



DURAN PURE

Primary packaging including a
wide range of services

DURAN PURE bottle with DIN thread GL 45
and dust cover
Cat. No. 81 801 54 03



Detailed view of dust cover



DURAN PURE Premium Cap GL 45
Cat. No. 89 108 86 79



DURAN PURE Premium Cap GL 45
STERICLIN®-packed
Cat. No. 89 299 28 06



YOUR DEMAND – OUR SOLUTION: DURAN PURE

New product line with service plus

The DURAN Group is a DIN EN ISO 9001 certified company, which has been going strong for many years in supplying the international pharmaceutical industry with products for a wide range of applications.

Whether in fundamental research, or in manufacturing processes of pharmaceutical products, our bottles provide optimum protection, even for sensitive media.

Our primary packaging solution DURAN PURE contains the individual components:

DURAN PURE Bottle with DIN thread GL 45 and dust cover

- Batch certification
- Statement of conformity
- Dust cover is installed directly after tempering DURAN PURE bottles. At this stage, the inner surface of the bottle has the highest purity level. The dust cover preserves the purity and prevents contamination of the inner surface of the bottles.

DURAN PURE Premium Cap from TpCh260TZ, GL 45

- Batch certification
- Statement of conformity
- Available in two versions: packed in PE bags or STERICLIN®-packed

The qualification package provides extensive documentation for product and supplier qualification.

The documentation is available for downloading at www.duran-group.com.



DURAN PURE PREMIUM CAP

The Premium Cap is optimally suited for use in the pharmaceutical industry. Two versions are available: packed in Polyethylen bags or STERICLIN®-packed. Without STERICLIN®-packaging the Premium Cap is suitable for dry heat sterilisation up to 260 °C.

Premium Cap from TpCh260, STERICLIN®-packed

STERICLIN®-packaging is a sterile barrier system(SBS). Those paper / film see-through pouches are compliant in accordance to DIN ISO 11607.

The sterilisation proof paper is an effective barrier against germs and bacteria, yet it permits the transmission of air, steam, or sterilisation gases.

Premium Caps are sealed in the SBS under Class 7 clean room conditions. The clean room conditions are in accordance to EN ISO 14644-1. No pre-cleaning of the SBS-sealed Premium Caps is therefore necessary. After sterilisation the Premium Cap can be stored STERICLIN®-packed up to 6 months without any loss of sterility.

Supply:

STERICLIN®-packed Premium Caps are supplied „ready-for-sterilisation.“ The sterilisation is carried out by the customer.

Sterilisation:

Steam sterilisation is the recommended method with pre-vacuuming and temperatures from 121 °C to 134 °C for 20 minutes each. Three indicators for STEAM-, EO-, and FORM-sterilisation are imprinted on the pouches indicating completed sterilisation through a change in colors.



ADVANTAGES:

- No pre-cleaning necessary
- Sterilisation of STERICLIN®-packed Premium Caps
- Sterile storage up to 6 months
- Retrace Code (traceability)

DURAN PURE – OUR SERVICE FOR YOUR PRODUCT AND SUPPLIER QUALIFICATION

An integral part of the DURAN PURE line is the qualification package.

Aside from comprehensive documentation we offer a wide range of services. The documentation is available for downloading at www.duran-group.com. Follow the icon.

Qualification Package DURAN PURE

- **Batch Certificate**
with certificate of conformity and certificate of analysis.
- **Qualification Documentation**
contains information for product and supplier qualification.
- **Individual Certificates**
such as BSE/TSE, USP, and FDA conformity, certified for food applications, REACH, RoHs.
- **Change Service**
comprises qualification documentation and individual certificates. You are automatically informed about changes with reference to products, new analyses, or test results.
- **Questionnaire Processing**
for product and supplier qualifications. Please send the questionnaires directly to the Product Manager Pharmaceutical Industry using pharma@duran-group.com.
- **Audits**
We offer to conduct payable audits for DURAN PURE products. To schedule an audit, please enter your preferred audit date in the audit schedule.

QUALIFICATION PACKAGE DURAN PURE

Documents for Download



Supporting Service Features



SERVICE PLUS

Comparison of DURAN® Laboratory glass bottle and DURAN PURE bottle

DURAN® Laboratory Glass Bottle	DURAN PURE Bottle
Glass Type I (USP, Ph.Eur., JP conformity)	Glass Type I (USP, Ph.Eur., JP conformity) Dust cover
	Qualification Package
Standard specification	DURAN PURE specification
Standard batch certificate	Batch certificate with test certificate
	Qualification documentation
	Individual certificates
	Audits
	Change service, Questionnaire processing

Comparison of Premium Cap and DURAN PURE Premium Cap

Premium Cap TpCh260TZ	DURAN PURE Premium Cap from TpCh260TZ
USP Class VI conformity	USP Class VI conformity
	Optionally with and without STERICLIN®-packaging
	Qualification Package
Standard specification	DURAN PURE specification
Standard batch certificate	Batch certificate with test certificate
	Qualification documentation
	Individual certificates
	Audits
	Change service, Questionnaire processing

ADVANTAGES AT A GLANCE

DURAN PURE primary packaging solution

- Traceability using Retrace Code
- Suitable for dry heat sterilisation
- Includes comprehensive documentation and service
- Change service automatically informs about product related changes. No need to become active in acquiring up-to-date information

DURAN PURE Bottle with dust cover

USP, Ph.Eur. and JP conformity • USP <660> • Ph.Eur. 3.2.1 • JP 7.01 Method I

Glass type I is a neutral glass and virtually inert

Conforms with DIN ISO 3585

Transparency allows content and filling level control

DURAN PURE Premium Cap

USP class VI conformity • USP <87>, <88> • ISO 10993-5

PTFE-sealed silicone seal is platinum cured and FDA-compliant

- FDA CFR 21 §177.1550 for PTFE
- FDA CFR §177.2600 for elastomers

No dye additives

Outstanding temperature resistance from -196 °C to +260 °C

THE DURAN PURE RANGE

is available at your labware dealer

DURAN PURE Bottle with DIN thread GL 45 and dust cover

Cat. No.	Capacity ml	Packaging Unit (PU)	Minimum Order Quantity (1 pallet)
81 801 44 07	500	10	360 pcs.
81 801 54 03	1 000	10	210 pcs.
81 801 63 05	2 000	10	120 pcs.
81 801 73 01	5 000	1	48 pcs.
81 801 86 06	10 000	1	30 pcs.
81 801 91 05	20 000	1	12 pcs.

DURAN PURE Premium Cap from TpCh260TZ with DIN thread GL 45

Cat. No.	DIN Thread	Packaging Unit (PU)	Minimum Order Quantity
89 108 86 79	GL 45	5*	1 PU
89 299 28 06	GL 45 STERICLIN®	20**	1 PU

* Premium Caps per PE bag

** 4 STERICLIN® bags with 5 Premium Caps



CONTACT

DURAN Group GmbH
Hattenbergstraße 10
D-55122 Mainz

Product Management
Pharmaceutical Industry

Tel.: +49 (0)6131 / 1445 4907
Fax: +49 (0)6131 / 1445 4016
pharma@duran-group.com
www.duran-group.com



DURAN Group GmbH

Hattenbergstraße 10

D-55122 Mainz

Tel. +49 (0)6131 / 1445 4131

Fax +49 (0)6131 / 1445 4016

info.duran@duran-group.com

www.duran-group.com

