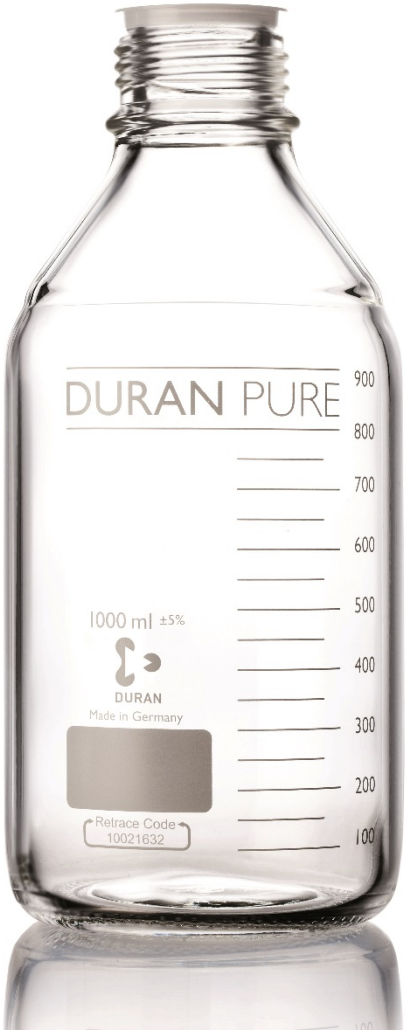
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Specification

DURAN PURE bottle, clear

Volume	ISO 4796-1 Standard	Wide neck
25ml	81 801 14 01	
100ml	81 801 24 06	
250ml	81 801 36 08	
500ml	81 801 44 07	81 860 44 03
1000ml	81 801 54 03	81 860 54 08
2000ml	81 801 63 05	81 860 63 01
5000ml	81 801 73 01	81 860 73 06
10.000ml	81 801 86 06	81 860 86 02
20.000ml	81 801 91 05	81 860 91 01

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Product Specification DURAN PURE Bottle 25ml – 20.000ml, clear

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Product Specification DURAN PURE Bottle 25ml – 20.000ml, clear

1 Generally Admitted

Product properties and product characteristics are defined in the article related product specification and article drawing.

The products described in this specification are produced with due regard to the quality management system DIN ISO 9001. All products fulfill the quality standard determined in the article specification and drawing.

DURAN® meets the requirements of DIN ISO 3585.

2 Scope

This product specification is the basis for quality assurance at DWK Life Sciences. It applies, from the validity date of this specification, to all articles supplied with the article numbers:

Volume	ISO 4796-1 standard	Wide neck
25ml	81 801 14 01	
100ml	81 801 24 06	
250ml	81 801 36 08	
500ml	81 801 44 07	81 860 44 03
1000ml	81 801 54 03	81 860 54 08
2000ml	81 801 63 05	81 860 63 01
5000ml	81 801 73 01	81 860 73 06
10.000ml	81 801 86 06	81 860 86 02
20.000ml	81 801 91 05	81 860 91 01

Description:

DURAN PURE bottle with protective cover

3 Validity

This product specification is valid from the date of release and supersedes all prior versions.

4 Product

DURAN® Borosilicate glass 3.3 is resistant to water, acids, saline solutions, organic substances and also halogens such as bromine, chlorine, iodine and organic substances.
Only hydrofluoric acid, boiling phosphoric acid and strong alkalis cause appreciable surface removal of the glass (glass corrosion) at elevated temperatures (>100°C).

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General technical, constructed value data		
Thermal conductivity λ_w at 100°C		1.2 W • m^{-1} • K^{-1}
Mean specific heat capacity C_p (20°C; 100°C)		0.8 J • g^{-1} • K^{-1}
Modulus of elasticity E (Young`s modulus)		64 GPa
Poisson `s–ratio μ		0.20
Stress-optical coefficient K		4.0 • 10^{-6} mm^2• N^{-1}
Refractive index (λ = 587,6 nm) n_d		1.473
Dielectric properties (1 MHz 25°C)	dielectric constant ε	4.6
	dielectric loss factor tan δ	37 • 10^{-4}
Temperature for the specific electrical resistance of 10^{-6} Ω • cm (DIN 52 326) $t_{k\ 100}$		250°C
Coefficient of mean linear thermal expansion α (20°C; 300°C) acc. to DIN ISO 7991		3.3 • 10^{-6} • K^{-1}
Transformation temperature T_g		525°C
Density ρ at 25°		2.23g • cm^{-3}
Temperature of the glass at viscosity η in dPa • s:		
	10^{13} (annealing point)	560°C
	$10^{7,6}$ (softening point)	825°C
	10^4 (working point)	1260°C

4.1 Chemical Composition

DURAN® has the following, approximate composition (weight percentage).

SiO_2	B_2O_3	Na_2O & K_2O	Al_2O_3
81	13	4	2

4.2 Chemical Resistance

4.2.1 General

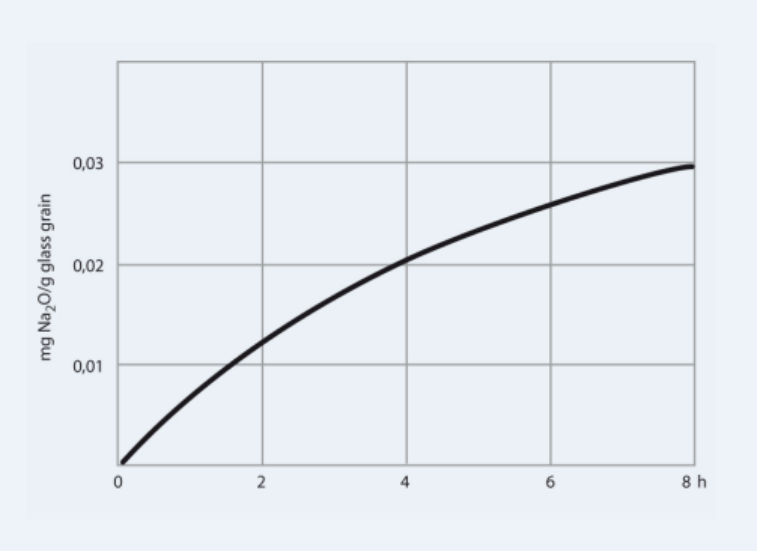
Due to the almost inert properties of DURAN® Glass, interactions do not occur. An Ion exchange between medium and glass can be excluded.

Acid resistance	Acid resistance	Hydrolytic resistance	Alkalis resistance
Class S 1 (DIN 12116)	≤ 100 µg Na_2O per dm^2 (ISO 1776)	Class HGB 1 (ISO 719) Class HGA 1 (ISO 720)	Class A 2 (ISO 695)

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4.2.2 Hydrolytic Resistance

DURAN® corresponds to “Class 1” of 5 different hydrolytic resistance classes in accordance with ISO 719 (98 °C). The amount of Na_2O/g glass grain leached out after 1 hour in water at 98 °C is measured. For DURAN® the quantity of Na_2O leached out is less than 31 µg/g of glass grain.
DURAN® also corresponds to “Class 1” of 3 different hydrolytic resistance classes in accordance with ISO 720: (121 °C). The quantity of Na_2O leached out after 1 hour in water at 121 °C is less than 62 µg/g of glass grain.
Due to its good hydrolytic resistance, DURAN® meets the requirements of the USP and EP for neutral glass that corresponds to glass type 1. It can therefore be used in an almost unrestricted way in pharmaceutical applications and in contact with foodstuff.

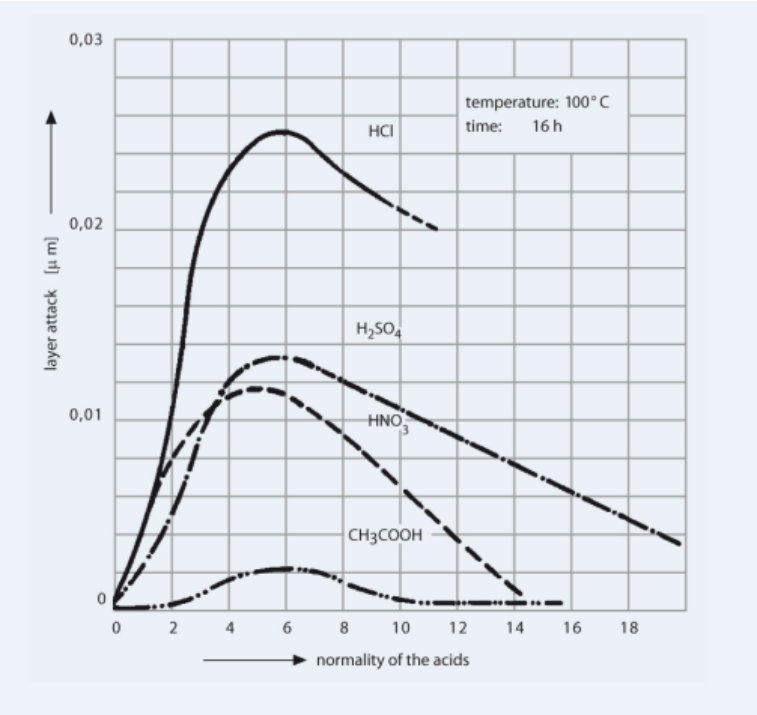


Example: Hydrolytic attack on DURAN® as a function of time (100˚C)

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4.2.3 Acid Resistance

DURAN® corresponds to “Class 1” of 4 different acid classes in accordance with DIN 12116. As the surface removal after boiling for 6 hours in normal HCl is less than 0.7 mg/100 cm^2, DURAN® is classed as acid-resistant borosilicate glass.
The quantity of alkaline metal oxides leached out in accordance with ISO 1776 is less than 100 µg Na_2O/100 cm^2.

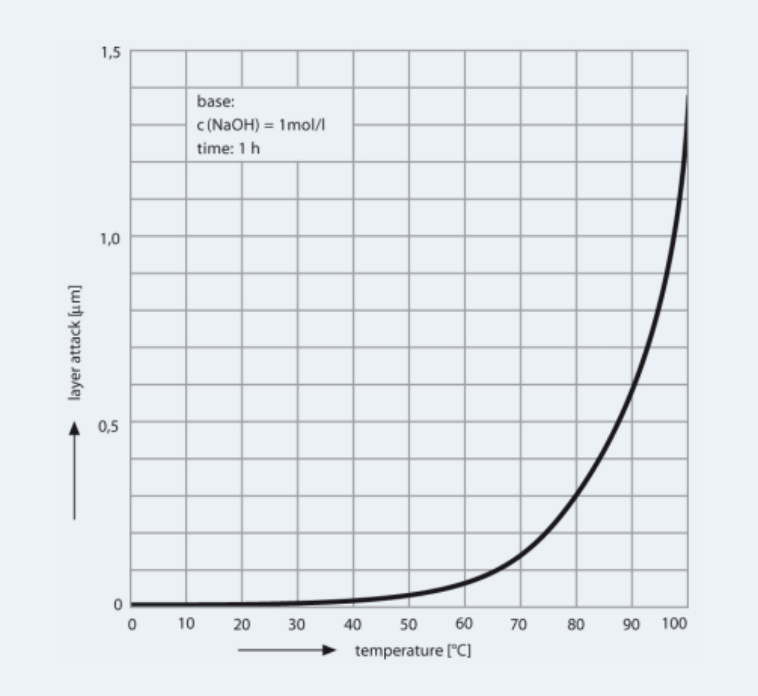


Example: Acid attack on DURAN® as a function of acid concentration

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4.2.4 Alkali Resistance

DURAN® corresponds to “Class 2” of 3 different alkali classes in accordance with ISO 695. The surface erosion after 3 hours boiling in a mixture of equal volume fractions of sodium hydroxide solution (concentration 1 mol/l) and sodium carbonate solution (concentration 0.5 mol/l) is only 134 mg/100 cm^2.



Example: Alkali attack on DURAN® as a function of temperature

4.3 Physical Properties

4.3.1 Thermal Shock Resistance

Temperature resistance when heated and thermal shock resistance

Standard application: Do not heat above 500°C
T_g DURAN®: 525°C
If heated above 525°C, the material softens.

Regarding a very low coefficient of linear expansion ($\alpha = 3.3 \cdot 10^{-6}\ K^{-1}$), a feature of DURAN® is its high thermal shock resistance up to $\Delta T = 100$ K. For a temperature change of 1K, the glass changes by only $3.3 \cdot 10^{-6}$ relative length units, resulting in low levels of mechanical strain where a thermal gradient exists.

Temperature resistance at low temperatures

DURAN® can be cooled down to approx. – 196°C and is therefore suitable for use with liquid nitrogen if the glass surface is intact and proper procedures are used.

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4.3.2 Optical Properties

In the spectral range from about 310 to 2200 nm the absorption of DURAN® is negligibly low. It is clear and colourless. Fairly large layer thicknesses (axial view through pipes) appear slightly yellow/ greenish.

4.3.3 Pressure Resistance

DURAN PURE bottles are not suitable for application with pressure or under vacuum.

4.3.4 Cleaning

DURAN PURE bottles are suitable for manual cleaning as well as automated cleaning.

4.3.5 Sterilisation

DURAN PURE bottles are suitable for autoclaving as well as dry heat and plasma sterilization (H_2O_2).
In respect of sterilisation especially of DURAN PURE bottles the following information should be observed:
To avoid overpressure all bottles should kept open during autoclaving.

Alongside the standardised procedures described above, individually modified methods are also applicable to all DURAN PURE bottles for example using high temperatures.

DURAN® is not a cerium-stabilised glass therefore gamma-ray sterilisation is only partially suitable.
DURAN® may appear brown coloured after gamma-ray sterilisation.

5 Traceability

5.1 Lot

A lot is a certain amount of products defined by production order, produced in a range of operational steps, expected as homogenous lot.

5.2 Retrace Code

Regarding quality assurance together with traceability of packaging and auxiliaries each article is identified with a so called “Retrace Code”.
This eight-digit identification number enables tracing to the production date of the article.
On the DWK Life Sciences website the qualification documentation for this article including the batch certificate can be downloaded by entering the article number and/or Retrace Code.

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6 Quality

DURAN PURE articles are produced according to relevant documents. Those are product specification and article drawing. The geometric realization follows the valid drawing.

All tests are performed with “unarmed eyes” at an illumination of approximate 800 lux. The viewing distance is an arm`s length (app. 50 cm).

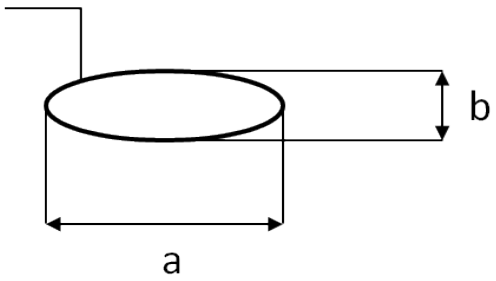
Frequentness refers to one article.
All tests are conducted using a sampling procedure according to AQL DIN/ISO 2859-1.
Based on single random sampling, general inspection level II is used.

6.1 Characteristic

For the evaluation of the sizes of characteristics the equivalent diameter is the basis.
Variant forms to the circular shape like oval or elliptical characteristics will be measured by using the equivalent diameter.

Definition of the equivalent diameter:

Characteristic

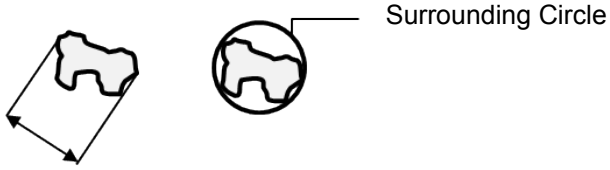


L = equivalent diameter of the characteristic
a = length of glass characteristic
b = width of glass characteristics

Therefore, the equivalent diameter L is:

$$L = \frac{a + b}{2}$$

All the other characteristics will be measured according to their actual size respectively due to the surrounding circle:



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6.1.1 (Non) acceptable Characteristics

6.1.1.1 (Non) acceptable Characteristics DURAN PURE Bottle 25ml – 2000ml

The inspection of visible characteristics has to fulfill the following:

Characteristics	Extent	Volume V = 25ml	Volume V = 100ml	Volume V = 250ml	Volume V = 500ml	Volume V = 1000ml	Volume V = 2000ml
Bubbles closed	L ≤ 0,5 mm	admissible	admissible	admissible	admissible	admissible	admissible
	0,5 mm < L ≤ 2,0 mm	2	2	3	3	3	4
	2,0 mm < L ≤ 4,0 mm	0	0	0	0	1	2
	L > 4,0 mm	0	0	0	0	0	0
Bubbles open		not admissible	not admissible	not admissible	not admissible	not admissible	not admissible
Knots	L ≤ 0,5 mm	3	3	3	3	4	5
	0,5 mm < L ≤ 2,0 mm	0	0	0	0	0	0
	L > 2,0 mm	2	2	3	3	3	4
Stones surrounded by glass	L ≤ 1,0 mm	2	2	3	3	3	4
	L > 1,0 mm	0	0	0	0	0	0
Stones not surrounded by glass		not admissible	not admissible	not admissible	not admissible	not admissible	not admissible
Minimum distance between two characteristics		5mm	5mm	10mm	10mm	10mm	10mm
Allowed characteristics in total per article		3*	3*	5*	5*	5*	5*

* bubbles (closed) and knots up to L ≤ 0,5 mm, are not defined as characteristic.

Characteristics	Remark
Bubble	Big air pockets in the glass
Stone	Non-transparent inclusions in the glass – caused by non-melted batch or particles of fireproof stone material
Knot	Transparent inclusions in the glass

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6.1.1.2 (Non) acceptable Characteristics for DURAN PURE Bottle 5000ml

The inspection of visible characteristics has to fulfill the following:

Characteristics	Size	Volume V = 5000ml
Bubbles closed	L ≤ 0,5 mm	admissible
	0,5 mm < L ≤ 2,0 mm	6
	2,0 mm < L ≤ 4,0 mm	2
	L > 4,0 mm	0
Bubbles open		Not admissible
Knots	L ≤ 0,5 mm	admissible
	0,5 mm < L ≤ 2,0 mm	7
	L > 2,0 mm	0
Stones surrounded by glass	L ≤ 1,0 mm	4
	L > 1,0 mm	0
Stones not surrounded by glass		Not admissible
Min. distance between two characteristics		15mm
Maximum amount of admissible characteristics on one article		7*

* bubbles (closed) and knots up to L ≤ 0,5 mm, are not defined as characteristic.

Characteristics	Remark
Bubble	Big air pockets in the glass
Stone	Non-transparent inclusions in the glass – caused by non-melted batch or particles of fireproof stone material
Knot	Transparent inclusions in the glass

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6.1.1.3 (Non) acceptable Characteristics for DURAN PURE Bottle 10.000ml – 20.000ml

The inspection of visible characteristics has to fulfill the following:

Characteristics	Size	Volume V = 10.000ml	Volume V = 20.000ml
Bubbles closed	L ≤ 0,5 mm	admissible	admissible
	0,5 mm > L ≤ 2,0 mm	8	10
	2,0 mm > L ≤ 4,0 mm	2	2
	L ≥ 4,0 mm	0	0
Bubbles open		not admissible	not admissible
Knots	L ≤ 0,5 mm	admissible	admissible
	0,5 mm > L ≤ 2,0 mm	9	12
	2,0 mm > L ≤ 4,0 mm	5	6
	L ≥ 4,0 mm	0	0
Stones surrounded by glass	L ≤ 1,0 mm	8	10
	L ≥ 1,0 mm	2	4
Stones not surrounded by glass		not admissible	not admissible
Min. distance between two characteristics		15 mm	20 mm
Maximum amount of admissible characteristics on one article		12*	15*

* bubbles (closed) and knots up to L ≤ 0,5 mm, are not defined as characteristic.

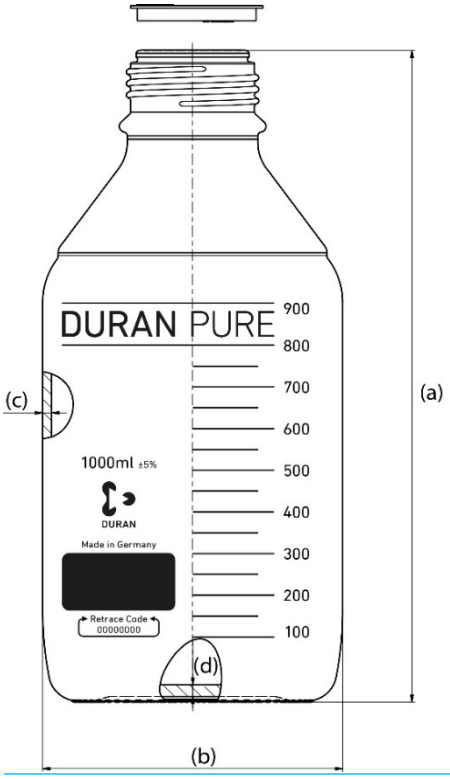
Characteristics	Remark
Bubble	Big air pockets in the glass
Stone	Non-transparent inclusions in the glass – caused by non-melted batch or particles of fireproof stone material
Knot	Transparent inclusions in the glass

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6.1.2 Other Visual Characteristics

Characteristics which are not particularly specified but visual identifiable and do not affect serviceability are unacknowledged as defect.

6.2 Geometry Characteristics and Measuring Equipment/ Methods



Extract of article drawing 1000ml to show the geometry characteristics:

This exemplary description only serves a clear definition of the descriptions used.
The valid article drawing has to be used for the dimensional inspection and evaluation.

Characteristic	Measuring equipment / Method
(a) height	vernier height gauge
(b) diameter	caliper / gauge
(c) wall thickness	wall thickness measuring device
(d) ground thickness	wall thickness mea suring device

6.3 Optical Path Difference and Inspection Method

Measuring of the optical path difference in the glass is performed after the Lehr process (annealing process).

Optical path difference < 150 nm/cm

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6.4 Definition AQL-Classes for Characteristics

6.4.1 Definition AQL-Classes for Characteristics Bottles 25ml – 2000ml

Characteristics as listed below are tested according to following Accepted Quality Limits:

Characteristics	AQL
Logistic	
Pieces on pallet	2.5
Compliance with palleting standards	2.5
Complete accompanying document	1.0
Print image	
Burnt-in print	1.0
Print layout	1.0
Printing characteristics	2.5
Geometry	
All wall thicknesses	2.5
All diameters	2.5
Total height	2.5
Thread characteristics	2.5
Contour characteristics	2.5
Filling volume	2.5
breakage	1.0
Glass defects	
Cracks	1.0
Mouthpiece characteristics	2.5
Sticking glass splinters	2.5
Folds / waves	2.5
Monkey swing	2.5
Residual tension	2.5
Scratches	2.5
Surface characteristics	
Stains, dirt, imprints	2.5

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6.4.2 Definition AQL-Classes for Characteristics Bottles 5000ml

Characteristics as listed below are tested according to following Accepted Quality Limits:

Characteristics	AQL
Logistic	
Complete content	1.0
Compliance with palleting standards	2.5
Complete accompanying document	1.0
Print image	
Burnt-in print	1.0
Print layout	1.0
Print height	1.0
Printing characteristics	2.5
Geometry	
All wall thicknesses	2.5
All diameters	2.5
Total height	2.5
Thread characteristics	2.5
Contour characteristics	2.5
Glass defects	
Cracks	1.0
Breaks	1.0
Glass characteristics	2.5
Surface characteristics	2.5
Sticking glass splinters	1.0
Cast characteristics	2.5
Melting off Characteristics	2.5
Residual tension	2.5
Scratches	2.5
Surface characteristics	
Dirt, stains, imprints	2.5

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6.4.3 Definition AQL-Classes for Characteristics Bottles 10.000ml – 20.000ml

Characteristics as listed below are tested according to following Accepted Quality Limits:

Characteristics	AQL
Logistic	
Pieces on pallet	2.5
Compliance with palleting standards	2.5
Complete accompanying document	1.0
Print image	
Burnt-in print	1.0
Print layout	1.0
Printing characteristics	2.5
Geometry	
All wall thicknesses	2.5
All diameters	2.5
Total height	2.5
Thread characteristics	2.5
Contour characteristics	2.5
Filling volume	2.5
breakage	1.0
Glass defects	
Cracks	1.0
Mouthpiece characteristics	2.5
Sticking glass splinters	2.5
Folds / waves	2.5
Monkey swing	2.5
Residual tension	2.5
Scratches	2.5
Surface characteristics	
Stains, dirt, imprints	2.5

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7 Compliance with standards of DURAN PURE botttles

7.1 Compliance with Food Contact Regulations

DURAN® glass is compliant with the requirements of the following guidelines, laws and regulations:

- ISO 7086-1 + 2 – Glass Hollowware in contact with food – Release of Lead and Cadmium
- ISO 6486-1 + 2 – Ceramic ware, glass-ceramic ware and glass dinnerware in contact with food – Release of lead and cadmium
- DIN EN 1388-1 Silicate Surfaces – Determination of Release of Lead and Cadmium
- (EC) 1935/2004 – Materials and articles intended to come into contact with food
- (EC) 2023/2006 – Good Manufacturing Practice for materials and articles intended to come into contact with food
- 2005/31/EC – Analytical method for ceramic articles intended to come into contact with foodstuffs
- LFGB – Requirements regarding leaching of lead and cadmium
- FDA CPG 7117.06 – Ceramic Food Bearing Surfaces – Cadmium
- FDA CPG 7117.07 – Ceramic Food Bearing Surfaces – Lead
- California Proposition 65 (California's Safe Drinking Water & Toxic Enforcement Act of 1986)

DURAN® glass is acknowledged as GRAS (Generally Recognized as Safe) under the FDA CFR Code of Federal Regulations Title 21 (CFR 21) (FDA acknowledgement letter Food Contact Substance Formulation (FCF) 000127).

DURAN® glass is therefore suitable for use in contact with foodstuff according to the above mentioned standards and regulations. This fact does not absolve the distributor of foodstuff from thorough testing to confirm compliance with the legal requirements of the applicable laws, guidelines and regulations (national and/or international) regarding Food Safety.

7.2 Statement on BSE/TSE

We hereby confirm that DURAN® glass consists of raw material without any biological origin or genetically modified organism (GMO). No materials of animal origin are used or added during the manufacturing process.

The manufacturing of DURAN® glass involves minimum melting temperatures of 1500 °C for several hours, where all the raw materials are melted together. After forming, the glass products are tempered in an oven at more than 400 °C before being slowly cooled. Due to the high temperatures, we can act on the assumption that any and all biological substances are destroyed during production. Accordingly, transmission of animal spongiform encephalopathy agents (Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy) via the glass material is extremely improbable.

Please note that analysis of the raw materials and/or finished goods for presence of the above mentioned substances is not performed on a routine basis.

7.3 Chemicals, regulations and standards

REACH Regulation (EU) No. 1907/2006

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is the European Union's (EU) chemical substances regulatory framework. The REACH Regulation (1907/2006/EC) makes the industry responsible for providing customers with appropriate safety information on Substances of Very High Concern (SVHC) contained in products in concentration above 0.1% weight by weight (w/w) to allow safe use of the product.

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DURAN® Glass (printed)
To the best of our knowledge, the printed products listed above do not contain any substance currently flagged as SVHC above the threshold as intended in the REACH Regulation.

Coalition of Northeastern Governors (CONEG)

Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product.

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)

DURAN® does not contain any monomer.

Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)

BHT and BHA are not used in the manufacture of or formulation of this product.

Ozone Depleting Chemicals (ODCs)

We confirm that the product contains no ODC`s according to „Annex I EU Regulation 1005/2009/EC“.

Toys Safety

The phthalates listed in Annex XVII of Regulation (EU) No. 1907/2006 are not added in the manufacture of or the formulation of this product.

Phthalates

Phthalates, as defined by the regulations REACH, RoHS and California Proposition 65, are not intentionally used in the manufacture or the formulation of this product. The limits for Phthalates, as stipulated by REACH, RoHS and California Proposition 65 are not exceeded by this product.

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Melamine

According to the CDER guidance for industry "Pharmaceutical Components at Risk for Melamine Contamination" we can confirm that DURAN® contains no Melamine components.

Melamine are not used in the manufacture of or formulation of this product:

- Adenine
- Albumin
- Amino Acids derived from casein protein hydrolysates
- Ammonium salts
- Calcium pantothenate
- Caseinate or Sodium caseinate
- Chlorophyllin copper complex sodium
- Colloidal oatmeal
- Copovidone
- Crospovidone
- Dihydroxyaluminum aminoacetate
- Gelatin
- Glucagon
- Guar gum
- Hyaluronidase
- Imidurea
- Lactose
- Melphalan
- Povidone
- Povidone-Iodine
- Protamine sulfate
- Protein hydrolysate (powder) for injection
- Taurine
- Thioguanine
- Urea
- Wheat bran
- Zein

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Acrylamide

Acrylamide (CAS number 79-06-1) is not used in the manufacture of or the formulation of this product.

Aromatic Amines

Aromatic amines are not used in the manufacture of or formulation of this product.

Asbestos Material

Asbestos is not used in the manufacture of or formulation of this product.

Bisphenol A

Bisphenol A is not used in the manufacture of or the formulation of this product.

Dioxin Contamination

Dioxin is not used in the manufacture of or formulation of this product. Dioxin is not known to be formed during processing of this product.

Epichlorohydrin

Epichlorohydrin (CAS number 106-89-8) is not used in the manufacture of or the formulation of this product.

Nonylphenol

Nonylphenol and Nonylphenol ethoxylates are not used in the manufacture of or the formulation of this product.

Alkylphenol

Alkylphenol is not used in the manufacture of or the formulation of this product.

Organo-tin Compounds

Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds are not used in the manufacture of or the formulation of this product.

Styrene and Polystyrene

Styrene (chemical name: ethenylbenzene) (CAS number 100-42-5) and polystyrene resins are not used in the manufacture of or the formulation of this product.

Vinyl Chloride and Polyvinyl Chloride (PVC)

Vinyl chloride (CAS number 75-01-4) and PVC resins are not used in the manufacture of or the formulation of this product.

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Benzotriazole and 2-Mercaptobenzothiazole (MBT)

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol [also called 2-(2'-Hydroxy-3',5'-di-t-butylphenyl) benzotriazole] (CAS No. 3846-71-7) and 2-Mercaptobenzothiazole [also called 2(3H)-Benzothiazolethione or Benzothiazole-2-thiol or MBT] (CAS No. 149-30-4) are not used in the manufacture of or formulation of this product.

Nanomaterials

NANOMATERIALS (insoluble or biopersistent and intentionally manufactured materials with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm) are not used in the manufacture of or the formulation of this product.

Polycyclic Aromatic Hydrocarbons (PAHs)

Those products are not used for the manufacture of DURAN®:

- 1,2-dihydro-acenaphthene (CAS# 83-32-9)
- Acenaphthylene (CAS# 208-96-8)
- Fluorene (CAS# 86-73-7) anthracene (CAS# 120-12-7)
- Benz(a)anthracene (CAS# 56-55-3)
- Benzo(a)pyrene (CAS# 50-32-8)
- benzo(b)fluoranthene (CAS# 205-99-2)
- Benzo(e)pyrene (CAS# 192-97-2)
- Benzo(ghi)perylene (CAS# 191-24-2)
- Benzo(j)fluoranthene (CAS# 205-82-3)
- Benzo(k)fluoranthene (CAS# 207-08-9)
- Chrysene (CAS# 218-01-9)
- Dibenzo(a,h)anthracene (CAS# 53-70-3)
- Fluoranthene (CAS# 206-44-0)
- Fluorene (CAS# 86-73-7)
- Indeno(1,2,3-cd)pyrene (CAS# 193-39-5)
- Naphthalene (CAS# 91-20-3)
- Phenanthrene (CAS# 85-01-8)
- Pyrene (CAS# 129-00-0)

Dimethyl Fumarate (DMF) - Regulation (EU) No. 1907/2006 Annex XVII

Dimethyl fumarate [2-butenedioic acid (2E)-, dimethyl ester] (DMF) (CAS#: 624-49-7): The product does not contain this restricted substance.

Triclosan (2,4,4’-trichloro-2’-hydroxydiphenyl ether)

Triclosan (2,4,4’-trichloro-2’-hydroxydiphenyl ether) Cas. N.3380-34-5 is not used in the manufacture of or formulation of this product.

Composting - CEN Standard prEN 13432

This product is not suitable for composting.

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7.4 RoHS Directive 2011/65/EU (incl. amendment 2015/863/EU)

Directive 2011/65/EU of the European Union on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) becomes operative as from the 8th of June, 2011. The list of hazardous substances was updated on the 31th of March 2015 by putting in force directive 2015/863/EU.

DURAN® Glass (printed)
The printing inks used on DURAN® Glass articles to indicate branding, volume graduations, Retrace coding, and other information, are exempt from the RoHS Directive 2011/65/EU.

ANNEX III Applications exempted from the restriction in Article 4(1) are as follows:
1. Laboratory glass products (classified as category 11) fall under Exemption 21 - Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses.
2. Consumer glass products (classified as category 1 - 7) Lead and Cadmium are not used in the manufacture of the printing inks.

7.5 Heavy Metals

In the following, a summary of tests performed by an independent specialized laboratory concerning testing on

Lead and Cadmium release – analysis according to directive 2005/31/EC of DURAN® Laboratory bottles

Applied analytical techniques:
The sample was exposed to 4% acetic acid for 24 hours at 22°C, as given in DIN EN 1388-1 and according to the regulations of directive 2005/31/EC. The lead and cadmium content of the extraction solution was determined via inductively coupled plasma atomic-emission spectroscopy (ICP-OES).

Analytical findings

	Dim.	Result	Limit acc. to 2005/31/EC	Limit acc. to FDA
Lead (Pb)	µg/l	<5	4000	2000
Cadmium (Cd)	µg/l	<0,5	300	500

Assessment
The concentrations of lead and cadmium within the extraction solutions are clearly below the limits. The sample, as analysed, complies with the requirements given in Directive 2005/31/EC and EU Regulation No. 1935/2004 as well as the requirements of FDA (CPG 7117.06) and FDA (CPG 7117.07).

The test results verify that DURAN® glass is compliant with the above mentioned regulations.

7.6 Conflict Minerals

With respect to the Dodd-Frank Wall Street Reform and Consumer Protection Act, we hereby confirm that DURAN® glass does not contain any of the so-called Conflict Minerals as defined in Sec. 1502 of said Act.

- Gold
- Tungsten
- Tantalum
- Tin

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We cannot exclude the possibility that traces of these elements may be present, but below the limits of detection.

7.7 Latex, natural rubber

We hereby confirm that DURAN® glass does not contain naturally occurring latex, natural rubber as intentionally added components during the manufacturing of DURAN® glass products. Please note that analysis of the raw materials and/or finished goods for presence of the above mentioned substances is not performed on a routine basis.

7.8 Allergens

We hereby confirm that no ingredients or processing aids listed in Annex II of Regulation (EU) No. 1169/2011, causing allergies or intolerances, have been used in the manufacture or preparation of the above mentioned DURAN® glass products. Please note that analysis of the raw materials and/or finished goods for presence of the above mentioned substances is not performed on a routine basis.

7.9 Nitrosamine

We hereby confirm that no nitrosamines and no nitrosamine containing materials are used as raw materials nor used during the manufacturing process of all primary glass packaging products manufactured from DURAN® borosilicate glass 3.3.

7.10 Kosher

We hereby confirm that DURAN® glass complies with the Kashrut regulations for the preparation and consumption of food and beverages. DURAN® glass does not contain any substances that are forbidden according to the Jewish kosher standards. Therefore, DURAN® glass can be classified as kosher in accordance to the Halakha.This statement was confirmed with the rabbi Vernikowsky of the Jewish community of Mainz.

8 Technical safety information sheet for DURAN® Glass

1. Identification of the substance/preparation and of the company

Trade name: DURAN®

Identification of the material: Borosilicate glass 3.3 (special glass)

CAS number: 65997-17-3

Use: Manufacture of laboratory glassware, industrial glassware, special industrial glassware, glass for use in pharmaceutical manufacturing processes and glass for electrical household appliances and other household items.

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Manufacturer:

DWK Life Sciences GmbH
Otto-Schott-Straße 21
D-97877 Wertheim / Main
technical@DWK.com

Telephone number: +49 (0)9342 / 802-0; Fax: +49 (0) 9342 / 802-110

2. Potential hazards

In the event of glass breakage, risk of injury from shards. In the event of high and long term exposure to dust (e.g. caused by machining) there is a risk of silicosis.

3. Composition/information on ingredients

DURAN® has the following approximate composition (in % by weight):

SiO_2	B_2O_3	Na_2O & K_2O	Al_2O_3
81%	13%	4%	2%

4. First aid measures

If in contact with the skin
Wash dust off thoroughly with soap and water; if there are glass splinters, consult a doctor.

If in contact with the eyes
Rinse dust out with running water; if there are glass splinters, consult an eye specialist.

If swallowed
Consult a doctor.

If inhaled
As dust: ensure a good supply of fresh air; consult a doctor.

5. Fire fighting measures

Suitable extinguishing agents
Material itself is non-flammable. Select extinguishing agents according to the surrounding fire.

Special hazards caused by the substance, its products of combustion or resulting gases
In the event of hot glass coming into contact with cold extinguishing agent, there is a risk of flying splinters.

Special protective equipment for combating the fire
Possibly a safety helmet with eye protection (due to risk of splinters).

6. Accidental release measures

Personal precautionary measures

In the event of dust accumulation against the wind direction, remove and use P2 dust mask.

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Environmental protection measures
None required.

Cleaning/collection procedures
Physical collection, risk of injury from shards in the event of glass breakage.

7. Handling and storage

Handling
Avoid dust accumulation. Do not eat, drink or smoke at the workplace. Ensure good personal hygiene. With standard applications, do not heat to over 500°C. T_g: 525°C
Heating beyond 525°C will result in softening of the material.

Storage
Items should be stored dry and/or under normal conditions.

8. Exposure control and personal protection equipment

Additional information on the design of technical installations
In the event of dust accumulation and heating the material to over 825°C, an extraction system should be provided.

Components with workplace related limit values that have to be monitored

Component	MAK
Quartz	0.15
mg/m^3 F Dust	6
mg/m³ F	

Personal protection equipment
When handling this product, observe general hygiene measures.

Respiratory protection: In the event of dust accumulation use P2 mask.
Hand protection: To prevent cuts, wear cut resistant gloves.
Eye protection: In the event of splintering, wear safety glasses.

9. Physical and chemical properties

Form:	Solid
Colour:	Transparent
Odour:	Odourless
Transformation temperature T_g:	
	5
25°C	
Density ρ at 25°C:	2.23 g • cm^{-3}
Solubility in water:	
Insoluble	

10. Stability and reactivity

Thermal decomposition, hazardous reactions, hazardous decomposition products
Not stated

For standard applications, do not heat beyond T_g 525°C.

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11. Toxicological information

According to our experience, the material has no effects on health when used and handled according to specifications. The material is physiologically harmless.

12. Ecological information

Environmentally neutral, biologically inert. Not biologically degradable, insoluble in water.

13. Disposal instructions

Disposal in accordance with official regulations.

14. Transport information

Not hazardous goods as defined by transport regulations.

15. Statutory provisions

Not a hazardous working material as defined by the Chemicals Act or the Ordinance on Hazardous Substances.

16. Other information

With the above statements, which are in line with the current status of our knowledge and experience, we aim to describe our product with regard to any safety requirements, but do not provide any guarantee or assurance of properties. Users are responsible for examining and testing our material in order to be satisfied that the material is suitable for the specific application. Users are also responsible for appropriate, safe and legal usage, as well as for the processing and handling of our material.

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9 Packaging

Articles are packed and controlled according to valid DWK Life Sciences packaging standard, to ensure that there will be no damage (within the capability of the packaging) or loss in transit production/packaging/storage at DWK Life Sciences and delivery to customer.

The EURO palettes used are identified according to IPPC-DE-HE 493027 HT/DB. A confirmation of the manufacturer in accordance with IPP-ISPM 15 exists.

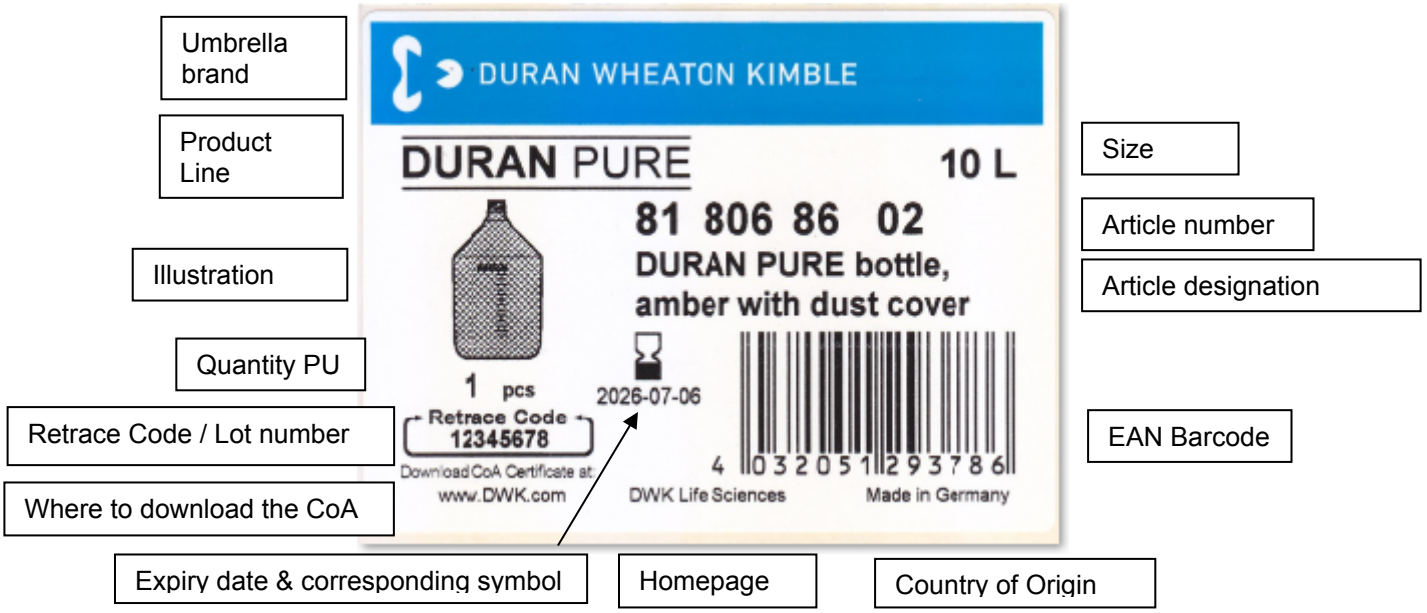
10 Identification

Each packaging unit is identified with a label and each pallet with a DWK Life Sciences pallet note containing the following information:

- Manufacturer
- Article drawing
- Article-number (DWK - pallet note)
- Article description
- Retrace Code (lot number)
- Pallet number (DWK - pallet note)
- Production date (DWK - pallet note)
- Packaging unit and number of pieces
- EAN-Barcode
- Expiry date (label)

Single cardboard boxes are identified by a label according to packaging standard.

Example using the 10000ml label:



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11 Storage

Recommended Shelf-life

DWK recommends a 5-year shelf life from the date of manufacture (as indicated by the YYYY-MM-DD expiry date stated on the PURE Bottle packaging labels, and Certificates of Analysis CoAs) if stored under the recommended storage conditions.

Recommended storage conditions:

Storage in a Dry Place (less than 40% relative humidity) with a Controlled Room Temperature (20-25°C) as defined in USP <659>. Avoid exposing products to sunlight and other sources of ultra-violet light (UV). Excursions during storage in warehouses and during shipping are allowed.

12 Waste management

DURAN® glass is compliant with the requirements of the following guidelines, laws and regulations: 94/62/EC (VerpackV) – Packaging and Packaging Waste.

13 Complaints

To register a complaint please contact your distributor and the DWK Life Sciences service team by using the following email address: complaint@dwk.com

Reasons for an objection are only exceeded quality limits or characteristics defined in this article specification.
Because of costs caused by reworking, sorting out, destruction or return consignment of defect articles, the customer has to talk directly with a person in charge of DWK Life Sciences before processing the complaint.

The following information beside the reason for the complaint needed:

- Article description
- Article number
- Retrace Code
- Pallet number
- Order number and/or Invoice number
- Quantity of defect articles / total delivery quantity
- Delivery date at customer
- Manufacturing date
- Delivery note number

In addition a sample of the defect article has to be provided.

14 Appendices

- Valid article drawing
- Valid thread drawing
- Valid specification and drawing of protective cover