

DURAN® PURE

INTERMEDIATE BIOLOGIC BOTTLE SYSTEM
WITH COMPREHENSIVE QUALIFICATION AND
VALIDATION PACKAGE

NEW!
GLS80 WIDE MOUTH VERSION



**DURAN
WHEATON
KIMBLE**

Excellence in your hands

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DURAN® PURE

Intermediate Biologic Bottle System with Comprehensive Qualification Package

DURAN® PURE

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

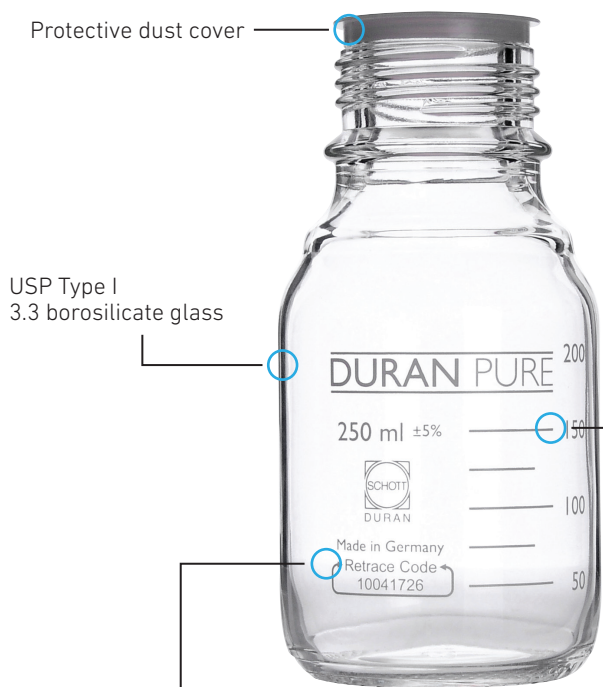
DURAN PURE offers a complete, USP compliant range of bottles from 25mL to 20L. These validation ready sizes are scalable from pilot to production volumes, with the added durability to go from hot “sterile” fills to cold storage.

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
Comprehensive validation package <ul style="list-style-type: none">• Certificate of Analysis (CoA)• Type III Drug Master File (DMF)• Qualification documentation	DURAN PURE meets the official requirements for documented proof of suitability and traceability of primary packaging material
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
Supply from a single production lot	Simplifies traceability
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
cGMP change control management	By mutual agreement, planned product related changes will be communicated



DURAN® PURE GLASS BOTTLES & SCREW CAPS



Documented lot management and traceability using the "Retrace Code"

DURAN® PURE Glass Bottles (Caps are sold separately)

- Conforms to USP <660>, Ph. Eur. 3.2.1 and JP 7.01 Method 1
- Glass type I is a neutral glass and practically inert
- Dust cover conforms to DIN ISO 3585

Cat. No. Clear Glass	Cat. No. Amber Glass	Volume (mL)	DIN Thread	Bottles per Case	Bottles per Pallet
13-710-912	02-913-014	25	GL25	10	940
13-710-913	02-913-015	100	GL45	10	540
13-710-914	02-913-016	250	GL45	10	280
13-710-915	02-913-017	500	GL45	10	360
13-710-916	02-913-018	1 000	GL45	10	210
13-710-917	02-913-019	2 000	GL45	10	120
13-710-918	02-913-020	5 000	GL45	1	48
13-710-919	02-913-021	10 000	GL45	1	30
13-710-920	02-913-022	20 000	GL45	1	12

DURAN® PURE Wide Mouth Glass Bottles (Caps are sold separately)

Cat. No. Clear Glass	Cat. No. Amber Glass	Volume (mL)	DIN Thread	Bottles per Case	Bottles per Pallet
02-913-023	02-913-026	500	GLS80	10	280
02-913-024	02-913-027	1 000	GLS80	10	210
02-913-025	02-913-028	2 000	GLS80	10	120

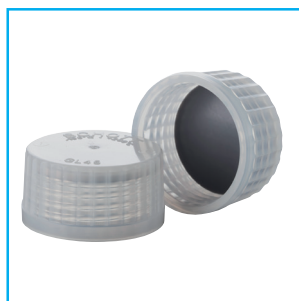
DURAN® PURE GLS80 Screw Caps

Cat. No.	DIN Thread	Description	Caps / CS
02-913-031	GLS80	DURAN PURE Premium Screw Cap	5

DURAN® PURE Premium Screw Caps

- Conforms to USP Class VI <87>, <88> and ISO 10993-5
- No added colorants
- Outstanding temperature resistance from -196°C to 260°C
- PTFE-coated silicone seal is catalytically cured and conforms with FDA
 - FDA 21 CFR §177.1550 for PTFE
 - FDA 21 CFR §177.2600 for elastomers

Cat. No.	DIN Thread	Description	Caps / CS
13-710-921	GL25	DURAN PURE Premium Screw Cap	5
13-710-922	GL45	DURAN PURE Premium Screw Cap	5
02-913-032	GL45	DURAN PURE Premium Lip Seal Cap	5



DURAN® PURE — QUALIFICATION DOCUMENTATION AVAILABLE ONLINE

DURAN PURE bottles and closures meet the requirements of the national and international pharmacopeias, 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.

	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

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To fax an order, use 1-800-926-1166
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To fax an order, use 1-800-463-2996
To order online: fishersci.ca



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