



DURAN PURE

Pharmaceutical primary packaging
with comprehensive qualification
support

DURAN PURE Bottle with DIN GL 45 thread and protective dust cover
Article number: 81 801 54 03



Detailed view of the protective dust cover



DURAN PURE Premium GL 45 Screw Cap
Article number: 89 108 86 79



DURAN PURE Premium GL 45 Screw Cap
pre-packed in STERICLIN® pouches
Article number: 89 299 28 06



DURAN PURE – A NEW PRODUCT RANGE FOR PHARMA PRODUCTION

DURAN® borosilicate glass 3.3 is a type I neutral glass with many desirable characteristics and is the proven solution for primary packaging used in the production and transport of pharmaceutical products. Originally developed over 120 years ago by Otto Schott, DURAN® glass has superior temperature and chemical properties compared to many other packaging materials. DURAN® borosilicate glass 3.3 is gas-tight, virtually inert, chemically stable, non-porous and has excellent resistance to aqueous solutions. Due to its boron-silica matrix, the glass is resistant to the temperature extremes seen in manufacturing processes, such as during heat sterilization or depyrogenation. These special properties of DURAN® glass and its long history have shown it to be a safe and stable primary packaging material.

The DURAN Group combines the technical know-how of more than 650 employees at three production facilities in Germany and Croatia, with over a century of experience manufacturing laboratory glassware from DURAN® borosilicate glass 3.3. The DURAN Group is dedicated to high product quality, and operates a quality management system that conforms to ISO 9001:2008. Alongside standard and customer specific laboratory glassware, the DURAN Group has been a long-standing supplier to pharmaceutical research and production facilities worldwide. As a result, we are familiar with the exacting requirements demanded by national and international regulatory authorities, and are a competent project partner for primary packaging.

DURAN PURE is a new range of primary packaging products dedicated to the specific requirements and needs of the pharmaceutical industry. The bottles and closures in the range fully meet the requirements laid down in the international pharmacopoeias, and offer full protection for sensitive and valuable pharmaceutical products. DURAN PURE products are available with a full range of documents and certification that meet the detailed requirements of the regulatory authorities.

DURAN PURE product range

- DURAN PURE Type I Glass Bottle with protective dust cover and dedicated DURAN PURE Premium Screw Caps are available as standard items from stock
- A comprehensive qualification package providing product information and supplier qualification, is available for download from www.duran-group.com
- All stock items comply with the current pharmacopoeia requirements and are registered as Type III: Packaging Material Drug Master Files (DMF)
- Package includes support services: completion of supplier questionnaires, management of change control and audits of manufacturing facilities
- Customer specific DURAN PURE products are available on request



DURAN PURE PRODUCT RANGE

DURAN PURE Clear Glass Bottle Range available from stock²

| Article number | Volume ml | DIN Thread size | Bottles per pack | Bottles per pallet (from same lot) |
|----------------|-----------|-----------------|------------------|------------------------------------|
| 81 801 14 01 | 25 | GL 25 | 10 | 1 560 |
| 81 801 24 06 | 100 | GL 45 | 10 | 660 |
| 81 801 36 08 | 250 | GL 45 | 10 | 420 |
| 81 801 44 07 | 500 | GL 45 | 10 | 360 |
| 81 801 54 03 | 1 000 | GL 45 | 10 | 210 |
| 81 801 63 05 | 2 000 | GL 45 | 10 | 120 |
| 81 801 73 01 | 5 000 | GL 45 | 1 | 48 |
| 81 801 86 06 | 10 000 | GL 45 | 1 | 30 |
| 81 801 91 05 | 20 000 | GL 45 | 1 | 12 |

Premium Screw Cap pre-packed and ready-to-sterilize

The Premium Screw Caps are packed in see-through STERICLIN®¹ pouches under ISO Class 7 cleanroom conditions. The STERICLIN® pouches conform to ISO 11607, and have indicators for steam, ethylene oxide and formaldehyde sterilization.

BENEFITS

- Cleaning of the caps is not required
- Can be sterilized directly in the STERICLIN® pouches
- Sterile storage for up to 6 months
- Pouch contains caps from a single manufacturing lot

DURAN PURE Premium Screw Caps made from fluoropolymer (PFA – TpCh260TZ)²

| Article number | DIN Thread size | Description | Caps per pack |
|----------------|-----------------|---|---------------|
| 89 108 13 06 | GL 25 | DURAN PURE Premium Screw Cap | 5 |
| 89 108 86 79 | GL 45 | DURAN PURE Premium Screw Cap | 5 |
| 89 299 13 04 | GL 25 | DURAN PURE Premium Screw Cap STERICLIN® | 20 |
| 89 299 28 06 | GL 45 | DURAN PURE Premium Screw Cap STERICLIN® | 20 |

¹ STERICLIN® is a registered trademark of the VP Group

² In addition, we are happy to advise and assist you on specific DURAN® glass primary packaging containers and closures to meet your requirements. Please contact us via email at: pharma@duran-group.com

BENEFITS OF CHOOSING DURAN PURE FOR PRIMARY PACKAGING

The DURAN PURE product line offers many advantages for pharmaceutical manufacturing compared to the standard DURAN® media bottles

| | Standard DURAN® Media Bottle | DURAN PURE Bottle |
|---|--|--|
| Glass | DURAN® borosilicate 3.3 neutral Glass Type I | DURAN® borosilicate 3.3 neutral Glass Type I |
| Particle contamination prevention measures | None. Cap and pouring ring (if supplied) are added to the bottle after storage in an uncontrolled area | Protective dust cover is applied in-line at the end of the manufacturing process while the glass still has a very high level of cleanness |
| Quality Control | Final inspection by acceptable quality limit (AQL) in accordance with ISO 2859-1:1999 | <ul style="list-style-type: none"> Final inspection by acceptable quality limit (AQL) in accordance with ISO 2859-1:1999 Additional 100% visual control check and control step Greater in-process control |
| Certificate of conformance | Lot specific certificate of conformance is available via "Retrace Code" internet download | Lot specific certificate of conformance is available via "Retrace Code" internet download (Includes USP, Ph. Eur., JP analysis per lot) |
| Full Qualification documentation for each item and each lot is available via an internet download | No | Yes |
| Lot traceability | Standard DURAN caps are not lot managed and polymer material is not pharmacopoeia compliant | 100% lot traceability of DURAN PURE Bottles and cap components |
| Supply of bottles and caps from a single manufacturing lot | No | Yes |
| Drug Master Files (DMF) registration | None | Registered as Type III: Packaging Material Drug Master Files (DMF) |
| Completion of supplier questionnaires | No | Yes |
| Customer audits of manufacturing facilities | No | Yes |
| Change control agreements | No | Yes |
| Volume graduations | Standard accuracy | Improved accuracy |

DURAN PURE QUALIFICATION PACKAGE

Documents available via internet

Batch certificate of conformance



Qualification documentation



Single certificates



Supporting services

Change Control Management



Questionnaire completion



Supplier Site audits





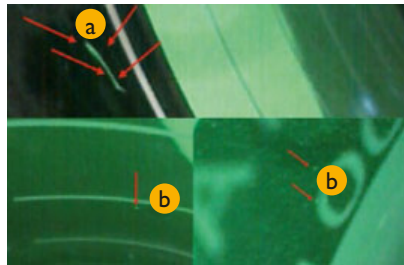
COMPARISON OF PARTICLE CONTAMINATION LEVELS IN STANDARD DURAN® MEDIA BOTTLE WITH THE DURAN PURE BOTTLE AND DUST COVER

An independent testing laboratory (SGS Institut Fresenius, Germany) analyzed the inner surfaces of standard DURAN® media bottles and DURAN PURE Bottles for the presence of particle and fiber contaminants.

DURAN PURE Bottle test results

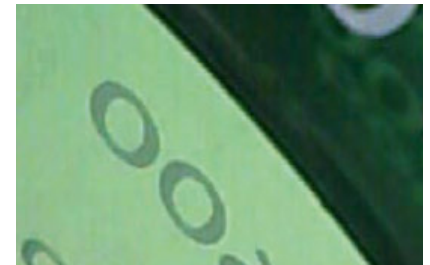
The results showed that in the DURAN PURE Bottles no fiber or particles (visible and sub-visible) could be detected.

Standard DURAN® Media Bottle



- Fibers (a) and particles (b) were detected.

DURAN PURE Bottle



- No fibers or (visible or sub-visible) particles were detected.
- Surface has a very high level of cleanliness – but not “ready-to-use” as the bottles are not manufactured under controlled environmental conditions.

PRODUCT LINE FEATURES

DURAN PURE Glass Bottle

Conforms to a borosilicate 3.3 glass as defined by:

- ISO 3585:1998

Conforms to glass screw-neck bottle standards:

- ISO 4796-1:2000
- DIN 168-1:1998-04

Conforms to a Type I neutral glass as defined by:

- USP <660>
- Ph.Eur. 3.2.1
- JP 7.01 Method I
- ASTM E438-92(2011)

Type III: Packaging Material Drug Master File (DMF)

Documented lot management and traceability using the “Retrace Code”

Full qualification documentation

Suitable for most sterilization methods such as steam, ethylene oxide, chemical, and dry heat sterilization

Glass is a Type I, neutral glass and practically inert

Wide usage temperature range from -70°C to $+500^{\circ}\text{C}$
High thermal shock resistance up to a differential of 100 K

Glass transparency permits visual checks on content status and fill volume

Protective dust cover to minimize particle contamination

DURAN PURE Premium Screw Cap made from fluoropolymer (PFA – TpCh260TZ)

Conforms to USP Class VI

- USP <87>, <88>
- ISO 10993-5:2009

PTFE coating of Premium Cap liner conforms to:

- FDA 21 CFR 177.1550 – Perfluorocarbon resins

Silicone Cap liner is platinum-catalyzed and conforms to:

- FDA 21 CFR 177.2600 Rubber articles intended for repeated use

Type III: Packaging Material Drug Master File (DMF)

Documented lot management and traceability using the “Retrace Code”

Full qualification documentation

Suitable for most sterilization methods such as steam, ethylene oxide, chemical and dry heat sterilization

All polymers are colorant and pigment free

Wide usage temperature range from -196°C to $+260^{\circ}\text{C}$

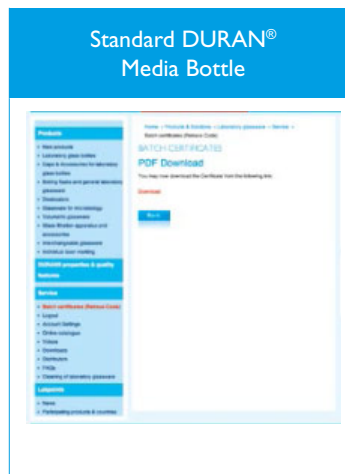
Material contact surfaces made from PTFE

Available in a cleanroom packed, “ready-to-sterilize” STERICLIN® pouch

DURAN PURE – MORE THAN JUST A CONTAINER

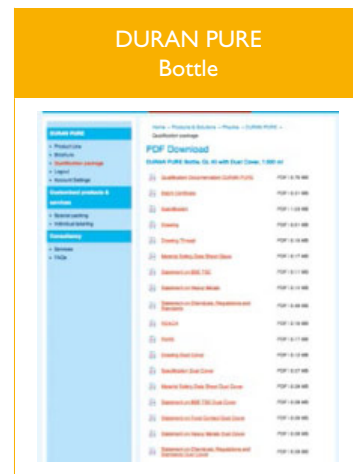
| | Standard DURAN® Media Bottle and Screw Cap | DURAN PURE Bottle/Premium Screw Cap |
|--|--|---|
| Certificate of conformity DURAN® | ✓ | ✓ |
| Certificate of conformity USP Class VI | ✗ | ✓ |
| Product specification | ✗ | ✓ |
| Technical drawing | ✗ | ✓ |
| Material Safety Data Sheet (MSDS) | ✓ | ✓ |
| REACH compliance certificate | ✓ | ✓ |
| Certificate of food contact safety | ✓ | ✓ |
| BSE/TSE/GMO certification | ✓ | ✓ |
| Certificate of heavy metal content | ✗ | ✓ |
| Lot certificate* | ✓ | ✓ |
| Certificate of Analysis (CoA) | ✗ | ✓ |
| Qualification documentation | ✗ | ✓ |
| Auditing capability | ✗ | ✓ |
| Supplier questionnaire | ✗ | ✓ |
| Drug Master File (DMF), Type III | ✗ | ✓ |

* If applicable



The lot specific certificates of conformity for the standard DURAN® media bottles are available at: www.duran-group.com/Products & Solutions/Laboratory Glassware

Lot Certificate



The qualification documentations for DURAN PURE articles are available at: www.duran-group.com/Products & Solutions/Pharma

Qualification documentation available online

DURAN PURE PRODUCT RANGE – SUMMARY OF FEATURES AND BENEFITS

| DURAN PURE | Benefits |
|---|---|
| 100% visual control of the DURAN PURE Bottles and Premium Screw Caps | All the supplied packaging material meets the specified quality standard, reducing the risk of rejection. |
| Protective dust cover | DURAN® glass is melted at over 1500°C producing a smooth, non-porous fire-polished surface that is free of particle contaminants. The protective dust cover is applied immediately after cooling, and prevents contamination of the inside of the bottle during shipping, making it easier to clean before use. |
| Premium Screw Cap pre-packed in STERICLIN® pouches | Easy to use as supplied ready-to-sterilize. Permits storage of sterilized caps up to 6 months. |
| Comprehensive documentation package <ul style="list-style-type: none"> • Certificate of Analysis (CoA) • Type III Drug Master File (DMF) • Qualification documentation | DURAN PURE meets 100% of the official requirements for documented proof of suitability and traceability of primary packaging material. |
| Supply from a single production lot | Simplifies traceability. |
| 100% traceability of components <ul style="list-style-type: none"> • Bottle • Screw cap • Cap sealing liner | DURAN PURE meets the documentation and production requirements of national and international pharmacopeias for primary packaging materials. |
| Change control management | By mutual agreement, any planned product related changes will be communicated for authorization and approval. |
| Manufacturing site audits | Included as part of DURAN PURE supporting services but by prior arrangement. |
| Customized primary packaging | DURAN PURE Bottles and Caps can be adapted to your requirements. |





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