PANAXIA
Pharmaceutical Industries

Certificate of Conformance

Authorisation of Batch Release for sale in the EU

Product name, dose, dosage form and pack size:	Naxiva Panaxol THC 25mg/ml CBD 25mg/ml
Client:	Neuraxpharm Arzneimittel GmbH
Market:	Germany
Batch number:	FP25004-02DE
Quantity	1350 KITS
Manufacturing Date:	03/09/2025
Expiry date:	09/2027
Active Ingredient Concentration:	THC 2.6% (w/w) (25mg/ml) CBD 2.6% (w/w) (25mg/ml)
Plant strain/s:	Master Kosh, Tchlet, Charlotte Angel, Zohar

Deviations noted during manufacture:

☐ No Critical/Major deviations

☑ Critical/Major deviations were reported and properly investigated and closed

The following document are attached-

- *Finished Product CoA*
- *Herbal substance CoA*
    - *Herbal substance batch Number: 24/205-MT, 24/080-MT, 24/168-MT Herbal substance Strain: Master Kosh*
    - *Herbal substance batch Number: 25/108-MT Herbal substance Strain: Tchlet*
    - *Herbal substance batch Number: 25/109-MT Herbal substance Strain: Zohar*
    - *Herbal substance batch Number: 25/087-MT Herbal substance Strain: Charlotte Angel*
- *Package COA*
    - *10ml amber glass bottles - batch number: 23/337-MT*
    - *10ml amber glass bottles cap- batch number: 23/142-MT*
    - *1ml sterile graduated syringes for patient dosing: batch number: 25/031-MT*

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- *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 have been carried out in full compliance with EU GMP and the technical agreement current version. 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 Zerafa 08 05 2025
Signature & Date Name

Product Name: NAXIVA-PANAXOL THC 25mg/mL CBD 25mg/mL
Reference Specification Legacy Number: F-COA-008-DE

Batch Details			
Batch number -Bulk oil	FN 25004-02	**Manufacturing date**	09/2025
Batch number - Finish product	FP25004-02DE (25004-02)	**Expiry date**	09/2027

Test	Test Method	Specifications	Result
Identification			
TLC identification	SOP QC-179-MT/ VA1112 *DAB* £	Zonal pattern of test solution conforms to the zonal pattern of the reference solution	Complies
Organoleptic properties			
Appearance	SOP QC-136-MT Visual inspection *DAB* £	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	Complies
Heavy metals[1,2]			
Cadmium	SOP 77405 ICP-MS *Ph. Eur. 2.4.27* ◊	≤ 1.0 ppm	< 0.05 ppm
Lead		≤ 5.0 ppm	< 0.1 ppm
Mercury		≤ 0.1 ppm	< 0.05 ppm
Physico-chemicals			
Relative density	SOP-183-MT / VA1044 *Ph. Eur. 2.2.5* ◊	Indicative	0.95
Water content	SOP-175-MT/ VA25322 Karl Fisher *Ph. Eur. 2.5.12* ◊	≤0.5%	< 0.2%
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT/ VA45110 *Ph. Eur. 2.8.18* ◊	≤ 2 µg/Kg	<LOQ
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	< LOQ
Microbiological Quality[1]			
TAMC	MW024-01/ *VA52090,* *Complies to Ph. Eur. 2.6.12* ◊	≤ 10^4 CFU/mL	< 100 CFU/ml
TYMC		≤ 10^2 CFU/mL	< 10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01/ *VA52090,* *Complies to Ph. Eur 2.6.31* ◊	< 10^2 CFU/mL	< 10 CFU/ml
E.Coli		Absent in 1mL	Absent in 1 ml
Salmonella		Absent in 25 mL	Absent in 25 ml
Residual solvent[3]			
Ethanol	QC-140-MT/ VA12301 GC-HS-FID	≤ 5000 ppm	< 5000 ppm
Assay - Cannabinoids concentration (%w/w)			
CBN	QC-181-MT *DAB* £	≤ 2.5% m/m	0.1%
CBD		2.47% - 2.73% m/m (95-105 % from label claim)	2.59%
Δ9-THC		2.47% - 2.73% m/m (95-105 % from label claim)	2.60%

Product Name: NAXIVA-PANAXOL THC 25mg/mL CBD 25mg/mL
Reference Specification Legacy Number: F-COA-008-DE

Batch Details			
Batch number -Bulk oil	FN 25004-02	**Manufacturing date**	09/2025
Batch number - Finish product	FP25004-02 DE (25004-02)	**Expiry date**	09/2027

Test	Test Method	Specifications	Result
Identification			
TLC identification	SOP QC-179-MT/ VA1112 *DAB* £	Zonal pattern of test solution conforms to the zonal pattern of the reference solution	Complies
Organoleptic properties			
Appearance	SOP QC-136-MT Visual inspection *DAB* £	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	Complies
Heavy metals[1,2]			
Cadmium	SOP 77405 ICP-MS *Ph. Eur. 2.4.27* ◊	≤ 1.0 ppm	< 0.05 ppm
Lead		≤ 5.0 ppm	< 0.1 ppm
Mercury		≤ 0.1 ppm	< 0.05 ppm
Physico-chemicals			
Relative density	SOP-183-MT / VA1044 *Ph. Eur. 2.2.5* ◊	Indicative	0.95
Water content	SOP-175-MT/ VA25322 Karl Fisher *Ph. Eur. 2.5.12* ◊	≤0.5%	< 0.2%
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT/ VA45110 *Ph. Eur. 2.8.18* ◊	≤ 2 µg/Kg	<LOQ
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	< LOQ
Microbiological Quality [1]			
TAMC	MW024-01/ *VA52090, Complies to Ph. Eur. 2.6.12* ◊	≤ 10^4 CFU/mL	< 100 CFU/ml
TYMC		≤ 10^2 CFU/mL	< 10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01/ *VA52090, Complies to Ph. Eur 2.6.31* ◊	< 10^2 CFU/mL	< 10 CFU/ml
E.Coli		Absent in 1mL	Absent in 1 ml
Salmonella		Absent in 25 mL	Absent in 25 ml
Residual solvent[3]			
Ethanol	QC-140-MT/ VA12301 GC-HS-FID	≤ 5000 ppm	< 5000 ppm
Assay - Cannabinoids concentration (%w/w)			
CBN	QC-181-MT *DAB* £	≤ 2.5% m/m	0.1%
CBD		2.47% - 2.73% m/m (95-105 % from label claim)	2.59%
Δ9-THC		2.47% - 2.73% m/m (95-105 % from label claim)	2.60%

Product Name: NAXIVA-PANAXOL THC 25mg/mL CBD 25mg/mL
Reference Specification Legacy Number: F-COA-008-DE

Batch Details			
Batch number -Bulk oil	FN 25004-02	**Manufacturing date**	09/2025
Batch number - Finish product	FP25004-02 DE	**Expiry date**	09/2027

Vitamin E	QC-149-MT / VA14060	≥ 0.4% m/m	0.5%
Pesticide Residue [1,2]			
Pesticides	SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS *Ph. Eur.2.8.13* ◊	*Complies with the limits indicated in Ph. Eur.2.8.13*	Complies

Aflatoxins UQL- Under quantification limit; LOQ Aflatoxin B1, B2, G1: 0,5 µg/kg; LOQ Aflatoxin G2: 1,0 µg/kg.
Residual Solvents UDL – Under detection limit. The result of Ethanol that is less than 170ppm is reported UDL.
Residual Solvents UQL – Under quantification limit. The result of Ethanol that is less than 500ppm is reported UQL.
Assay URL – Under reporting level. The concentration of CBN that are less than 0.05% from the label amount of THC and CBD are reported URL (0.001% w/w)
◊ Current version of monograph
£ DAB *Cannabis extractum normatum* monograph
1. Performed by approved outsource laboratory
2. Pesticides and Heavy metals – To be performed every 20th Batch. When skip lot testing is performed both results are reported from the Inflorescence COA.
3. Residual Solvent – To be performed every 20th batch.

Consecutive batch no:	***Pesticides and Heavy metals testing required on Finished product:***
	☒ Yes; ☐ No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: _____

☒ PASS ☐ FAIL		
QC Reviewed by: Rosanna Demola	**Signature:** Rosanna Demola	**Date:** September 17, 2025
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.**		
Approved by: Shani Bonan	**Signature:**	**Date:** September 17, 2025

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
04.12.2024	Shani Bonan	02	1. Included Residual Solvent skip-lot testing 2. Adding the method's number of QSI	1. CC-0000016 2. CC-0000022
11/02/2025	Shani Bonan	03	1. Remove Ochratoxin test	1. CC-0000033
17/06/2025	Shani Bonan	04	1. Updated Format of COA	1. CAPA-0000028

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

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Daniele Grasso	QA Specialist	20-Jun-2025 19:19
Send for Approval	Shani Bonan	QC Manager	22-Jun-2025 13:54
Review	Shani Bonan	QC Manager	22-Jun-2025 13:54
Approve	Shani Bonan	QC Manager	22-Jun-2025 13:54
Approve	Irene Zanetti	Qualified Person	23-Jun-2025 09:04
QA Approval	Chris Desira	Head of Quality Assurance	25-Jun-2025 14:38
Approve	Chris Desira	Head of Quality Assurance	25-Jun-2025 14:38

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

Reference Specification Legacy number: F-SPC-008-MT

Panaxia Malta Batch No:	PRT Number:	Expiry Date:
FN25004-02	WP-000016-MT	09/2027

1. Specifications:

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
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%	< 0.21.
Heavy metals[1,2]			
Cadmium [1,2]	SOP 77405 ICP-MS *Ph. Eur. 2.4.27* ◊	≤ 1.0 ppm	< 0.05 ppm
Lead [1,2]		≤ 5.0 ppm	< 0.1 ppm
Mercury [1,2]		≤ 0.1 ppm	< 0.05 ppm
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT/ VA45110 *Ph. Eur. 2.8.18* ◊	≤ 2 µg/Kg	< LOQ
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	< LOQ
Microbiological Quality [1,3]			
TAMC	MW024-01/*VA52090* *Complies to Ph. Eur. 2.6.12* ◊	≤ 10^4 CFU/mL	< 100 CFU/ml
TYMC		≤ 10^2 CFU/mL	< 10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01/ *VA52090* *Complies to Ph. Eur 2.6.31* ◊	< 10^2 CFU/mL	< 10 CFU/ml
E.Coli		Absent in 1 mL	Absent in 1 ml
Salmonella		Absent in 25 mL	Absent in 25ml
Residual solvent [4]			
Ethanol	QC-140-MT/ VA12301 GC-HS-FID	≤ 5000 ppm	< 5000 ppm

Assay			
CBN [3]	QC-181-MT *DAB* [£]	≤ 2.5% m/m	0.1%
CBD		2.47% - 2.73% m/m (95-105 % from label claim)	2.59%
Δ9-THC		2.47% - 2.73% m/m (95-105 % from label claim)	2.60%
Vitamin E	QC-149-MT/ VA14060	≥ 0.4% m/m	0.5%
Pesticide Residue [1,2]			
Pesticides	SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS *Ph. Eur.2.8.13* [◊]	*Complies with the limits indicated in Ph. Eur.2.8.13*	complies

Aflatoxins UQL- Under quantification limit; LOQ Aflatoxin B1, B2, G1: 0,5 µg/kg; LOQ Aflatoxin G2: 1,0 µg/kg
Residual Solvents UDL – Under detection limit. The result of Ethanol that is less than 170ppm is reported UDL.
Residual Solvents UQL – Under quantification limit. The result of Ethanol that is less than 500ppm is reported UQL.
Assay URL – Under reporting level. The concentration of CBN that are less than 0.05% from the label amount of THC and CBD are reported URL (0.001% w/w)
[◊] Current version of monograph
[£] DAB *Cannabis extractum normatum* monograph
1. Performed by approved outsource laboratory
2. Pesticides and Heavy metals – To be performed every 20th Batch. When skip lot testing is performed both results are reported from the Inflorescence COA.
3. For the France batch the result needs to be also approved to the limit and tests in Appendix-1
4. Residual solvent - To be performed every 20th Batch.

Consecutive batch no:	***Pesticides and Heavy metals testing required on Finished product:***
18	☐ Yes; ☑ No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: FN25004-01 as per PAN-0618

2. Packaging:

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

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

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

3. Shelf life: 24 months

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

☑ **PASS** ☐ **FAIL**		
Analysed by: ROSANNA DEMOLA	**Signature:** RD	**Date:** 17/09/2025
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 approved by: Shani Bonan	**Signature:**	**Date:** 9/17/2025 | 6:35 AM PDT

Appendix-1-For France market

Test	Test Method	Specifications	Result
Identification			
HPLC PDA-UV Spectrum Identification	SOP QC-181-MT HPLC *DAB* £	UV spectra of THC and CBD peaks on the sample chromatograms conform to that on the standard chromatograms	
Packaging:			
Appearance of the external packaging	SOP QC-347-MT	Intact box and glass bottles, readable labels, no cracks, and visible defects	
Microbiological Quality [1]			
Salmonella	MW024-01/ *VA52090* *Complies to Ph. Eur. 2.6.12 / 2.6.13* ◊	Absent in 10 ml	
S. aureus		Absent in 1 ml	
Assay			
CBN	QC-181-MT *DAB* £	≤ 1.0% m/m	~~0.1+-~~ RD 17/09/2025

RD 17/09/2025

☐ **PASS** ☐ **FAIL**

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

REVISION HISTORY				
Date	**Name of corrector**	**Version no**	**Details of correction (including Chapter No)**	**Reason of correction**
12/03/2024	Shani Bonan	01	New Document	CCF-MT-2024-23
13/10/2024	Shani Bonan	02	1. Adding the method's number of QSI 2. Adding Residual solvent - To be performed every 20th Batch.	1. CC-0000022 2. CC-0000016
11/02/2025	Shani Bonan	03	1. Remove Ochratoxin test	2. 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	11-Feb-2025 18:50
Send for Approval	Chris Desira	Head of Quality Assurance	18-Feb-2025 14:13
Review	Chris Desira	Head of Quality Assurance	18-Feb-2025 14:13
Approve	Chris Desira	Head of Quality Assurance	18-Feb-2025 14:14
Approve	Shani Bonan	QC Manager	18-Feb-2025 14:55
QA Approval	Irene Zanetti	Qualified Person	18-Feb-2025 16:51
Approve	Irene Zanetti	Qualified Person	18-Feb-2025 16:51

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

23/337-MT

SGD S.A.
Simplified joint stock company with capital of 44 081 866 Euros - Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D : FR 29 552 012 585
Head Office and Sales Departements : 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

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.
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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
Minox thread diameter	mm	15,680	15,980	15,690	15,820	15,765	0,030
Opening diameter	mm	10,450	10,750	10,610	10,750	10,696	0,035
Total height	mm	57,400	58,600	57,880	58,250	58,094	0,081
Neck finish diameter	mm	17,700	18,000	17,700	17,800	17,740	0,025
Bead diameter	mm	19,800	20,200	19,900	20,040	19,985	0,026
Neck finish height	mm	13,500	13,900	13,520	13,710	13,610	0,042

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Postal address : Tour Liberty - 17 place des Reflets - CS 30300 - 92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 09.11.2023

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BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001
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Customer's product code	PRT-GI000201-MT		
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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

PZ-FBL Band/Vol. 18,19,20,22,34 aktuelle Ausgabe / current Ed.	Prüfzertifikat nach Fehlerbewertungsliste (Editio Cantor Verlag) Test Certificate acc. to Defect Evaluation List	Remy & Geiser GmbH Werk I / Plant I Remy & Geiser Str. 1 98553 Hinternah

Kunde: / customer: Panaxia Pharmaceuticals

Art.-Bez.: / article name: DOSIERVERSCHLUSS / dosage closure
DOSIERVERSCHLUSSRSV 5,0 OVII /SPRITZEN-EINSATZNW18 W/TR

Auftr.-Nr. / Order No.: 21124205
Ihre Auftr.-Nr.: / Your order no.: PO21001728
LS-Nr.: / Packing slip no.: 22244775
Stückzahl: / Pieces supplied: 30000

Ident.-Nr. / Article no.: 6615MA
Ihre Ident.-Nr.: / Your article no.: CM-2074
Chargen-Nr.: / Batch no.: 127870
Stichprobe: / sampling size: 50 (315) quant. (qual)

Herstelldatum: / date of manufacture: 02/2022
Verfallsdatum: / shelf life if sterile then: 02/2027 sterile02/2025
Ursprungsland: / Country of origin: Deutschland
Zchn-Nr.: / drawing no.: 03006608-01

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: / 1. component part:	RANDTROPFER-SCHRAUBKAPPERSK 5,0 OVII NW18 W Purell ACP6541A (PEHD)	HT-MAB PE 9071 weiss /white 2-2,5%
2. Einzelteil: / 2. component part:	DOSIERHILFESPRITZEN-EINSATZ NW18 TR Purell 1840H (PELD)	
3. Einzelteil: / 3. component part:	#NV #NV	#NV
4. Einzelteil: / 4. component part:	#NV #NV	#NV
5. Einzelteil: / 5. component part:	0	

Stichprobenumfang nach Fehlerbewertungsliste (Quantitative Prüfung) / Sampling inspection to defect Evaluation list (quantitative (tests)
Entscheidung: + entspricht / Decision: + accepted
Prüfvermerk: / insp. Remark: QK

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	❶❷❸❹Palette 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	❷❺Packschema falsch / Packaging scheme incorrect	0,00	0	+
1/3/4/5	❶❷❸❹Kennzeichnung der Palette / ❶❷❸❹❺ Gebinde muss der Vorschrift entsprechen / Labeling of the Pallet / Container must comply with the specification	0,00	0	+
5/6/7	❶❷❸❹Einzelverpackung (Sterilverpackung) beschädigt, verschmutzt, unvollständig / Individual packs (Sterile Packing), damaged, soiled, incomplete	0,00	0	+
8/9	❷❸Lieferantenstichprobe / Begleitpapiere, Qualitätsdokumente, Prüfzertifikat falsch / fehlen / Suppliers random sample / Accompanying documents, quality documents, test certificate incorrect / missing	0,00	0	+
	Untermischung / Intermixing			
1	❶❷❸❹❺Untermischung / Intermixing	0,00	0	+
	Ausgangsmaterial / Starting material			
1/2	❶❷❺Das 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	❷Grundglas, 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	❺zusammenhaftende bzw. klebrige Gummiteile / rubber parts adhering to one another or sticking	0,40	0 (3)	+
	Sauberkeit / Cleanlines			
1/5/6/7	❶❹Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, ❶❷❸❹ Grenzwerte für Partikel überschritten / Agreed limits for particles exceeded	0,00	0	+
1/3/8	❶❷❸Fremdeinschlüsse-Aussehen stark beeinträchtigt, > 1mmØ oder Anhäufung ❸mehrere 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	❶❹ 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	❷❹Nicht entfernbare Verunreinigungen innen ≥ 0,3mm² / Non-removable contamination inside ≥ 0,3mm²	0,40	0 (3)	+
2/4	❶❹entfernbare Verunreinigungen innen ≥ 0,3mm², außen ≥ 0,5mm2 / Removable contamination inside ≥ 0,3mm², outside ≥ 0,5mm²	1,00	0	+
3/4/7/9/10	❹ Brandstellen / Scorched spots ❶❷❸Fremdeinschlüsse-Aussehen wenig beeinträchtigt < 1mm Ø / Foreign bodies enclosed- appearance less impaired, < 1mm Ø, Lose Materialreste / Loose material residues	2,50	3 (12)	+

Ident.-Nr. Article no.:	6615MA	Ihre Ident.-Nr.: Your article no.:	CM-2074	Chargen-Nr.: Batch no.:	127870	Stichprobe: sampling size:	50 (315) quant. (qual)
Verarbeitungsfehler / Processing Errors							
2/7/15/17	❶Nicht ausgeformte Gummiteile,Risse, Riefen, Kerben, Löcher, Dichtigkeit (Funktion) beeinträchtigt / Incompletely formed rubber parts,tears, grooves, notches, holes, seal and or function impaired / Formgrat, Stanzfehler anhaftetende Fellreste / Flash, punching errors ❹❺Risse, Spalten, Löcher, Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, clefts, holes, partsincompletely injected, seam breaks open ❷Durchgehende Risse / Wall penetrating cracks ❸Kanal verstopft keine Dosierung möglich / Duct blocked dossage 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	❺Starke Formnähte u./o Rückstände an den Anspritzpunkten / Marked mould joints and or residues at the injection points Stark verzogene Teile / Markedly warpeditems ❸Deformierung / Deformation ❶❹ Anspritzpunkt entspricht nicht (seitlich max 0,5mm, zentarl max. 0,7mm) / Injection point does not comply (lateral max. 0,5mm, centeral max. 0,7mm) Überspritzungen, ❸Formgrate an Dichtstellen (Over-injection, flash at the sealing points	0,10	0 (1)	+
8/9/12/15/19/08.1	❷Anrisse / Incipient cracks Absplitterungen im Dichtungsbereich / Chipping in area of seal Blasen, Einschlüsse>1,0mm / Gas bubbles, inclusions > 1mm, Kühlspannung außer Toleranz / Cooling stress out of tolerance Abgeplatzte Stelle(n), Deformierung/en oder Glasspitze(n) am vorderen Teil (Kugel) / Clipped place(s), deformity(ies) or glass spike(s) on tip (ball) ❶ Oberfläche, Kontur uneben / Surface, Shape uneven	0,40	0 (3)	+
6/8/12/13	❷verformte Behältnisse / Deformed containers Kratzer (Breite ≥0,2mm, Länge ≥ 20mm) / Scratches (width ≥ 0,2mmand length ≥ 20mm ❹❺Falten, Kerben, Kratzer, Formgrat / Folds, notches, scratches, flash	2,50	3 (12)	+
Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing							
1	❸Kanal 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 or agreement, Verbindungsstege abgerissen- anzahlmäßig mehr als die Hälfte der Stege / Connecting strip torn off-numerically more than half of the studs, ❹❺❻ Dichtigkeit / test for	0,00	0	+
1/2/3/6	❷Scheibel Ø, Tropfloch Ø, Biegung außerhalb der Toleranz / Diameter of annular flange, dropper hole, bend out of the tolerance ❶ sonstige Maße, Winkel, Radien außer Toleranz / Other dimensions, angles, radii out of tolerance ❸ Abmessungen a.T. / Dimensions out of tolerance ❹weitere Maße außer Toleranz / Other dimensions out of tolerance, Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing	0,10	0 (1)	+
1/3	❶❹ 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 ❷Druckfarbe falsch / Printing color incorrect, Druckbild fehlt, falsch / Prinzting image missing or incorrect	0,00	0	+
1/6/7	❺Gravur 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, ❶❹ Farbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion	0,10	0 (1)	+
4	❷Druckfarbe haftet nicht / Printing does not adhere	0,40	0 (3)	+
Montage / Mounting							
13/15	❶Kindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, Außenteil gerissen / External part torn	0,00	0	+
1/2/4/5/9/17/19	❶❸❻ Einzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts damaged by mounting, Teile falsch montiert / Parts incorrect mounted, ❸Pipette zu tief in Sauger eingesetzt / Pipette set too deep into the teat, Tropfeinsdatz 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

❶Kunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps ❷Behältnisse aus Röhrenglas / Containers Made of Tubular Glass ❸ Gummiteile / Rubber Parts ❹Spritzgussteile aus Kunststoff: Verschlüsse; Dichteinlagen und Dosierhilfen (Tropfer etc.) / Injection-moulded Parts Made of Plastic: Closures ❺Applikatoren 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 testet in accordance with the valid inspection and testing standards (*Sterility conforming ISO 11135 or 11137 in its current version)according to the specification (documentet procedure, technical drawing) and the Defect Evaluation List an did not exceed the permissible limits. Where alternative aggreement for the above product exist between the costumer 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 nach2023/2006 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 costumer (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 Date:

Freigabe: ja / yes release:

Prüfer: i.A.

ADDITIONAL BY QA

Signature

Date 10.03.2022

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: 31/01/2025

Approved by: 31/01/2025

Format No. FQC/021-06/00

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

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

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

FRM-KD-118.02

This document is created electronically and is valid without signature.

24/098-MT

SGD S.A.
Simplified joint stock company with capital of 44 081 866 Euros - Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D : FR 29 552 012 585
Head Office and Sales Departements : 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 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/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	17,880	17,810	0,036
Bead diameter	mm	19,800	20,200	19,840	20,050	19,989	0,044
Neck finish height	mm	13,500	13,900	13,500	13,620	13,570	0,025

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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

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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
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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

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