/Kg | < LOQ |
| Total Aflatoxins (B1, B2, G1, G2) | | ≤ 4 µg/Kg | < LOQ |
| Microbiological Quality¹ | | | |
| TAMC | MW024-01 | ≤ 10 ⁴ CFU/ml | < 100 CFU/ml |
| TYMC | <i>Complies to Ph. Eur. 2.6.12</i> [◇] | ≤ 10 ² CFU/mL | < 10 CFU/ml |
| Bile-tolerant gram-negative bacteria | MW024-01 | < 10 ² CFU/ml | < 10 CFU/ml |
| E.Coli | <i>Complies to Ph. Eur 2.6.31</i> [◇] | 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 <i>DAB</i> [£] | ≤ 2.5% m/m | 0.0% |
| CBD | | 2.47% - 2.73% m/m (95-105 % from label claim) | 2.58% |
| Δ9-THC | | ≤ 0.16% m/m | 0.11% |

Product Name: NAXIVA-PANAXOL CBD 25mg/mL
Reference Specification Legacy number: F-COA-009-DE

| <i>Batch Details</i> | | | |
|--------------------------------------|----------------|---------------------------|---------|
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| Batch number - Finish product | 25008-00 | Expiry date | 11/2027 |
| MT- Batch number | FP 25008-00 DE | | |

| | | | |
|---|--|---|----------|
| | | (\leq 6% from CBD label claim) | |
| Vitamin E | QC-149-MT / VA14060 | \geq 0.4% m/m | 0.5% |
| Pesticide Residue ^{1,2} | | | |
| Pesticides | SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS <i>Ph. Eur.2.8.13</i> [◇] | <i>Complies with the limits indicated in Ph. Eur.2.8.13</i> | Complies |

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

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

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

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

[◇] 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 number: | Pesticides and Heavy metals testing required on Finished product: |
| 4 | <input type="checkbox"/> Yes; <input checked="" type="checkbox"/> No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: 25/087-MT |

PASS **FAIL**

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

REVISION HISTORY

| Date | Name of corrector | Version no | Details of correction (including Chapter No) | Reason of correction |
|------------|-------------------|------------|---|--------------------------------|
| 12.03.2024 | Shani Bonan | 01 | New Document | CCF-MT-2024-23 |
| 28/10/2024 | Shani Bonan | 02 | 1. Adding the method's number of QSI 2. Adding Residual solvent - To be performed every 20 th Batch | 1. CC-0000022 2. CC-0000016 |
| 11/02/2025 | Shani Bonan | 03 | Remove Ochratoxin test | CC-0000033 |
| 17/06/2025 | Shani Bonan | 04 | 1. Updated Format of COA | 1. CAPA-0000028 |
| 07/01/2026 | Shani Bonan | 05 | Add a box for Malta batch number | CC-0000084 |

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 | 07-Jan-2026 15:45 |
| Send for Approval | Chris Desira | Head of Quality Assurance | 07-Jan-2026 16:09 |
| Review | Chris Desira | Head of Quality Assurance | 07-Jan-2026 16:09 |
| Approve | Chris Desira | Head of Quality Assurance | 07-Jan-2026 16:09 |
| Approve | Irene Zanetti | Qualified Person | 08-Jan-2026 09:02 |
| Approve | Shani Bonan | QC Manager | 14-Jan-2026 10:31 |
| QA Approval | Ivan Vidmar | Senior QA Specialist | 14-Jan-2026 10:47 |

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

Reference Specification Legacy number: F-SPC-009-MT

| | | |
|--|------------------------------------|--------------------------------|
| Panaxia Malta Batch No: FN25008-00 | PRT Number: WP-000014-MT | Expiry Date: 11/2027 |
|--|------------------------------------|--------------------------------|

1. Specifications:

| Test | Test Method | Specifications | Result |
|--|--|--|-----------------|
| Identification¹ | | | |
| 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 |
| Physico-chemicals¹ | | | |
| Relative density | SOP-183-MT / VA1044 Ph. Eur. 2.2.5 [◇] | Indicative | 0.91 |
| Water content | SOP-175-MT/ VA25322 Karl Fisher Ph. Eur. 2.5.12 [◇] | ≤0.5% | <0.2% |
| Heavy metals^{1,2} | | | |
| Cadmium | SOP 77405 ICP-MS Ph. Eur. 2.4.27 [◇] | ≤ 1.0 ppm | 0.05 ppm |
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| Aflatoxin B1 | SOP QC-131-MT/ VA45110 Ph. Eur. 2.8.18 [◇] | ≤ 2 µg/Kg | < LOQ |
| Total Aflatoxins (B1, B2, G1, G2) | | ≤ 4 µg/Kg | < LOQ |
| Microbiological Quality¹ | | | |
| TAMC | MW024-01/VA52090 | ≤ 10 ⁴ CFU/mL | < 100 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 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 solvent³ | | | |
| Ethanol | QC-140-MT/VA12301 GC-HS-FID | ≤ 5000 ppm | NA |
| Assay | | | |
| CBN | QC-181-MT DAB [£] | ≤ 2.5% m/m | 0.0% |
| CBD | | 2.47% - 2.73% m/m (95-105 % from label claim) | 2.58% |
| Δ9-THC | | ≤ 0.16% m/m (≤ 6% from CBD label claim) | 0.11% |
| Vitamin E ¹ | QC-149-MT / VA14060 | ≥ 0.4% m/m | 0.5% |



| Pesticide Residue ^{1,2} | | | |
|---|---|--|----------|
| Pesticides | SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS <i>Ph. Eur. 2.8.13</i> [◇] | <i>Complies with the limits indicated in Ph. Eur. 2.8.13</i> | Complies |

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

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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 THC and CBN that are less than 0.05% from the label amount of CBD are reported URL (0.001%)

[◇] Current version of monograph

[£] DAB Cannabis extractum normatum monograph

1. Performed by approved outsource laboratory.

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

| | |
|----------------------------------|---|
| Consecutive batch number: | Pesticides and Heavy metals testing required on Finished product: |
| 4 | <input type="checkbox"/> Yes; <input checked="" type="checkbox"/> No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: <u>25/087-MT</u> |

2. Packaging:

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

2.1. **Child Resistant Caps (WP-000045-MT):** a screw cap tamper evident and child safety lock (PK-000013-MT).

2.2. **Non-Child Resistant Caps (WP-000014-MT):** a screw cap tamper evident (PK-000008-MT).

3. **Shelf life:** 24 months

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

PASS **FAIL**

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




| REVISION HISTORY | | | | |
|-------------------------|-------------------|------------|--|--------------------------------|
| Date | Name of corrector | Version no | Details of correction (including Chapter No) | Reason of correction |
| 12/03/2024 | Shani Bonan | 01 | New Document | CCF-MT-2024-23 |
| 28/10/2024 | Shani Bonan | 02 | 1. Adding the method's number of QSI 2. Adding Residual solvent - To be performed every 20 th Batch. | 1. CC-0000022 2. CC-0000016 |
| 11/02/2025 | Shani Bonan | 03 | Remove Ochratoxin test | CC-0000033 |

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


Signatory Table

| Action Name | User Name | Title | Signature Date |
|------------------------------|---------------|---------------------------|-------------------|
| Send for Review (Written By) | Shani Bonan | QC Manager | 13-Feb-2025 08:18 |
| Review | Chris Desira | Head of Quality Assurance | 18-Feb-2025 14:02 |
| Send for Approval | Chris Desira | Head of Quality Assurance | 18-Feb-2025 14:11 |
| Approve | Chris Desira | Head of Quality Assurance | 18-Feb-2025 14:12 |
| Approve | Shani Bonan | QC Manager | 18-Feb-2025 14:57 |
| Approve | Irene Zanetti | Qualified Person | 21-Feb-2025 08:40 |
| QA Approval | Irene Zanetti | Qualified Person | 21-Feb-2025 08:41 |

* 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 Pharmaceuticals Art.-Bez.: / article name: DOSIERVERSCHLUSS / dosage closure DOSIERVERSCHLUSSRSV 5,0 OVII / SPRITZEN-EINSATZNW18 W/TR | | Stückzahl: 30000 Pieces supplied: | | 50 (315) quant. (qual) | |
| Auftr.-Nr. 21124205 Order No.: | | Ihre Auftr.-Nr.: PO21001728 Your order no.: | | LS-Nr.: 22244775 Packing slip no.: | |
| Ident.-Nr. 6615MA Article no.: | | Ihre Ident.-Nr.: CM-2074 Your article 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 | |
| Zeich.-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: | | Einfärbung: colouring agents: | | | |
| 1. Einzelteil: RANDTROPFER-SCHRAUBKAPERSK 5,0 OVII NW18 W 1. component part: Purell ACP6541A (PEHD) | | HT-MAB PE 9071 weiss /white 2-2,5% | | | |
| 2. Einzelteil: DOSIERHILFESPRITZEN-EINSATZ NW18 TR 2. component part: Purell 1840H (PELD) | | | | | |
| 3. Einzelteil: #NV 3. component part: #NV | | #NV | | | |
| 4. Einzelteil: #NV 4. component part: #NV | | #NV | | | |
| 5. Einzelteil: 0 5. component part: | | | | | |
| 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 Entscheidung Defects 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 1 1 Kennzeichnung der Palette / 1 1 1 1 1 1 Gebinde muss der Vorschrift entsprechen / Labeling of the Pallet / Container must comply with the specification | 0,00 | 0 | + | |
| 5/6/7 | 1 1 1 1 Einzelverpackung (Sterilverpackung) beschädigt, verschmutzt, unvollständig / Individual packs (Sterile Packing), damaged, soiled, incomplete | 0,00 | 0 | + | |
| 8/9 | 2 2 2 2 Lieferantenstichprobe / Begleitpapiere, Qualitätsdokumente, Prüfzertifikat falsch / fehlen / Suppliers random sample / Accompanying documents, quality documents, test certificate incorrect / missing | 0,00 | 0 | + | |
| Untermischung / Intermixing | | | | | |
| 1 | 1 1 1 1 1 1 Untermischung / Intermixing | 0,00 | 0 | + | |
| Ausgangsmaterial / Starting material | | | | | |
| 1/2 | 1 1 1 1 Das Material (EP Edition 9.4 - 3.1.3; 3.1.4) (EP Edition 9.5 - 3.1.5; 3.1.6) / Die Einfärbung muss der Vorschrift entsprechen / The material / The colour must comply with the specification | 0,00 | 0 | + | |
| 1/2/3/4/5 | 2 2 Grundglas, Wasserbeständigkeit der Innenoberfläche/gemäß Glasgießmethode. Lichtdurchlässigkeit, Farbe entspricht nicht der Vorschrift / Base glass, Water resistant of internal surface /acc.glass grain method, Light transmission of base glass. Color of base glass does not meet specification | 0,00 | 0 | + | |
| 10 | 2 2 Zusammenhaftende bzw. klebrige Gummiteile / rubber parts adhering to one another or sticking | 0,40 | 0 (3) | + | |
| Sauberkeit / Cleanliness | | | | | |
| 1/5/6/7 | 1 1 1 1 Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, 1 1 1 1 Grenzwerte für Partikel überschritten / Agreed limits for particles exceeded | 0,00 | 0 | + | |
| 1/3/8 | 1 1 1 1 Fremdeinschlüsse-Aussehen stark beeinträchtigt, > 1mmØ oder Anhäufung 2 mehrere fest anhaftende Fremdkörper, Flecken ≥ 0,2mm ² / lose Partikel / Foreign bodies enclosed appearance markedly impaired, > 1mm Ø / Brandstellen flächenförmig / Burn-marks >2mm diameter | 0,10 | 0 (1) | + | |
| 2/4 | 1 1 Im Material eingeschlossene Fremdkörper / Brandstellen punktförmig 0,5- 2mm Ø / Foreign bodies incorporated in the material / Scorch dots 0,5- 2mm Ø | 0,40 | 0 (3) | + | |
| 1 | 2 2 Nicht entfernbare Verunreinigungen innen ≥ 0,3mm ² / Non-removable contamination inside ≥ 0,3mm ² | 0,40 | 0 (3) | + | |
| 2/4 | 1 1 Entfernbbare Verunreinigungen innen ≥ 0,3mm ² außen ≥ 0,5mm ² / Removable contamination inside ≥ 0,3mm ² , outside ≥ 0,5mm ² | 1,00 | 0 | + | |
| 3/4/7/9/10 | 2 2 Brandstellen / Scorched spots 1 1 1 1 Fremdeinschlüsse-Aussehen wenig beeinträchtigt < 1mm Ø / Foreign bodies enclosed- appearance less impaired, < 1mm Ø, Lose Materialreste / Loose material residues | 2,50 | 3 (12) | + | |

| Verarbeitungsfehler / Processing Errors | | | | |
|--|---|--------------|--------|---|
| 2/7/15/ 17 | ⓈNicht ausgeformte Gummiteile, Risse, Riefen, Kerben, Löcher, Dichtigkeit (Funktion) beeinträchtigt / Incompletely formed rubber parts, tears, grooves, notches, holes, seal and or function impaired / Formgrad, Stanzfehler anhaftende Fallreste / Flash, punching errors ⓈRisse, Spalten, Löcher. Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, clefs, holes, parts incompletely injected, seam breaks open ⓈDurchgehende Risse / Wall penetrating cracks ⓈKanal verstopft keine Dosierung möglich / Duct blocked dosage impossible, im Bereich des Abtropfrandes und der dichtenden Flächen geraut- Dichtigkeit nicht gegeben / Roughness in the area of the dropping rim and of the sealing areas-seal not possible | 0,00 | 0 | + |
| 1/3/4/9/ 13 | ⓈStarke Formnähte u./o Rückstände an den Anspritzpunkten / Marked mould joints and or residues at the injection points Stark verzogene Teile / Markedly warped items ⓈDeformierung / Deformation ⓈAnspritzpunkt entspricht nicht (seitlich max 0,5mm, zentral max. 0,7mm) / Injection point does not comply (lateral max. 0,5mm, central max. 0,7mm) Überspritzungen, ⓈFormgrate an Dichtstellen (Over-injection, flash at the sealing points | 0,10 | 0 (1) | + |
| 8/9/12/ 15/19/ 08.1 | ⓈAnrisse / Incipient cracks Absplittierungen im Dichtungsbereich / Chipping in area of seal Blasen, Einschlüsse > 1,0mm / Gas bubbles, inclusions > 1mm, Kühlschönung außer Toleranz / Cooling stress out of tolerance Abgeplatzte Stelle(n), Deformierung/en oder Glasspitze(n) am vorderen Teil (Kugel) / Clipped place(s), deformity(ies) or glass spike(s) on tip (ball) ⓈOberfläche, Kontur uneben / Surface, Shape uneven | 0,40 | 0 (3) | + |
| 6/8/12/ 13 | Ⓢverformte Behältnisse / Deformed containers Kratzer (Breite ≥ 0,2mm, Länge ≥ 20mm) / Scratches (width ≥ 0,2mm and length ≥ 20mm) ⓈFallen, Kerben, Kratzer, Formgrad / Folds, notches, scratches, flash | 2,50 | 3 (12) | + |
| Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing | | | | |
| 1 | ⓈKanal Ø a.T. / Duct diameter out of tolerance, Dosierung/Tropfgeschwindigkeit muss der Vorschrift (Prüfvorschrift nach Vereinbarung) entsprechen / Dosage/dropping speed must comply with the specification (testing procedure according to agreement, Verbindungsstege abgerissen- anzahlmäßig mehr als die Hälfte der Stege / Connecting strip torn off- numerically more than half of the studs, ⓈDichtigkeit / test for | 0,00 | 0 | + |
| 1/2/3/6 | ⓈScheibel Ø, Tropffloch Ø, Biegung außerhalb der Toleranz / Diameter of annular flange, dropper hole, bend out of the tolerance Ⓢsonstige Maße, Winkel, Radien außer Toleranz / Other dimensions, angles, radii out of tolerance ⓈAbmessungen a.T. / Dimensions out of tolerance Ⓢweitere Maße außer Toleranz / Other dimensions out of tolerance, Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing | 0,10 | 0 (1) | + |
| 1/3 | ⓈGravur fehlt, falsch u./o. unvollständig. / Engraved text missing, incorrect and/or incomplete. Druck, Prägung fehlt, falsch u/o unvollständig / Overprinting, embossed text missing, incorrect and/or incomplete Gewinde fehlt oder ist nur mangelhaft ausgebildet / Thread missing or only inadequately formed ⓈDruckfarbe falsch / Printing color incorrect, Druckbild fehlt, falsch / Printing image missing or incorrect | 0,00 | 0 | + |
| 1/6/7 | ⓈGravur für Dosierung unvollständig - Dosierung nicht möglich / Engraved marks for dosage incomplete - Dosage not possible. Abmessungen entsprechen nicht / Dimensions do not comply, Text fehlt, falsch oder nicht lesbar / text absent, incorrect or illegible, Dosierung a.T. / Dosage out of tolerance, ⓈFarbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion | 0,10 | 0 (1) | + |
| 4 | ⓈDruckfarbe haftet nicht / Printing does not adhere | 0,40 | 0 (3) | + |
| Montage / Mounting | | | | |
| 13/15 | ⓈKindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, Außenteil gerissen / External part torn | 0,00 | 0 | + |
| 1/2/4/5/ 9/17/19 | ⓈEinzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts damaged by mounting, Teile falsch montiert / Parts incorrect mounted, ⓈPipette zu tief in Sauger eingesetzt / Pipette set too deep into the seat, Tropfeinsatz durch Montage beschädigt / Dropper insert damaged by mounting | 0,10 | 0 (1) | + |
| * falls zutreffend die dazugehörige Fehlerbewertungsliste * if applicable the relevant Defect Evaluation List (1) Skip-Lot verfahren: skip-batch Process | | | | |
| ⓈKunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps ⓈBehältnisse aus Röhrglas / Containers Made of Tubular Glass ⓈGummiteile / Rubber Parts ⓈSpritzgussteile aus Kunststoff: Verschlüsse; Dichteinlagen und Dosierhilfen (Tropfer etc.) / Injection-moulded Parts Made of Plastic: Closures ⓈApplikatoren und Messeinrichtungen aus Kunststoff / Applicators and Measuring Devices Made of Plastic | | | | |
| Hiermit bestätigen wir, dass die Qualität des oben bezeichneten Produktes nach den gültigen Prüfnormen ("Sterilität entsprechend ISO 11135 bzw. 11137 in der jeweiligen aktuellen Ausgabe) gemäß Spezifikation (Ausführungsvorschrift, technischer Zeichnung) sowie der jeweils gültigen Fehlerbewertungsliste hergestellt, verpackt, *sterilisiert und geprüft wurden und die dabei zulässigen Grenzwerte nicht überschritten wurden. Soweit für das obige Produkt abweichende Vereinbarungen zwischen Hersteller bzw. Lieferant und Verwender (Kunden) bestehen, werden diese zugrunde gelegt. We hereby confirm that the quality of the products described above has been produced, packed, *sterilized, inspected and tested in accordance with the valid inspection and testing standards ("Sterility conforming ISO 11135 or 11137 in its current version) according to the specification (documented procedure, technical drawing) and the Defect Evaluation List and did not exceed the permissible limits. Where alternative agreement for the above product exist between the customer and the manufacturer and/or supplier, the relevant values have been based on these. | | | | |
| *falls zutreffend / if applicable Vereinbarte Artikelspezifikationen beinhalten die Unbedenklichkeit der Materialien nach Verordnung (EU) Nr. 10/2011, 1935/2004, RL94/62/EG, 1907/2006, 1223/2009, deren Herstellung nach 2023/2006 und deren aktuellen Ergänzungen. Gleichzeitig wird die Konformität nach ISO 13485 (aktuelle Ausgabe) und RL 93/42/EWG (Verordnung 2017/745) bestätigt Agreed article Specifications includes the compliance of the materials with EU-regulations 10/2011/EC, 1935/2004/EC, guidelines 94/62/EC, 1907/2006/EC, 1223/2009/EC, whose manufacturing based on 2023/2006/EC and the current amendments. At the same time, conformity with ISO 13485 (current edition) and RL 93/42 / EEC (Regulation 2017/745) is confirmed. | | | | |
| Für Folgeschäden beim Kunden (unerwartete Unterbrechung an Abfüllanlage, Prüfaufwand, Rückruf usw.), wird keine Haftung übernommen solange die Vorgaben gemäß Fehlerbewertungsliste eingehalten sind. For secondary failures by the customer (secondary failures bottling plant, additional tests, product recall etc.) to assume no liability as long as the standard in accord with Defect Evaluation List are adhered to. | | | | |
| Vorstehende Angaben entbinden nicht von der Durchführung einer Wareneingangskontrolle The above particulars do not release the customer from the of obligation to carry out an inspection of goods received. | | | | |
| Datum: 21.02.2022 | Freigabe: ja / yes | Prüfer: I.A. | | |
| Date: | release: | | | |

Approved by: 
 Date: 20.03.2022



SGD S.A.
Simplified joint stock company with capital of 44 061 866 Euros -
Nanterre Trade and Companies Register N°E552 012 585 - VAT ID :
FR 29 552 012 585
Head Office and Sales Departments : Tour Liberty - 17 place des
Reffets - 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 Reffets - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 09.11.2023

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery address

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

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

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

THE SPECIFICATIONS IN FORCE

TO THE CURRENT ISO 15378 VERSION

THE HYDROLYTIC RESISTANCE

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

ARSENIC

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

SPECTRAL TRANSMISSION

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



SGD S.A.
Simplified joint stock company with capital of 44 051 866 Euro -
Nanterre Trade and Companies Register N°B552 012 565 - VAT ID :
FR 29 552 012 565
Head Office and Sales Departments : Tour Liberty - 17 place des
Reffets - 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 Reffets - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 09.11.2023

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery address

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

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

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.
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90 36 00 - Fax:+33(0)1 40 90 36 01
Postal address : Tour Liberty - 17 place des Reffets - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 09.11.2023

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

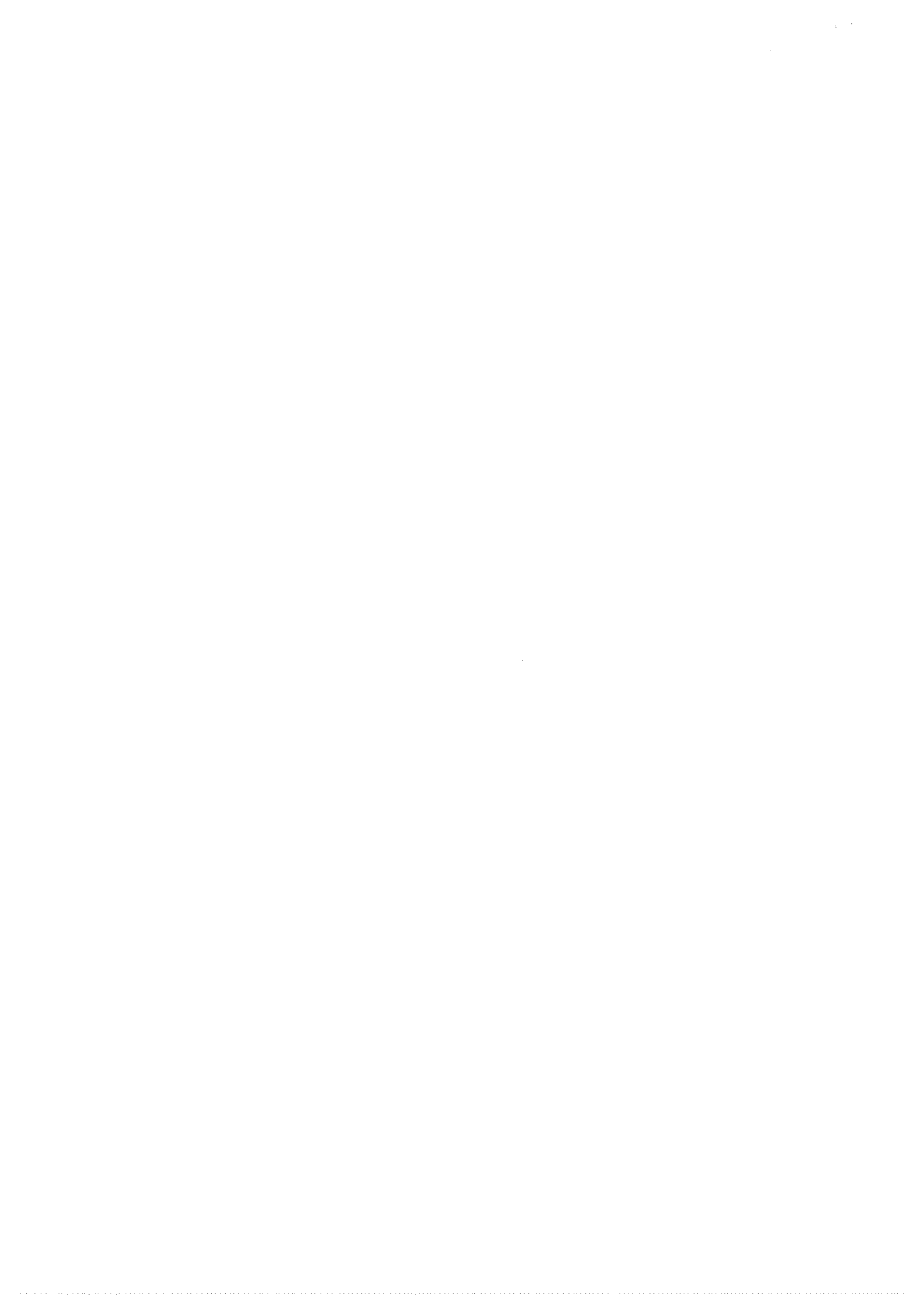
| | | | |
|-------------------------|-----------------|--------------------|--------------------------|
| Customer's order | PO23000277 | from | 04.09.2023 |
| Customer's product code | PRT-GI000201-MT | | |
| Delivery | 81535153 | Quantity Delivered | 34.320 PCE |
| SGD Product Code | 52490 04 001 | 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





24/08-MT

SGD S.A.
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FR 29 552 012 585
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Reffets - 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 Reffets - CS 30300 -
92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 30.09.2024

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery address

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

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

Glass quality

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

Glass measurements

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



SGD S.A.
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 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 30.09.2024

Customer PANAXIA PHARMACEUTICAL MALTA / 39810
 BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001
 BBG3000 ESTATE BIRZEBBUGA MT

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

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

THE SPECIFICATIONS IN FORCE

TO THE CURRENT ISO 15378 VERSION

THE HYDROLYTIC RESISTANCE

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

ARSENIC

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

SPECTRAL TRANSMISSION

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



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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 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 30.09.2024

Customer

PANAXIA PHARMACEUTICAL MALTA / 39810

BBG3000 ESTATE BIRZEBBUGA MT

Delivery address

PANAXIA PHARMACEUTICAL MALTA / 39810001

BBG3000 ESTATE BIRZEBBUGA MT

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

Glass characteristics

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

Quality Manager

Aline BAILLET



Hubert De Backer nv

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

F.a.o. : QUALITY DEPARTMENT

Temse, 22/11/2024

CERTIFICATE OF CONFORMITY

This delivery contains the following articles :

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

Approved by : Jimmy De Bergé
Dispatch department

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

Released by : Gianina Sarman
QA department

This document is created electronically and is valid without signature.

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

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

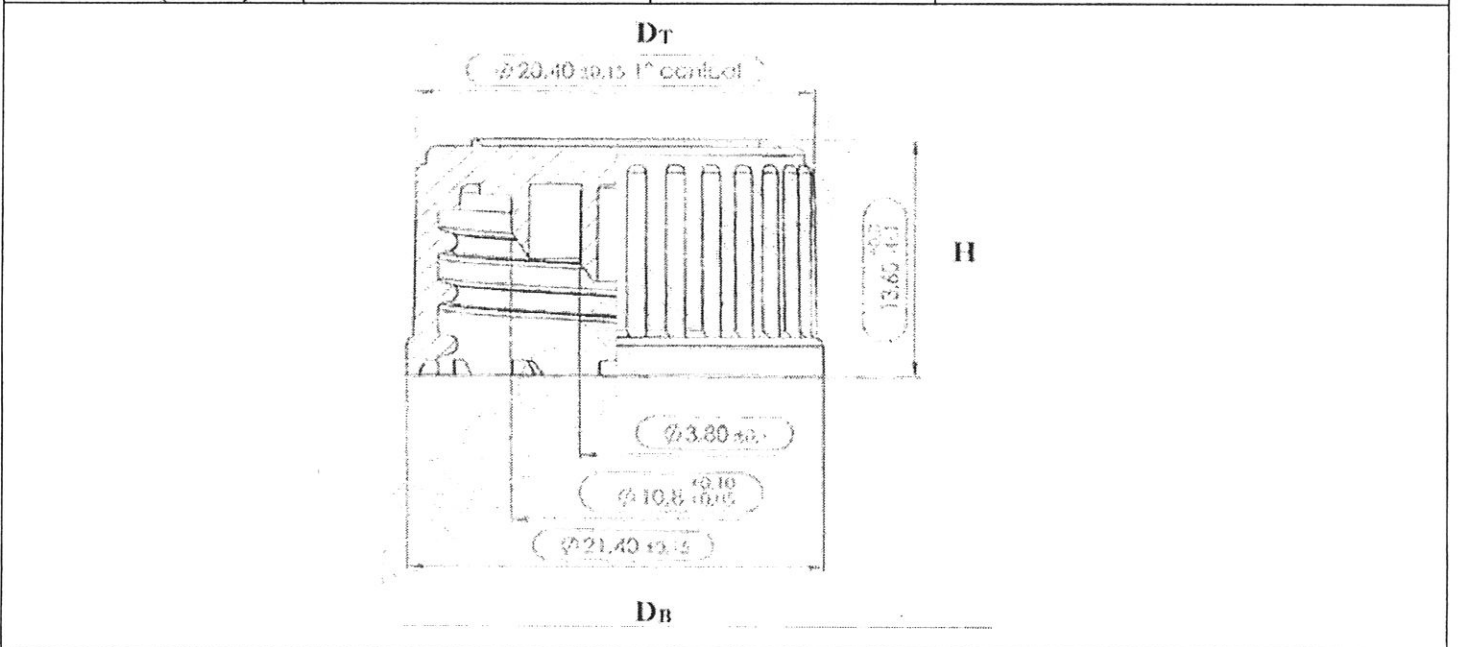
| Article number | Manufacturer | Item |
|----------------|-----------------------------------|---|
| 004 | Sensoplast Packmitteltechnik GmbH | Screw caps with bore seal for spatula and brush DIN 168 GL-18 |

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

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

1. Specifications:

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



MASTER

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

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

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

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

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

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

PASS **FAIL**

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

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

REVISION HISTORY

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

BHARAT RUBBER WORKS

Healthcare Packaging Solutions

CERTIFICATE OF ANALYSIS

Product: 1ml Dosing Syringe

Product Code: SYPN01-WH - CE

Batch/Lot No.: BRV250075

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

MFG Date: 27/01/2025

Date: 31/01/2025

Batch/Lot size: 50,000 NOS

Challan No.: EXP/52/2024-25

Exp Date: 3 Years from MFG.

Party's Name: ORIGIN PACKAGING LTD

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

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

Analyzed by:




Party
31/01/2025

Approved by:

[Signature]
31/01/2025

Format No. FQC/021-06/00

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