

Certificate of Analysis



Article no.	Retrace Code/Batch/Lot no.	Date of Manufacture
891169109	26	2023-09-11 - 2023-09-27

Article description

DURAN PURE Quick Release Closure (PSU) GLS 80

DURAN PURE Product Certificate

The articles listed under "article number" are hereby confirmed to have been produced using a quality system conforming to ISO 9001 and comply with the DWK Life Sciences quality standards.

Drawing No: 0743109-GZA-GLS80-C

The related product specification: Product Specification DURAN PURE screw cap, GLS 80 (Doc ID 38040, 002/07.2023)

Number of units per bag: 5

Cap material: Thermoplast (HT-amorph) without additional dye

Parameter	Value
Density	1.35 - 1.45 g/cm ³
Tensile strength at yield:	approx. 80 - 85 MPa
Hardness:	130 MPa
Modulus of elasticity:	2400 MPa
Temperature resistance:	+180 °C

Sealing material

Parameter	Silicone mixture	PTFE film
Spec. weight:	1.16 ± 0.02 g/cm ³	2.19 g/cm ³
Tensile strength:	> 5 N/mm ²	≥ 25 N/mm ²
Hardness:	65 ± 5 Shore A	> 54 Shore D
Elongation:	> 300 %	≥ 280 %
Temperature resistance:	+200 °C	+200 °C

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Production and inspection - Cap

It is hereby confirmed that this product has been produced according to the recommendations aligned with the basic rules of DIN ISO 15378 and that the quality has been verified according to the relevant standard inspection plan in accordance with the specification and technical drawing. The acceptable limits have not been exceeded in the process.

Final Inspection Cap

Visual Inspection of samples (Sample Size: 125)	AQL 0.10	AQL 0.40	AQL 2.50
Total defects	0	0	0
Acceptance number	0	1	7

Tests (Extent of random samples: 50)	AQL 0.10	AQL 0.40	AQL 2.50
Test on the bottle	0	0	0
Scraping on the thread	0	0	0
Total defects	0	0	0
Acceptance number	0	0	5

Dimensional inspection of random samples	Nominal dimension	Upper tolerance	Lower tolerance	Min	Max	Mean
Overall height (mm)	40.00 +0.30/-0.30	40.30	39.70	40.18	40.25	40.22
Inner depth (mm)	37.00 +0.30/-0.30	37.30	36.70	37.04	37.08	37.06
Thread core diameter (mm)	77.70 +0.30/-0.30	78.00	77.40	77.85	77.92	77.89
Thread outer diameter (mm)	80.70 +0.30/-0.30	81.00	80.40	80.75	80.81	80.78
Lower outer diameter (mm)	88.50 +0.30/-0.30	88.80	88.20	88.55	88.63	88.59

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Final Inspection - PTFE coated silicone seal

Lot No.: 18696/23

Date of Manufacture Silicone Seal: 2023-06-08

Inspection quantity according to AQL	Inspection level	AQL	Quantity	OK	not OK
defects per 100 items	I	2.5	32	32	0

*AQL test instruction: reduced Lot (n=32) Accept.=3

Attributes

Description	Specification	Lower tolerance	Upper tolerance
Diameter	79.0 +/- 0.3 mm	78.91	79.09
Strength	3.0 +/- 0.4 mm	2.94	3.12

Statistics

Attribute	Ok	not OK	Mean	Min	Max	R	s	Cp	Cpk
Diameter	32	0	78.99	78.91	79.09	0.18	0.04	2.70	2.57
Strength	32	0	3.04	2.94	3.12	0.18	0.04	2.49	-

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Declaration of Conformity

Material in contact with ingredients is compliant with USP Class VI – 121 °C and FDA 21 CFR § 177.1550.

The silicone is compliant with FDA 21 CFR § 177.2600 and BfR (German Federal Institute for Risk Assessment) Recommendation XV.

The PTFE is compliant with FDA 21 CFR § 177.1550 and BfR Recommendation LI.

The material combination has additionally been tested according to the pharmaceutical standards DIN 58367 and Ph.Eur. Section 3.1.9.

DWK Inspection and Release site:

DWK Life Sciences GmbH
Hattenbergstrasse 10
D-55122 Mainz

Issued by:  _____ Issuance date: 2023-09-28
Mariska Jefferson
Quality Manager

Approved by:  _____ Approval date: 2023-09-28
Alexander Cross
Vice President Quality Europe