

Validation Ready DURAN PURE Bottles

Process Biologic Bottle System  
with Comprehensive Qualification Support



# WHEATON®

## Process Biologic Bottle System with Comprehensive Qualification Support

### DURAN PURE – MORE THAN JUST A CONTAINER

From R&D through Phase III trials, the task of selecting and validating biologic intermediate packaging is a complex matrix of requirements. The inherent properties of DURAN PURE 3.3 borosilicate glass bottles and fluoropolymer screw caps can fulfill your requirement matrix.

DURAN PURE delivers raw material purity with the following features:

- Chemically inert
- Wide usage temperature range
- Excellent gas barrier
- Low leachable/extractable profile
- Biocompatibility

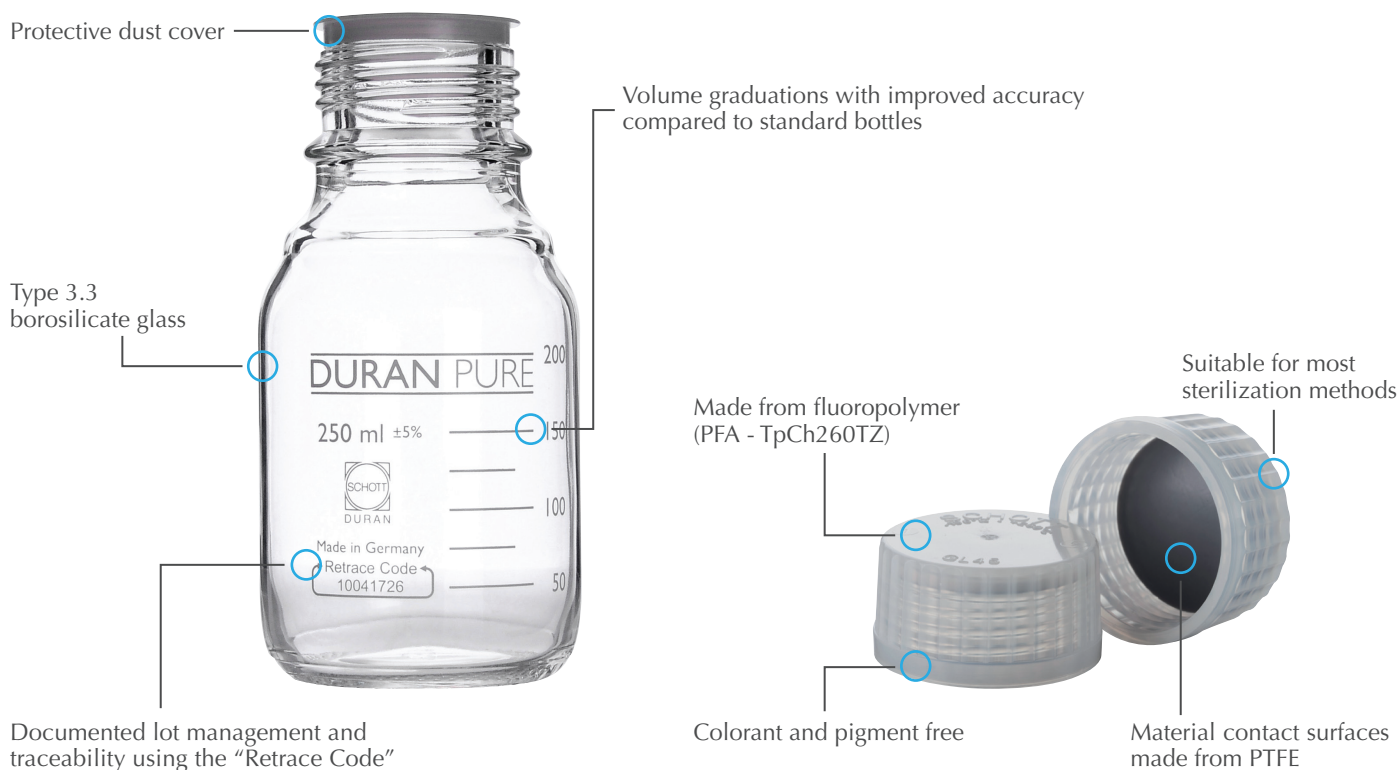
DURAN PURE offers a complete, USP compliant range of bottles from 25mL to 20L. These validation ready sizes are scalable from pilot to production volumes, with the added durability to go from hot “sterile” fills to cold storage.

The DURAN PURE bottle and closure provide moisture permeation rates that support bottle-closure integrity for process biologics; it's the protective environment for long-term stability assurance. DURAN PURE Process Bottle System is supported by a comprehensive, easy to access online validation document package and support services.

DURAN PURE Features	Benefits
100% traceability of components <ul style="list-style-type: none"><li>• Bottle</li><li>• Screw cap</li><li>• Cap sealing liner</li></ul>	DURAN PURE meets the documentation and production requirements of national and international pharmacopeias for primary packaging materials.
Supply from a single production lot	Simplifies traceability
Comprehensive documentation package <ul style="list-style-type: none"><li>• Certificate of Analysis (CoA)</li><li>• Type III Drug Master File (DMF)</li><li>• Qualification documentation</li></ul>	DURAN PURE meets the official requirements for documented proof of suitability and traceability of primary packaging material.
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 reduces the risk 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.



### DURAN PURE CLEAR GLASS BOTTLES & SCREW CAPS



#### DURAN PURE Clear Glass Bottles (Caps are sold separately)

Cat. No.	Volume (mL)	DIN Thread Size	Bottles / CS	Bottles per Pallet (from same lot)
W818011401	25	GL 25	10	1560
W818012406	100	GL 45	10	660
W818013608	250	GL 45	10	420
W818014407	500	GL 45	10	360
W818015403	1000	GL 45	10	210
W818016305	2000	GL 45	10	120
W818017301	5000	GL 45	1	48
W818018606	10000	GL 45	1	30
W818019105	20000	GL 45	1	12

#### DURAN PURE Premium Screw Caps

Cat. No.	DIN Thread Size	Description	Caps / CS
W891081306	GL 25	DURAN PURE Premium Screw Cap	5
W891088679	GL 45	DURAN PURE Premium Screw Cap	5

Scan QR code below to view  
the DURAN PURE video



## DURAN PURE — QUALIFICATION DOCUMENTATION AVAILABLE ONLINE

DURAN PURE bottles and closures meet the requirements of the national and international pharmacopoeias, and are supported by a full range of documents and certifications that meet the detailed requirements of the regulatory authorities. A comprehensive qualification package providing product information and supplier qualification is available for download from [www.duran-group.com](http://www.duran-group.com).

- 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 screenshot shows the DURAN GROUP website with the navigation bar: Home, DURAN Group, Products & Solutions (selected), and About DURAN®. The left sidebar contains links for DURAN PURE (Product Line, Brochure, Qualification package, Logout, Account Settings), Customized products & services (Special packing, Individual labelling), and Consultancy (Services, FAQs). The main content area shows the breadcrumb: Home » Products & Solutions » Pharma » DURAN PURE » Qualification package. Below this is a 'PDF Download' section for 'DURAN PURE Bottle, GL 45 with Dust Cover, 250 ml'. A list of 12 PDF documents is provided with their respective file sizes:

Document Name	File Size
Specification DURAN PURE Bottle	PDF   0.99 MB
Drawing DURAN PURE Bottle	PDF   0.63 MB
Drawing Thread	PDF   0.20 MB
Material Safety Data Sheet DURAN Glass	PDF   0.40 MB
Statement on BSE TSE DURAN Glass	PDF   0.20 MB
Statement on Heavy Metals DURAN Glass	PDF   0.19 MB
Statement on Chemicals, Regulations and Standards DURAN Glass	PDF   0.50 MB
REACH Declaration of Conformity	PDF   0.17 MB
RoHS Declaration of Conformity	PDF   0.27 MB
Specification Dust Cover	PDF   0.28 MB
Drawing Dust Cover	PDF   0.12 MB

Scan QR code below to go to the DURAN qualification site.



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