

Accredited Testing Laboratories SCHOTT

Complete list of all accredited test methods in the flexible scope of accreditation according to D-PL-14645-01-00

The testing laboratory hereby publishes the list of all test methods in the flexible scope of accreditation.

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Updates/changes are marked in **green**. Newly introduced procedures according to category I or II are marked with "NEW in flexible scope".

Within the marked testing areas the laboratory is permitted, without prior information or approval of German accreditation body (DAkKS),

- 1) the free selection of standardized testing procedures or procedures equivalent to them.
- 2) the modification of testing procedures as well as new development of testing procedures.
- 3) the use of standardized testing procedures or procedures equivalent to them with different issue dates.

The original DAkKS accreditation certificate incl. annex can be found under www.dakks.de, Accredited Bodies, D-PL-14645-01-00. The testing procedures listed there are exemplary.

Tests are carried out in the following working areas:

Determination of the chemical composition of glasses, glass ceramics, oxide raw and inorganic materials as well as inorganic and organic liquids; Determination of the chemical resistance and ionic release of the surfaces of glass, glass ceramics and decorations;

Determination of physical properties (thermal, thermodynamic, elastic electrical, optical and surface properties) of glasses, glass ceramics, ceramics and composites, as well as the calculation of derived parameters from these metrics; Qualitative and quantitative analysis of the elemental depth profiles in glasses, glass ceramics, ceramics and thin films; High-resolution imaging of glasses, glass ceramics, powders, metals, finishes, coatings and fracture surfaces; Investigations on glasses, glass products and molds in the framework of defect and failure analysis; Determination of geometrical parameters (e.g. pore size, particle size, layer thickness, roughness); Determination of solid glass defects in glasses and glass ceramics in/ at/ on surfaces in the framework of glass defect diagnosis; Investigation of corrosion processes, leaching and hydration; Strength tests and fracture analysis (Fractography) of glasses, glass ceramics, plastics and composite materials (material and product properties); Determination of the volume fractions of gaseous substances in inclusions of oxide materials such as glasses and glass ceramics; Analysis of pharmaceutical packaging and their components regarding extractable and leachable constituents, contaminations and corrosion products.

Locations:

Otto-Schott-Straße 2, 55127 Mainz
Hattenbergstraße 10, 55122 Mainz
400 York Ave, Duryea/PA 18642 USA

Contents

Laboratory site Otte-Schott-Str. 2, 55127 Mainz

1 Determination of the concentrations and valence states of elements in glasses, glass ceramics, ceramics and other anorganic materials, glass- and ceramic raw materials, materials for treatment of glass surfaces (e.g. decoration colors), as well as other samples/materials (e.g. dust, sludge, condensates, water, eluates, metals, alloys, special steels) in combination glass production.....	6
1.1 Sample preparation, digestion methods (open digestions, melting digestion techniques, digestions in closed systems) ²⁾	6
1.2 by wet chemistry procedures	7
1.2.1 by Titrimetry ²⁾	7
1.2.2 by Gravimetry ²⁾	7
1.3 by spectrometric methods (FAAS, HG-AAS, CV-AAS, GFAAS, ICP-OES, ICP-MS, UV-VIS)	8
1.3.1 Atomic Absorption Spectrometry (FAAS, HG-AAS, CV-AAS, GFAAS) ²⁾	8
1.3.2 by Inductively Coupled Plasma (ICP-OES) ¹⁾	9
1.3.3 by Inductively Coupled Plasma and mass-selective detection (ICP-MS) ²⁾	10
1.3.4 UV/VIS-Spectrophotometry ²⁾	10
1.4 by Ion Chromatography (IC) ¹⁾	11
1.5 by solid state methods (XRF, Laser-ICP-MS, VGA/TGHE)	11
1.5.1 X-Ray Fluorescence-Analysis (XRF) ²⁾	11
1.5.2 Laser Ablation Inductively Coupled Plasma-Mass Spectrometry (LA-ICP-MS) ²⁾	12
1.5.3 Combustion Analysis/Carrier gas hot extraction (VGA/TGHE) ²⁾	12
2 Determination of the chemical resistance of glasses, glass ceramics, decorations on glasses or glass ceramics and other materials.....	13
2.1 Determination of resistance to liquid media	13
2.1.1 Ion release of surface	13
2.1.1.1 Sample preparation by extraction and leaching procedures ²⁾	13
2.1.1.2 by Titrimetry ¹⁾	14
2.1.1.3 by Atomic Absorption Spectrometry (FAAS, HG-AAS, GFAAS) ²⁾	16
2.1.1.4 by Inductively Coupled Plasma (ICP-OES) ²⁾	17
2.1.1.5 by Inductively Coupled Plasma with mass-selective detection (ICP-MS) ²⁾	20
2.1.1.6 by electrode measurement ¹⁾	22
2.1.1.7 by Ion Chromatography (IC) ³⁾	22
2.1.2 Mass loss and/or time needed for defined removal in μm by differential weighing and visual inspection ²⁾	23
2.1.3 Staining, Color and Gloss changes, Abrasion Resistance	24
2.1.3.1 Visual Inspection ²⁾	24
2.1.3.2 Differential weighing and visual inspection ¹⁾	24

2.2 Determination of the resistance against changing climate (humidity, temperature) by climate test chamber ²⁾	25
3 Thermal Characterization of glasses, glass ceramics, ceramics, sinter glasses, composites with glass or glass ceramic as well as raw materials of glass industry.....	25
3.1 Testing of thermal expansion (static, dynamic) of glasses, glass ceramics and plastics by inductive and optical methods for a temperature range of -180°C to 1300°C ²⁾	25
3.2 Determination of viscosity of glasses for a viscosity range of 100-5 x 10 ¹³ dPa s ²⁾	25
3.3 Determination of the rheological parameters of solids, slurries and highly viscous liquids ²⁾	27
3.4 Determination of the density of glasses, glass ceramics, ceramics and other materials ¹⁾	27
3.5 Thermal analysis (differential thermal analysis (DTA), differential scanning calorimetry (DSC) and calorimetry (specific heat)) on glasses, glass ceramics, ceramics and raw materials (powders) ²⁾	27
3.6 Determination of the thermal diffusivity of solids by flash method and calculation of the thermal conductivity ¹⁾	28
3.7 Determination of seal stress in glass by polarization microscopy ³⁾	28
3.8 Determination of crystallization properties of glasses by gradient furnace method ²⁾	28
3.9 Determination of Young`s Modulus, Shear Modulus and Poisson`s constant of glass, glass ceramic and ceramic by resonance method ²⁾	28
4 Electrical characterization of glasses, glass-ceramics, ceramics and other materials	28
4.1 Determination of the electrical contact resistance of glasses, glass-ceramics, ceramics and other materials ²⁾	28
5 Optical characterization of glasses, glass ceramics, ceramics, sintered glasses, composites with glass or glass ceramics as well as raw materials of the glass industry.....	29
5.1 Determination of transmission, reflection, remission, scattered light/haze, solarization, spectral color measurement, refractive index and dispersion, fluorescence of glasses, glass ceramics, liquids by spectroscopy ²⁾	29
5.2 Ellipsometric characterization of coatings and uncoated materials ²⁾	30
5.3 Stress measurements and stress-optical coefficient ²⁾	30
6 Characterization of glasses, glass ceramics, ceramics, metals, plastics and composite materials in micro and surface area.....	30
6.1 by Scanning Electron Microscopy/Energy Dispersive X-ray spectroscopy (SEM/EDX) ²⁾	30
6.2 by topographic methods (WLI, AFM, Laser-Interferometry) ²⁾	31
6.3 by Light Microscopy ²⁾	31
6.4 by Time-of-Flight-Secondary Ion Mass Spectrometry (ToF-SIMS) ²⁾	32
6.5 by Vibrational Spectroscopy ³⁾	32
7 Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾	32
8 Fracture analysis (fractography) on glasses, glass ceramics, ceramics and plastics by light microscopic methods ²⁾	34

9 Determination of the volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by mass spectrometry and Raman spectroscopy ²⁾	34
10 Analysis of pharmaceutical packaging and their components regarding extractable and leachable constituents, contaminations and corrosion products	35
10.1 Sample preparation ³⁾	35
10.2 by gas chromatography (GC-MS) ²⁾	35
10.3 by Liquid Chromatography (LC-MS) ²⁾	36
10.4 by Inductively Coupled Plasma (ICP-OES) ²⁾	36
10.5 by Inductively Coupled Plasma and mass-selective detection (ICP-MS) ²⁾	36
10.6 by UV-VIS-Spectrophotometry ³⁾	37
10.7 by Infrared Spectroscopy (IR) ³⁾	37
10.8 by Visual Inspection and Optical Microscopy ¹⁾	37
10.9 by Scanning Electron Microscopy/Energy Dispersive X-ray spectroscopy (SEM/EDX) ²⁾	38
10.10 by Raman Spectroscopy ³⁾	39

Laboratory site Hattenbergstraße 10, 55122 Mainz

1 Testing of thermal expansion (static, dynamic) of glasses, glass ceramics, ceramics, sinter materials, plastics and composites by inductive and optical methods for a temperature range of -50°C to +100°C ²⁾	40
2 Determination of optical properties (transmission and derived parameters, refractive index and dispersion) preferably on glasses by optical spectroscopy and optical refractography ²⁾	40
3 Determination of the density of glasses, glass ceramics, ceramics and other materials ³⁾	40

Laboratory site 400 York Ave, Duryea/PA 18642 USA

1 Characterization of glasses, glass ceramics, ceramics, metals, plastics and composite materials in micro and surface area as well as fracture analysis (fractography)	41
1.1 by Scanning Electron Microscopy/ Energy Dispersive X-ray spectroscopy (SEM/EDX) ²⁾	41
1.2 by Light Microscopy Methods ²⁾	41
2 Analysis of pharmaceutical packaging and their components regarding contaminations and corrosion products	41
2.1 by Visual Inspection and Optical Microscopy ¹⁾	41
2.2 by Scanning Electron Microscopy/ Energy Dispersive X-ray spectroscopy (SEM/EDX) ²⁾	42
2.3 by Inductively Coupled Plasma (ICP-OES) ¹⁾	42
2.4 by electrode measurement ¹⁾	42
3 Determination of the mass contents of elements in glasses, glass ceramics, ceramics and other anorganic materials, glass and ceramic raw materials	42

3.1 Sample preparation, digestion methods (open digestions, melting digestion techniques) ²⁾	42
3.2 by Optical Emission Spectroscopy with Inductively Coupled Plasma (ICP-OES) ³⁾	43

Laboratory location Otto-Schott-Straße 2, 55127 Mainz

1 Determination of the concentrations and valence states of elements in glasses, glass ceramics, ceramics and other anorganic materials, glass- and ceramic raw materials, materials for treatment of glass surfaces (e.g. decoration colors), as well as other samples/materials (e.g. dust, sludge, condensates, water, eluates, metals, alloys, special steels) in combination glass production

1.1 Sample preparation, digestion methods (open digestions, melting digestion techniques, digestions in closed systems)²⁾

ISO 10058-1 2008-12	Chemical analysis of magnesite and dolomite refractory products (alternative to the X-ray fluorescence method) - Part 1: Apparatus, reagents, dissolution and determination of gravimetric silica	NEW in flexible scope
DIN EN ISO 10058-1 2009-09	Chemical analysis of magnesite and dolomite refractory products (alternative to the X-ray fluorescence method) - Part 1: Apparatus, reagents, dissolution and determination of gravimetric silica	
ISO 21587-1 2007-02	Chemical analysis of aluminosilicate refractory products (alternative to the X-ray fluorescence method) - Part 1: Apparatus, reagents, dissolution and gravimetric silica	NEW in flexible scope
DIN EN ISO 21587-1 2007-12	Chemical analysis of aluminosilicate refractory products (alternative to the X-ray fluorescence method) - Part 1: Apparatus, reagents, dissolution and gravimetric silica	
DIN 52331 1995-05	Testing of glass – Crushing and drying of samples for chemical analysis (withdrawn standard)	
DIN 52340-3 1990-07	Testing of glass - Chemical analysis of colorless soda-lime-glass with SiO ₂ , CaO, MgO and Na ₂ O as main constituents; Decomposition methods - (withdrawn standard)	
DIN 52342-2 1980-01	Testing of raw materials for the production of glass - Chemical analysis of arenaceous quartz with at least 98 % silica,	

Part 2: Fusion process for the determination of Al₂O₃, Fe₂O₃ and TiO₂ as well as CaO, MgO, Na₂O and K₂O - (Modification: Application for further oxides)

01_SOP_00480
2018-02 Special digestion procedures for glasses, glass ceramics, ceramics, raw materials and other materials

1.2 by wet chemistry procedures

1.2.1 by Titrimetry²⁾

ISO 21078-1
2008-01 Determination of boron (III) oxide in refractory products - Part 1: Determination of total boron (III) oxide in oxidic materials for ceramics, glass and glazes NEW in flexible scope

DIN EN ISO 21078-1
2008-04 Determination of boron (III) oxide in refractory products - Part 1: Determination of total boron (III) oxide in oxidic materials for ceramics, glass and glazes (Modification: Digestion, no reprecipitation)

ChP 4009
2020-11 Determination of Boron Oxide NEW in flexible scope

YBB00232003-2015
2015-00 Determination of Boron Oxide

01_SOP_00475
2018-02 Titrimetric determination of main and minor components in glasses, glass ceramics and raw materials

1.2.2 by Gravimetry²⁾

ISO 247-1
2018-07 Rubber - Determination of ash - Part 1: Combustion method

ISO 8871-2
2020-05 Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization NEW in flexible scope

DIN EN ISO 8871-2
2020-09 Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization - (text in German and English)

DIN 51081 2002-12	Testing of oxidic raw materials and materials - Determination of change in mass on ignition - (Modification: material-related temperatures, sample amounts)
DIN 52340-2 1974-01	Testing of glass - Chemical analysis of colorless soda-lime-glass with SiO ₂ , CaO, MgO and Na ₂ O as main constituents; Part 2: Determination SiO ₂ (withdrawn standard)
01_SOP_00479 2018-02	Gravimetric determination of main and minor components in glasses, glass ceramics and raw materials

1.3 by spectrometric methods (FAAS, HG-AAS, CV-AAS, GFAAS, ICP-OES, ICP-MS, UV-VIS)

1.3.1 Atomic Absorption Spectrometry (FAAS, HG-AAS, CV-AAS, GFAAS)²⁾

ISO 10058-3 2008-12	Chemical analysis of magnesite and dolomite refractory products (alternative to the X-ray fluorescence method) - Part 3: Flame atomic absorption spectrophotometry (FAAS) and inductively coupled plasma atomic emission spectrometry (ICP-AES)	NEW in flexible scope
DIN EN ISO 10058-3 2009-09	Chemical analysis of magnesite and dolomite refractory products (alternative to the X-ray fluorescence method) - Part 3: Flame atomic absorption spectrophotometry (FAAS) and inductively coupled plasma atomic emission spectrometry (ICP-AES)	
DIN 52340-11 1997-11	Testing of glass - Chemical analysis of colorless soda-lime-glass with SiO ₂ , CaO, MgO und Na ₂ O as main constituents Part 11: Determination of BaO, CaO, MgO, Al ₂ O ₃ , Fe ₂ O ₃ , Cr ₂ O ₃ with FAAS and Na ₂ O and K ₂ O with FAES (withdrawn standard) (Modification: Applicatin on special glasses and glass ceramics, further elements, AAS-detection)	
DIN 52341 1993-10	Testing of glass - Chemical analysis of lead crystal glass and crystal glass (withdrawn standard) (Modification: Application on special glasses and glass ceramics, further elements)	

DIN 52342-7 1980-01	Testing of raw materials for the production of glass Chemical analysis of arenaceous quartz with at least 98 % silica Part 7: Determination of Na ₂ O and K ₂ O (standard withdrawn) (Modification: Detection with ICP-OES or FAAS)
01_SOP_00394 2018-02	Determination of alkaline and alkaline earth oxides in raw materials and materials by flame atomic absorption spectrometry (FAAS)
ICG/TC 2 - Handbook of recommended analytical methods, ISBN 92-95041-01-01, p.23 ff 2009-02	Determination of mercury in glass by cold vapour atomic absorption spectrometry (CVAAS)

1.3.2 by Inductively Coupled Plasma (ICP-OES)¹⁾

ISO 10058-3 2008-12	Chemical analysis of magnesite and dolomite refractory products (alternative to the X-ray fluorescence method) - Part 3: Flame atomic absorption spectrophotometry (FAAS) and inductively coupled plasma atomic emission spectrometry (ICP-AES)	NEW in flexible scope
DIN EN ISO 10058-3 2009-09	Chemical analysis of magnesite and dolomite refractory products (alternative to the X-ray fluorescence method) - Part 3: Flame atomic absorption spectrophotometry (FAAS) and inductively coupled plasma atomic emission spectrometry (ICP-AES)	
ISO 11885 2007-08	Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)	NEW in flexible scope
DIN EN ISO 11885 2009-09	Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES) (Modification: Application to digestions solutions, further elements)	

DIN 51086-2
2004-07

Testing of oxidic raw materials and materials for ceramics, glass and glazes - Part 2: Determination of Ag, As, B, Ba, Be, Bi, Ca, Cd, Ce, Co, Cr, Cu, Er, Eu, Fe, La, Mg, Mn, Mo, Nd, Ni, P, Pb, Pr, S, Sb, Se, Sn, Sr, Ti, V, W, Y, Yb, Zn, Zr by optical emission spectrometry with inductively coupled plasma (ICP-OES) -
(Modification: Determination of further elements)

1.3.3 by Inductively Coupled Plasma and mass-selective detection (ICP-MS)²⁾

ISO 17294-2
2016-07

Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 2: Determination of selected elements including uranium isotopes

NEW in flexible scope

DIN EN ISO 17294-2
2017-01

Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 2: Determination of selected elements including uranium isotopes
(Modification: Application to digestion solutions)

01_SOP_00478
2018-02

Semi-quantitative trace analysis of glasses, glass ceramics, raw materials and materials, dusts after sample digestion as well as aqueous extracts by ICP-MS

1.3.4 UV/VIS-Spectrophotometry²⁾

ISO 14719
2011-12

Chemical analysis of refractory material glass and glazes - Determination of Fe²⁺ and Fe³⁺ by the spectral photometric method with 1,10-phenanthroline

NEW in flexible scope

DIN EN ISO 14719
2012-03

Chemical analysis of refractory material glass and glazes - Determination of Fe²⁺ and Fe³⁺ by the spectral photometric method with 1,10-phenanthroline

DIN 51084
2008-11

Testing of oxidic raw and basic materials for ceramic, glass and glazes - Determination of fluoride content

DIN 51086-3
2007-04

Testing of oxidic raw and basic materials for ceramics, glass and glazes - Part 3: Spectrophotometric determination of chrome(VI) with diphenyl carbazide in the presence of chrome(III)

01_SOP_00481
2018-02 Spectrophotometric determination of halides and arsenic in glasses, glass ceramics, raw materials and refractory materials

01_SOP_00482
2018-02 Spectrophotometric determination of metal species in glasses, glass ceramics, raw materials and refractory materials

1.4 by Ion Chromatography (IC)¹⁾

ISO 10304-1
2007-08 Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate
(Modification: Determination, also of further anions, in aqueous extracts and digestion solutions and after combustion in solid samples) NEW in flexible scope

ISO 10304-1 Tech Corr
1
2010-05 Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate; Technical Corrigendum 1
(Modification: Determination, also of further anions, in aqueous extracts and digestion solutions and after combustion in solid samples) NEW in flexible scope

DIN EN ISO 10304-1
2009-07 Water quality -
Determination of dissolved anions by liquid chromatography of ions -
Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate
(Modification: Determination, also of further anions, in aqueous extracts and digestion solutions and after combustion in solid samples)

DIN 51084
2008-11 Testing of oxidic raw and basic materials for ceramic, glass and glazes - Determination of fluoride content

1.5 by solid state methods (XRF, Laser-ICP-MS, VGA/TGHE)

1.5.1 X-Ray Fluorescence-Analysis (XRF)²⁾

ISO 12677
2011-10 Chemical analysis of refractory products by X-ray fluorescence (XRF) - Fused cast-bead method NEW in flexible scope

DIN EN ISO 12677 2013-02	Chemical analysis of refractory products by X-ray fluorescence (XRF)- Fused cast-bead method
DIN 51001 2003-08	Testing of oxidic raw materials and basic materials - General bases of work for X-ray fluorescence method (XRF)
DIN 51001 Beiblatt 2010-05	Testing of oxidic raw materials and basic materials - General bases of work for X-Ray fluorescence method (XRF) - General survey on disintegration methods referred to groups of materials for the determination of test specimens for XRF
DIN 51418-2 2015-03	X-ray spectrometry - X-ray emission- and X-ray fluorescence analysis (XRF) - Part 2: Definitions and basic principles for measurements, calibration and evaluation of results
01_SOP_00483 2021-05	Semi-quantitative determination of the composition of unknown glasses, glass ceramics, raw materials and materials, dusts, pigments, metals and residues by WD-XRF as well as micro-area analysis with SSM-EDX module

1.5.2 Laser Ablation Inductively Coupled Plasma-Mass Spectrometry (LA-ICP-MS)²⁾

ASTM E 2927 2016-00	Standard Test Method for Determination of Trace Elements in Soda-Lime Glass Samples Using Laser Ablation Inductively Coupled Plasma Mass Spectrometry
01_SOP_00484 2018-02	Determination of trace components and ultratraces in glasses, glass ceramics and metals by Laser Ablation - Inductively Coupled Plasma Mass Spectrometry (LA-ICP-MS)

1.5.3 Combustion Analysis/Carrier gas hot extraction (VGA/TGHE)²⁾

ISO 14720-1 2013-03	Testing of ceramic raw and basic materials - Determination of sulfur in powders and granules of non-oxidic ceramic raw and basic materials - Part 1: Infrared measurement methods	NEW in flexible scope
DIN EN ISO 14720-1 2013-06	Testing of ceramic raw and basic materials - Determination of sulfur in powders and granules of non-oxidic ceramic raw and basic materials -	

Part 1: Infrared measurement methods

ISO 15350 2000-12	Steel and iron - Determination of total carbon and sulfur content - Infrared absorption method after combustion in an induction furnace (routine method)	NEW in flexible scope
DIN EN ISO 15350 2010-08	Steel and iron - Determination of total carbon and sulfur content - Infrared absorption method after combustion in an induction furnace (routine method)	
DIN 19539 2016-12	Investigation of solids - Temperature-dependent differentiation of total carbon (TOC400, ROC, TIC900)	
DIN 51085 2022-09	Testing of oxidic raw and basic materials – Determination of total sulphur content	
01_SOP_00485 2018-02	Determination of water, carbon, oxygen and nitrogen in glasses, glass ceramics, raw materials and metals by gas analysis (VGA/TGHE)	

2 Determination of the chemical resistance of glasses, glass ceramics, decorations on glasses or glass ceramics and other materials

2.1 Determination of resistance to liquid media

2.1.1 Ion release of surface

2.1.1.1 Sample preparation by extraction and leaching procedures²⁾

DIN EN 12457-2 2003-01	Characterization of waste – Leaching; Compliance test for leaching of granular and sludges - Part 2: One stage batch test at a liquid to solid ratio of 10 l/kg with particle size below 4 mm (without or with size reduction); (Modification: Application on glass)	
Ph. Eur. 3.2.9 2020-12	European Pharmacopoeia - 3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze- dried powders - Sample preparation of Solution S	
USP <1660> 2013-12	Evaluation of the inner surface durability of glass containers	

01_SOP_00474 2018-02	Chemical durability and extractable components of glasses and glass ceramics and other materials (Extractables and Leachables): Procedures for stresses, extraction and leaching of glasses and glass ceramics	
2.1.1.2 by Titrimetry¹⁾		
ISO 4802-1 2016-06	Glassware - Hydrolytic resistance of the interior surfaces of glass containers - Part 1: Determination by titration method and classification (in accordance with DIN EN ISO 4802-1, 2012-12)	
DIN ISO 4802-1 2017-02	Glassware - Hydrolytic resistance of the interior surfaces of glass containers - Part 1: Determination by titration method and classification (in accordance with DIN EN ISO 4802-1, 2012-12)	NEW in flexible scope
ISO 719 2020-09	Glass - Hydrolytic resistance of glass grains at 98 °C - Method of test and classification	NEW in flexible scope
DIN ISO 719 2021-12	Glass - Hydrolytic resistance of glass grains at 98 °C - Method of test and classification	
ISO 720 2020-09	Glass - Hydrolytic resistance of glass grains at 121 °C - Method of test and classification	NEW in flexible scope
DIN ISO 720 2021-12	Glass - Hydrolytic resistance of glass grains at 121 °C - Method of test and classification	
ChP 4001 2020-11	Test for hydrolytic resistance of glass grains at 121 °C - Determination of 121°C glass particle water resistance	NEW in flexible scope
ChP 4006 2020-11	Test and classification for hydrolytic resistance of interior surfaces	NEW in flexible scope

Test and classification for hydrolytic resistance of interior surfaces - Determination of internal surface water resistance

JP 18th edition 2021-06	Japanese Pharmacopoeia - 7. Test for Containers and Packing Materials - 7.01. Test for Glass Containers for Injections
Ph. Eur. 3.2.1 2019-01	European Pharmacopoeia - 3.2. Containers - 3.2.1. Glass containers for pharmaceutical use - Test A: Hydrolytic resistance of the inner surfaces of glass containers (Surface Test) - Test B: Hydrolytic resistance of glass grains (Glass Grains Test) - Test C: To determine whether the containers have been surface treated (Etching Test) - 3.2.9. Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders - Test: Acidity or Alkalinity Test: Reducing substances
USP <660> 2015-05	USP <660>, Containers-Glass - Chemical Resistance - Glass Grains Test - Surface Glass Test - Surface Etching Test
YBB00242003-2015 2015-00	Tests and classification for hydrolytic resistance of Interior Surfaces at 121°C
YBB00252003-2015 2015-00	Tests and Classification for Hydrolytic Resistance of Glass Grains at 121°C
YBB00362004-2015 2015-00	Test and Classification for Hydrolytic Resistance of Glass Grains at 98°C

2.1.1.3 by Atomic Absorption Spectrometry (FAAS, HG-AAS, GFAAS)²⁾

ISO 4802-2 2016-06	Glassware - Hydrolytic resistance of the interior surfaces of glass containers – Part 2: Determination by flame spectrometry and classification	
DIN ISO 4802-2 2017-02	Glassware - Hydrolytic resistance of the interior surfaces of glass containers – Part 2: Determination by flame spectrometry and classification	NEW in flexible scope
ISO 6486-1 2019-08	Ceramic ware, glass ceramic ware and glass dinnerware in contact with food - Release of lead and cadmium - Part 1: Test method	
ISO 10136-2 1993-07	Glass and glassware: Analysis of extract solutions - Part 2: Determination of sodium oxide and potassium oxide by flamespectrometric methods	
ISO 10136-3 1993-07	Glass and glassware: Analysis of extract solutions - Part 3: Determination of calcium oxide and magnesium oxide by flame atomic absorption spectrometry	
ISO 4531 2022-04	Vitreous and porcelain enamels - Release from enamelled articles in contact with food - Methods of test and limits	NEW in flexible scope
DIN EN ISO 4531 2022-08	Vitreous and porcelain enamels - Release from enamelled articles in contact with food - Methods of test and limits	
ISO 1776 1985-10	Glass - Resistance to attack by hydrochloric acid at 100 degrees C; Flame emission or flame atomic absorption spectrometric method	NEW in flexible scope
DIN ISO 1776 1988-05	Glass - Resistance to attack by hydrochloric acid at 100 °C -	

Flame emission or flame atomic absorption spectrometric method

DIN 52296
1989-12

Glass and glass ceramics -
Hydrolytic resistance of the surface of glass and glass ceramic plates at 98 °C -
Method of test and classification

DIN EN 1388-1
1995-11

Materials and articles in contact with foodstuffs -
Silicate surfaces -
Part 1: Determination of the release of lead and cadmium from ceramic ware

DIN EN 1388-2
1995-11

Materials and articles in contact with foodstuffs -
Silicate surfaces -
Part 2: Determination of the release of lead and cadmium from silicate surfaces other than ceramic ware

Ph. Eur. 3.2.1
2019-01

European Pharmacopoeia -
3.2. Containers -
3.2.1. Glass containers for pharmaceutical use -
Annex - Test for surface hydrolytic resistance-
determination by flame atomic absorption spectrometry (FAAS) -
Arsenic (HGAAS)

01_SOP_00473
2018-02

Determination of silicone in organic extracts by Graphite Furnace-Atomic Absorption Spectrometry (GFAAS)

2.1.1.4 by Inductively Coupled Plasma (ICP-OES)²⁾

ISO 4802-2
2016-06

Glassware-
Hydrolytic resistance of the interior surfaces of glass containers -
Part 2: Determination by flame spectrometry and classification
(Modification: Determination of further cations with ICP-OES or ICP-MS)

DIN ISO 4802-2
2017-02

Glassware -
Hydrolytic resistance of the interior surfaces of glass containers –
Part 2: Determination by flame spectrometry and classification

NEW in flexible scope

ISO 7086-1 2019-08	Glassware and glass ceramic ware in contact with food - Release of lead and cadmium - Part 1: Method of test (Modification: Detection with ICP-OES or ICP-MS)	
ISO 6486-1 2019-08	Ceramic ware, glass ceramic ware and glass dinnerware in contact with food - Release of lead and cadmium - Part 1: Test method	
ISO 11885 2007-08	Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)	NEW in flexible scope
DIN EN ISO 11885 2009-09	Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)	
ISO 4531 2022-04	Vitreous and porcelain enamels - Release from enamelled articles in contact with food - Methods of test and limits	NEW in flexible scope
DIN EN ISO 4531 2022-08	Vitreous and porcelain enamels - Release from enamelled articles in contact with food - Methods of test and limits	
DIN EN 1388-1 1995-11	Materials and articles in contact with foodstuffs - Silicate surfaces - Part 1: Determination of the release of lead and cadmium from ceramic ware (Modification: Detection with ICP-OES or ICP-MS)	
DIN EN 1388-2 1995-11	Materials and articles in contact with foodstuffs - Silicate surfaces - Part 2: Determination of the release of lead and cadmium from silicate surfaces other than ceramic ware (Modification: Detection with ICP-OES or ICP-MS)	
ISO 1776 1985-10	Glass; Resistance to attack by hydrochloric acid at 100 degrees C; Flame emission or flame atomic absorption spectrometric method	NEW in flexible scope

DIN ISO 1776 1988-05	Glass - Resistance to attack by hydrochloric acid at 100 °C - Flame emission or flame atomic absorption spectrometric method (Modification: Determination of further cations with ICP)
DIN 52296 1989-12	Glass and glass ceramics - Hydrolytic resistance of the surface of glass and glass ceramic plates at 98 °C; Method of test and classification (Modification: Determination of further cations with ICP-OES or ICP-MS)
Ph. Eur. 3.2.1 2019-01	European Pharmacopoeia - 3.2. Containers - 3.2.1. Glass containers for pharmaceutical use - Test A: Hydrolytic resistance of the inner surfaces of glass containers (Surface Test) - Test B: Hydrolytic resistance of glass grains (Glass Grains Test) - Test C: To determine whether the containers have been surface treated (Etching Test) - Annex - Test for surface hydrolytic resistance-determination by flame atomic absorption spectrometry (FAAS) (Modifikation: Bestimmung von weiteren Kationen mit ICP-OES oder ICP-MS)
USP <233> 2018-05	Chemical Test and Assays: Elemental Impurities - Procedures
USP <660> 2015-05	USP <660>, Containers-Glass - Chemical Resistance - Glass Grains Test - Surface Glass Test - Surface Etching Test (Modifikation: Detektion von Kationen mit ICP-OES oder ICP-MS)
01_SOP_00028 2020-10	Trace element analysis of aqueous extracts from glass, glass ceramics and pharmaceutical packaging with ICP-MS or ICP-OES

2.1.1.5 by Inductively Coupled Plasma with mass-selective detection (ICP-MS)²⁾

ISO 3749 2022-03	Glass syringes – Determination of extractable tungsten	NEW in flexible scope
ISO 4802-2 2016-06	Glassware- Hydrolytic resistance of the interior surfaces of glass containers - Part 2: Determination by flame spectrometry and classification (Modification: Determination of further cations with ICP-OES or ICP-MS)	
DIN ISO 4802-2 2017-02	Glassware - Hydrolytic resistance of the interior surfaces of glass containers – Part 2: Determination by flame spectrometry and classification	NEW in flexible scope
ISO 7086-1 2019-08	Glassware and glass ceramic ware in contact with food Release of lead and cadmium Part 1: Method of test (Modification: Detection with ICP-OES or ICP-MS)	
ISO 6486-1 2019-08	Ceramic ware, glass ceramic ware and glass dinnerware in contact with food - Release of lead and cadmium - Part 1: Test method	
ISO 4531 2022-04	Vitreous and porcelain enamels - Release from enamelled articles in contact with food - Methods of test and limits	NEW in flexible scope
DIN EN ISO 4531 2022-08	Vitreous and porcelain enamels - Release from enamelled articles in contact with food - Methods of test and limits	
ISO 17294-2 2016-07	Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 2: Determination of selected elements including uranium isotopes	NEW in flexible scope
DIN EN ISO 17294-2 2017-01	Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 2:	

	Determination of selected elements including uranium isotopes
DIN EN 1388-1 1995-11	Materials and articles in contact with foodstuffs - Silicate surfaces - Part 1: Determination of the release of lead and cadmium from ceramic ware (Modification: Detection with ICP-OES or ICP-MS)
DIN EN 1388-2 1995-11	Materials and articles in contact with foodstuffs - Silicate surfaces - Part 2: Determination of the release of lead and cadmium from silicate surfaces other than ceramic ware (Modification: Detection with ICP-OES or ICP-MS)
DIN 52296 1989-12	Glass and glass ceramics - Hydrolytic resistance of the surface of glass and glass ceramic plates at 98 °C - Method of test and classification (Modification: Determination of further cations with ICP-OES or ICP-MS)
Ph. Eur. 3.2.1 2019-01	European Pharmacopoeia - 3.2. Containers - 3.2.1. Glass containers for pharmaceutical use - Test A: Hydrolytic resistance of the inner surfaces of glass containers (Surface Test) Test B: Hydrolytic resistance of glass grains (Glass Grains Test) Test C: To determine whether the containers have been surface treated (Etching Test) Annex - Test for surface hydrolytic resistance-determination by flame atomic absorption spectrometry (FAAS) (Modifikation: Bestimmung von weiteren Kationen mit ICP-OES oder ICP-MS)
USP <233> 2018-05	Chemical Test and Assays: Elemental Impurities - Procedures
USP <660> 2015-05	USP <660>, Containers-Glass - Chemical Resistance Glass Grains Test Surface Glass Test -

Surface Etching Test
(Modification: Detection of cations with ICP-OES or ICP-MS)

YBB00372004-2015
2015-00 Tests for release of arsenic antimony, lead and cadmium

01_SOP_00028
2020-10 Trace element analysis of aqueous extracts from glass, glass ceramics and pharmaceutical packaging with ICP-MS or ICP-OES

2.1.1.6 by electrode measurement¹⁾

DIN 19268
2021-10 pH-measurement - pH-measurement of aqueous solutions with pH measuring chains with pH glass electrodes and evaluation of measurement uncertainty

DIN EN 27888
1993-11 Water quality - determination of electrical conductivity

2.1.1.7 by Ion Chromatography (IC)³⁾

ISO 10304-1
2007-08 Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate
(Modification: *Detection, also of further anions, in aqueous solutions*)

NEW in flexible scope

ISO 10304-1 Tech Corr
1
2010-05 Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate; Technical Corrigendum 1
(Modification: *Detection, also of further anions, in aqueous solutions*)

NEW in flexible scope

DIN EN ISO 10304-1
2009-07 Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate
(Modification: *Detection, also of further anions, in aqueous solutions*)

2.1.2 Mass loss and/or time needed for defined removal in μm by differential weighing and visual inspection²⁾

ISO 8424 1996-06	Raw optical glass - Resistance to attack by aqueous acidic solutions at 25°C - Test method and classification	
ISO 9689 1990-12	Raw optical glass - Testing of the resistance to attack by aqueous alkaline phosphate-containing solutions at 50°C - Testing and classification	
ISO 10629 1996-07	Raw optical glass - Resistance to attack by aqueous alkaline solutions at 50°C - Test method and classification	
ISO 695 1991-05	Glass; resistance to attack by a boiling aqueous solution of mixed alkali; method of test and classification	NEW in flexible scope
DIN ISO 695 1994-02	Glass: Resistance to attack by a boiling aqueous solution of mixed alkali - Method of test and classification	
DIN 12116 2001-03	Testing of glass - Resistance to attack by a boiling aqueous solution of hydrochloric acid - Method of test and classification	
JOGIS 2007-03	Japanese Optical Glass Industrial Standards - Measuring Method for Chemical Durability of Optical Glass (Powder Method)	
YBB00342004-2015 2015-00	Test for Resistance to Attack of Glass by Boiling Hydrochloric Acid	
YBB00352004-2015 2015-00	Test for Resistance to Attack of Glass by Boiling Aqueous Solution of Mixed Alkali	
01_SOP_00472 2018-02	Determination of the chemical resistance of glasses, glass ceramics and other materials after chemical stresses by differential weighing and visual inspection	

2.1.3 Staining, Color and Gloss changes, Abrasion Resistance

2.1.3.1 Visual Inspection²⁾

ISO 4794 1982-05	Laboratory glassware; Methods for assessing the chemical resistance of enamels used for colour coding and colour marking	NEW in flexible scope
DIN ISO 4794 1983-01	Laboratory glassware: Methods for assessing the chemical resistance of enamels, used for color and color marking	
USP <211> prior to 2013	Arsenic <211> Method I	
01_SOP_00476 2018-02	Determination of staining, color and gloss changes, abrasion resistance of glasses, glass ceramics and other materials after chemical stresses by visual inspection	

2.1.3.2 Differential weighing and visual inspection¹⁾

ISO 28706-2 2017-02	Vitreous and porcelain enamels - Determination of resistance to chemical corrosion - Part 2: Determination of resistance to chemical corrosion by boiling acids, boiling neutral liquids, alkaline liquids and/or their vapours	NEW in flexible scope
DIN EN ISO 28706-2 2017-07	Vitreous and porcelain enamels - Determination of resistance to chemical corrosion - Part 2: Determination of resistance to chemical corrosion by boiling acids, boiling neutral liquids and/or their vapours	
ISO 28706-4 2016-01	Vitreous and porcelain enamels - Determination of resistance to chemical corrosion - Part 4: Determination of resistance to chemical corrosion by alkaline liquids using a cylindrical vessel	NEW in flexible scope
DIN EN ISO 28706-4 2016-07	Vitreous and porcelain enamels - Determination of resistance to chemical corrosion - Part 4: Determination of resistance to chemical corrosion by alkaline liquids using a cylindrical vessel	

2.2 Determination of the resistance against changing climate (humidity, temperature) by climate test chamber²⁾

RTCA DO-160G
2010-12
Environmental Conditions and Test Procedures for Airborne Equipment -
Section 5 Category B, C (temperature variation) -
Section 6 (humidity)

01_SOP_00477
2018-02
Determination of the resistance of glasses, glass ceramics and composites with these materials after stresses by alternating climate and gases

3 Thermal Characterization of glasses, glass ceramics, ceramics, sinter glasses, composites with glass or glass ceramic as well as raw materials of glass industry

3.1 Testing of thermal expansion (static, dynamic) of glasses, glass ceramics and plastics by inductive and optical methods for a temperature range of -180°C to 1300°C²⁾

DIN 51045-1
2005-08
Determination of the thermal expansion of solids -
Part 1: Basic rules

ISO 7991
1987-12
Glass; Determination of coefficient of mean linear thermal expansion
NEW in flexible scope

DIN ISO 7991
1998-02
Glass - Determination of coefficient of mean linear thermal expansion

YBB00202003-2015
2015-00
Test for Coefficient of Mean Linear Thermal Expansion
NEW in flexible scope

01_SOP_00470
2021-05
Determination of the static and dynamic thermal expansion behaviour of solids by dilatometry and thermomechanical analysis

01_SOP_00469
2018-02
Determination of the compaction of glasses and glass ceramics by length comparison measurement

3.2 Determination of viscosity of glasses for a viscosity range of 100-5 x 10¹³ dPa s²⁾

ISO 7884-1
1987-12
Glass; Viscosity and viscometric fixed points; Part 1 : Principles for determining viscosity and viscometric fixed points
NEW in flexible scope

DIN ISO 7884-1
Glass - Viscosity and viscometric fixed points

1998-02	Part 1: Principles for determining viscosity and viscometric fixed points	
ISO 7884-2 1987-12	Glass; Viscosity and viscometric fixed points; Part 2 : Determination of viscosity by rotation viscometers	NEW in flexible scope
DIN ISO 7884-2 1998-02	Glass - Viscosity and viscometric fixed points Part 2: Determination of viscosity by rotation viscometers	
ISO 7884-3 1987-12	Glass; Viscosity and viscometric fixed points; Part 3 : Determination of viscosity by fibre elongation viscometer	NEW in flexible scope
DIN ISO 7884-3 1998-02	Glass - Viscosity and viscometric fixed points Part 3: Determination of viscosity by fibre elongation viscometer	
ISO 7884-4 1987-12	Glass; Viscosity and viscometric fixed points; Part 4 : Determination of viscosity by beam bending	NEW in flexible scope
DIN ISO 7884-4 1998-02	Glass - Viscosity and viscometric fixed points Part 4: Determination of viscosity by beam bending	
ISO 7884-6 1987-12	Glass; Viscosity and viscometric fixed points; Part 6 : Determination of softening point	NEW in flexible scope
DIN ISO 7884-6 1998-02	Glass - Viscosity and viscometric fixed points Part 6: Determination of softening point	
ISO 7884-7 1987-12	Glass; Viscosity and viscometric fixed points; Part 7 : Determination of annealing point and strain point by beam bending	NEW in flexible scope
DIN ISO 7884-7 1998-02	Glass - Viscosity and viscometric fixed points - Part 7: Determination of annealing point and strain point by beam bending	
ISO 7884-8 1987-12	Glass; Viscosity and viscometric fixed points; Part 8 : Determination of (dilatometric) transformation temperature	NEW in flexible scope

DIN ISO 7884-8
1998-02 Glass - Viscosity and viscometric fixed points -
Part 8: Determination of (dilatometric) transformation
temperature

01_SOP_00471
2018-02 Determination of the viscosity properties of glasses by
beam bending, fibre elongation and rotation
viscosimeters as well as dilatometric transformation
temperature

3.3 Determination of the rheological parameters of solids, slurries and highly viscous liquids²⁾

01_SOP_00671
2022-02 Determination of the rheological parameters of solids
using rheometric measurement techniques in rotational
and oscillation mode

01_SOP_00715
2022-02 Determination of the rheological parameters of slurries NEW in flexible
and liquids using rheometric measurement techniques in scope
rotational and oscillation mode

3.4 Determination of the density of glasses, glass ceramics, ceramics and other materials¹⁾

ISO 2781
2018-06 Rubber, vulcanized or thermoplastic – Determination of
density

ASTM C 693
1993-00 Standard Test Method for Density of Glass by Buoyancy
(Modification: Use of a surfactant additive as well as
smaller sample mass)

3.5 Thermal analysis (differential thermal analysis (DTA), differential scanning calorimetry (DSC) and calorimetry (specific heat)) on glasses, glass ceramics, ceramics and raw materials (powders)²⁾

DIN 51006
2005-07 Thermal analysis (TA) - Thermogravimetry (TG) -
Principles

DIN 51007
2019-04 Thermal analysis - Differential thermal analysis (DTA)
and differential scanning calorimetry (DSC) - General
Principles

01_SOP_00156
2022-08 Determination of the true and average specific heat
capacity of solids by calorimetric methods

01_SOP_00581
2018-02 Thermal analysis of solids by differential thermal analysis
(DTA), differential scanning calorimetry (DSC) and

thermogravimetric analysis (TGA) as well as simultaneous DTA-TGA

3.6 Determination of the thermal diffusivity of solids by flash method and calculation of the thermal conductivity¹⁾

ASTM E 1461
2013-00 Standard Test Method for Thermal Diffusivity by the Flash Method

DIN EN 821-2
1997-08 Advanced technical ceramics - Monolythic ceramics, thermophysical properties - Part 2: Determination of thermal diffusivity by the laser flash (or heat pulse method)

3.7 Determination of seal stress in glass by polarization microscopy³⁾

ISO 4790
1992-05 Glass-to-glass sealings; determination of stresses NEW in flexible scope

3.8 Determination of crystallization properties of glasses by gradient furnace method²⁾

ASTM C 829
1981-00 Standard Practices for Measurement of Liquidus Temperature of Glass by the Gradient Furnace Method

01_SOP_00486
2018-07 Determination of the crystallization properties of glasses and glass ceramics by the gradient furnace method

3.9 Determination of Young`s Modulus, Shear Modulus and Poisson`s constant of glass, glass ceramic and ceramic by resonance method²⁾

ASTM C 1259
2021-00 Standard Test Method for Dynamic Youngs Modulus, Shear Modulus, and Poissons Ratio for Advanced Ceramics by Impulse Excitation of Vibration

01_SOP_00502
2022-01 Determination of the dynamic Young`s modulus, shear modulus and Poisson`s coefficient of glasses, glass ceramics, ceramics and metals by impulse excitation of vibrations

4 Electrical characterization of glasses, glass-ceramics, ceramics and other materials

4.1 Determination of the electrical contact resistance of glasses, glass-ceramics, ceramics and other materials²⁾

DIN 52326
1986-05 Testing of glass; determination of electrical resistivity

01_SOP_00511
2018-02 Determination of the specific electric volume resistance of glasses and glass ceramics by current and voltage measurements

4.2 Determination of dielectric properties of glasses, glass ceramics, ceramics and other materials in the GHz range

IEC 61189-2-721
2015-04 Test methods for electrical materials, printed boards and other interconnection structures and assemblies – Part 2-721: Test methods for materials for interconnection structures – Measurement of relative permittivity and loss tangent for copper clad laminate at microwave frequency using split post dielectric resonator NEW in flexible scope

5 Optical characterization of glasses, glass ceramics, ceramics, sintered glasses, composites with glass or glass ceramics as well as raw materials of the glass industry

5.1 Determination of transmission, reflection, remission, scattered light/haze, solarization, spectral color measurement, refractive index and dispersion, fluorescence of glasses, glass ceramics, liquids by spectroscopy²⁾

ISO 15368
2021-03 Optics and optical instruments - Measurement of reflectance of plane surfaces and transmittance of plane parallel elements

Ph. Eur. 3.2.9
2020-12 European Pharmacopoeia -
3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders -
Test: Absorbance, Reference to Ph. Eur. 2.2.25 -
Test A: Infrared absorption spectrometry, Reference to Ph. Eur. 2.2.24

01_SOP_00487
2022-09 Determination of the spectral transmission, remission, reflection, scattering, color value and solarization of solids, especially glasses and glass ceramics, plastics and liquids by optical spectroscopy

01_SOP_00488
2018-02 Determination of the refractive index and dispersion of glasses, glass ceramics, plastics and solids by prism coupler method

01_SOP_00490
2018-02 Determination of the spectral fluorescence properties,
decay time and quantum yield of glasses, glass ceramics,
solids and liquids by fluorescence spectroscopy

Anal. Chem. 2010, 82,
p. 2129-2133
2010-00 Recommendations for Fluorescence Instrument
qualification: The new ASTM Standard Guide -
Paul de Rose, Ute Resch-Genger

5.2 Ellipsometric characterization of coatings and uncoated materials ²⁾

DIN 50989-1
2018-03 Ellipsometry - Part 1: Principles

01_SOP_00538
2022-02 Ellipsometric characterization of coatings and uncoated
materials

5.3 Stress measurements and stress-optical coefficient ²⁾

ISO 10345-2
1992-05 Glass - Determination of stress-optical coefficient -
Part 2: Bending test

ISO 11455
1995-03 Raw optical glass - Determination of birefringence

ASTM C 1422/ C1422 M
20a
2020-00 Standard Specification for Chemically Strengthened Flat
Glass

ASTM D 4093
1995-00 Test Method for Photoelastic Measurements of
Birefringence and Residual Strains in Transparent or
Translucent Plastic Materials

01_SOP_00509
2018-02 Determination of mechanical tensions, birefringence and
the stress-optical coefficient of transparent solids by
polarization-optical measurement methods

6 Characterization of glasses, glass ceramics, ceramics, metals, plastics and composite materials in micro and surface area

6.1 by Scanning Electron Microscopy/Energy Dispersive X-ray spectroscopy (SEM/EDX)²⁾

ISO 22309
2011-10 Microbeam analysis – Quantitative analysis using
energy-dispersive spectrometry (EDS) for elements with
an atomic number of 11 (Na) or above

DIN ISO 22309
2015-11 Microbeam analysis – Quantitative analysis using energy-dispersive spectrometry (EDS) for elements with an atomic number of 11 (Na) or above NEW in flexible scope

ASTM B 748
1990-00 Standard Test Method for Measurement of Thickness of Metallic Coatings by Measurement of Cross Section with a Scanning Electron Microscope

ASTM E 1078
2014-00 Standard Guide for Specimen Preparation and Mounting in Surface Analysis

01_SOP_00491
2018-02 High-resolution morphological surface characterization on glasses, glass ceramics, ceramics, metals, solid and composite materials by SEM as well as qualitative and quantitative analysis of surface composition by EDX

6.2 by topographic methods (WLI, AFM, Laser-Interferometry)²⁾

ASTM E 2382
2004-00 Guide to Scanner and Tip Related Artifacts in Scanning Tunneling Microscopy and Atomic Force Microscopy

01_SOP_00489
2022-05 Topographic determination on glasses, glass ceramics, ceramics, metals, plastics and composite materials by white-light interference microscopy

01_SOP_00537
2022-01 High-resolution determination of the surface topography of glasses, glass ceramics, ceramics, metals, plastics and composite materials and solids by atomic force microscopy

01_SOP_00752
2022-10 Determination of wavefront deformation by Fizeau phase laser interferometry NEW in flexible scope

6.3 by Light Microscopy²⁾

ISO 643
2019-12 Steels - Micrographic determination of the apparent grain size NEW in flexible scope

DIN EN ISO 643
2020-06 Steels - Micrographic determination of the apparent grain size

ASTM E 112
2013-00 Standard Test Methods for Determining Average Grain Size

DIN EN ISO 7458 2004-05	Glass containers - Internal pressure resistance - Test methods	
ISO 8113 2004-03	Glass containers - Resistance to vertical load - Test method	NEW in flexible scope
DIN EN ISO 8113 2004-05	Glass containers - Resistance to vertical load - Test method	
ISO 8510-2 2006-12	Adhesives - Peel test for a flexible-bonded-to-rigid test specimen assembly - Part 2: 180° peel	NEW in flexible scope
DIN EN ISO 8510-2 2010-12	Adhesives - Peel test for a flexible-bonded-to-rigid test specimen assembly - Part 2: 180 degree peel	
DIN EN 843-1 2008-08	Advanced technical ceramics - Mechanical properties of monolithic ceramics at room temperature Part 1: Determination of flexural strength	
ISO 1288-3 2016-02	Glass in building - Determination of the bending strength of glass - Part 3: Test with specimen supported at two points (four point bending)	NEW in flexible scope
DIN EN 1288-3 2000-09	Glass in building - Determination of the bending strength of glass - Part 3: Test with specimen supported at two points (four point bending)	
ISO 1288-5 2016-02	Glass in building - Determination of the bending strength of glass - Part 5: Coaxial double ring test on flat specimens with small test surface areas	NEW in flexible scope
DIN EN 1288-5 2000-09	Glass in building - Determination of the bending strength of glass - Part 5: Coaxial double ring test on flat specimens with small test surface areas	
ISO 11040-4 2015-04	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	NEW in flexible scope

ISO 11040-4 AMD 1 2020-02	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling; Amendment 1	NEW in flexible scope
DIN ISO 11040-4 2017-07	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	NEW in flexible scope
DIN EN 28510-1 2014-07	Adhesives - Peel test for a flexible-bonded-to-rigid test specimen assembly - Part 1: 90° peel	NEW in flexible scope
ASTM D 6862 2011-00	Standard Test Method for 90 Degree Peel Resistance of Adhesives	
01_SOP_00495 2018-02	Determination of the strength of brittle materials, plastics and composite materials by tensile and pressure tests with universal testing machines	

8 Fracture analysis (fractography) on glasses, glass ceramics, ceramics and plastics by light microscopic methods²⁾

DIN EN 843-6 2009-12	Advanced technical ceramics - Mechanical properties of monolithic ceramics at room temperature - Part 6: Guidance for fractographic investigation;
ASTM C 1256 1993-00	Standard Practice for Interpreting Glass Fracture Surface Features
PDA-TR 43 2013-00	Technical Report No. 43 (Revised 2013) - Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials
01_SOP_00496 2018-02	Fractography / fracture analysis on brittle materials by light microscopy

9 Determination of the volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by mass spectrometry and Raman spectroscopy²⁾

JIS K 0137 2010-05	General rules for Raman spectrometry
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01_SOP_00497
2018-02 Determination of volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by mass spectrometry

01_SOP_00504
2021-08 Determination of volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by Raman spectroscopy

10 Analysis of pharmaceutical packaging and their components regarding extractable and leachable constituents, contaminations and corrosion products

10.1 Sample preparation³⁾

ISO 10993-12
2021-01 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials NEW in flexible scope

DIN EN ISO 10993-12
2021-08 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

USP <1660>
2013-12 Evaluation of the inner surface durability of glass containers

USP <1663>
2018-08 Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems

USP <1664>
2015-08 Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems

10.2 by gas chromatography (GC-MS)²⁾

USP <621>
2017-08 Chromatography

PQRI
2006-09 Recommendation to FDA for E&L Testing for OINDP Best practices for Extractables and Leachables in orally inhaled and nasal drug products

01_SOP_00498
2018-02 Determination of plastic additives in and out of pharmaceutical packaging materials using gas chromatography - mass spectrometry

01_SOP_00684
2021-08 Gas chromatography - mass spectrometry for the analyses of extractable substances out of pharmaceutical packaging material

10.3 by Liquid Chromatography (LC-MS)²⁾

USP <621> Chromatography
2017-08

PQRI Recommendation to FDA for E&L Testing for OINDP
2006-09 Best practices for Extractables and Leachables in orally
inhaled and nasal drug products

01_SOP_00499 Determination of leachable monomers from cured
2018-02 adhesives using liquid chromatography - mass
spectrometry

01_SOP_00685 Liquid chromatography - mass spectrometry for the
2021-08 analyses of extractable substances out of
pharmaceutical packaging material

10.4 by Inductively Coupled Plasma (ICP-OES)²⁾

ICH Q3D Guideline Guideline for Elemental Impurities
2019-03

USP <730> Plasma spectrochemistry
2018-05

USP <233> Chemical Test and Assays: Elemental Impurities -
2018-05 Procedures

USP <1660> Evaluation of the inner surface durability of glass
2013-12 containers

01_SOP_00028 Trace element analysis of aqueous extracts from glass,
2020-10 glass ceramics and pharmaceutical packaging with ICP-
MS or ICP-OES

10.5 by Inductively Coupled Plasma and mass-selective detection (ICP-MS)²⁾

ICH Q3D Guideline Guideline for Elemental Impurities
2019-03

USP <730> Plasma spectrochemistry
2018-05

USP <233> 2018-05	Chemical Test and Assays: Elemental Impurities - Procedures	
USP <1660> 2013-12	Evaluation of the inner surface durability of glass containers	
01_SOP_00028 2020-10	Trace element analysis of aqueous extracts from glass, glass ceramics and pharmaceutical packaging with ICP- MS or ICP-OES	

10.6 by UV-VIS-Spectrophotometry³⁾

ISO 8871-1, Annex C 2003-10	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 1: Extractables in aqueous autoclavates	NEW in flexible scope
DIN EN ISO 8871-1 Anhang C 2004-11	Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 1: Extractables in aqueous autoclavates (text in German and English)	

10.7 by Infrared Spectroscopy (IR)³⁾

ISO 8871-2, Annex A 2020-05	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization	NEW in flexible scope
DIN EN ISO 8871-2 Anhang A 2020-09	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization (text in German and English)	

10.8 by Visual Inspection and Optical Microscopy¹⁾

ISO 8871-3, Section 3 2003-08	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released- particle count	NEW in flexible scope
ISO 8871-3 AMD 1 2018-01	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released- particle count; Amendment 1	NEW in flexible scope
DIN EN ISO 8871-3, Abschnitt 3 2019-08	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released- particle count	

(text German and English)

Ph. Eur. 2.9.20 2020-01	European Pharmacopoeia 2.9.20 Particulate contamination: Visible Particles
Ph. Eur. 3.2.9 2020-12	European Pharmacopoeia - 3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze- dried powders Test: Appearance of solution S Test: Ammonium, Reference to Ph. Eur. 2.4.1 Method A Test: Extractable heavy metals, Reference to Ph. Eur. 2.4.8 Test A Test: Volatile sulfides
PDA-TR 43 2013-00	Technical Report No. 43 (Revised 2013) Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials
USP <790> 2016-05	Visible particulates in injections
USP <1660> 2013-12	Evaluation of the inner surface durability of glass containers
10.9 by Scanning Electron Microscopy/Energy Dispersive X-ray spectroscopy (SEM/EDX)²⁾ ASTM F 1877 2016-00	Standard Practice for Characterization of Particles
USP <1181> 2014-12	Scanning Electron Microscopy
USP <1660> 2013-12	Evaluation of the inner surface durability of glass containers
01_SOP_00508 2018-02	Separation of particles from solution by filtration and analysis by SEM and EDS (qualitative analysis)

10.10 by Raman Spectroscopy³⁾

JIS K 0137

General rules for Raman spectrometry

2010-05

Laboratory location Hattenbergstraße 10, 55122 Mainz

1 Testing of thermal expansion (static, dynamic) of glasses, glass ceramics, ceramics, sinter materials, plastics and composites by inductive and optical methods for a temperature range of -50°C to +100°C ²⁾

DIN 51045-1
2005-08 Determination of the thermal expansion of solids -
Part 1: Basic rules

ISO 7991
1987-12 Glass; Determination of coefficient of mean linear NEW in flexible
thermal expansion scope

DIN ISO 7991
1998-02 Glass; Determination of coefficient of mean linear
thermal expansion

01_SOP_00470
2021-05 Determination of the static and dynamic thermal
expansion behaviour of solids by dilatometry and
thermomechanical analysis

2 Determination of optical properties (transmission and derived parameters, refractive index and dispersion) preferably on glasses by optical spectroscopy and optical refractography ²⁾

ISO 15368
2021-03 Optics and optical instruments - Measurement of
reflectance of plane surfaces and transmittance of plane
parallel elements

01_SOP_00487
2022-09 Determination of the spectral transmission, remission,
reflection, scattering, color value and solarization of
solids, especially glasses and glass ceramics, plastics and
liquids by optical spectroscopy

01_SOP_00510
2021-05 Determination of the refractive index and dispersion of
glasses with standard and/or precision accuracy by
optical refractography

3 Determination of the density of glasses, glass ceramics, ceramics and other materials ³⁾

ASTM C 693
1993-00 Standard Test Method for Density of Glass by Buoyancy
(Modification: Use of a surfactant additive)

Laboratory location 400 York Ave, Duryea/PA 18642 USA

1 Characterization of glasses, glass ceramics, ceramics, metals, plastics and composite materials in micro and surface area as well as fracture analysis (fractography)

1.1 by Scanning Electron Microscopy/ Energy Dispersive X-ray spectroscopy (SEM/EDX) ²⁾

ISO 22309
2011-10 Microbeam analysis – Quantitative analysis using energy-dispersive spectrometry (EDS) for elements with an atomic number of 11 (Na) or above

ASTM E 1078
2014-00 Standard Guide for Specimen Preparation and Mounting in Surface Analysis

01_SOP_00491
2018-02 High-resolution morphological surface characterization on glasses, glass ceramics, ceramics, metals, solid and composite materials by SEM as well as qualitative and quantitative analysis of surface composition by EDX

1.2 by Light Microscopy Methods²⁾

DIN EN 843-6
2009-12 Advanced technical ceramics - Mechanical properties of monolithic ceramics at room temperature - Part 6: Guidance for fractographic investigation;

ASTM C 1256
1993-00 Standard Practice for Interpreting Glass Fracture Surface Features

01_SOP_00496
2018-02 Fractography / fracture analysis on brittle materials by light microscopy

01_SOP_00501
2018-02 Sample characterization of glasses, glass ceramics, ceramics, metals, plastics, composite and solid materials by light microscopy

2 Analysis of pharmaceutical packaging and their components regarding contaminations and corrosion products

2.1 by Visual Inspection and Optical Microscopy ¹⁾

Ph. Eur. 2.9.20
2020-01 European Pharmacopoeia
2.9.20 Particulate contamination: Visible Particles

PDA-TR 43
2013-00 Technical Report No. 43 (Revised 2013) Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical

Manufacturing: Covering Ampoules, Bottles, Cartridges,
Syringes and Vials

USP <790>
2016-05 Visible particulates in injections

USP <1660>
2013-12 Evaluation of the inner surface durability of glass
containers

2.2 by Scanning Electron Microscopy/ Energy Dispersive X-ray spectroscopy (SEM/EDX)²⁾

ASTM F 1877
2016-00 Standard Practice for Characterization of Particles

USP <1181>
2014-12 Scanning Electron Microscopy

USP <1660>
2013-12 Evaluation of the inner surface durability of glass
containers

01_SOP_00508
2018-02 Separation of particles from solution by filtration and
analysis by SEM and EDS (qualitative analysis)

2.3 by Inductively Coupled Plasma (ICP-OES)¹⁾

USP <730>
2018-05 Evaluation of the inner surface durability of glass
containers

USP <1660>
2013-12 Evaluation of the inner surface durability of glass
containers

2.4 by electrode measurement¹⁾

DIN 19268
2021-10 pH-measurement - pH-measurement of aqueous
solutions with pH measuring chains with pH glass
electrodes and evaluation of measurement uncertainty
NEW in flexible
scope

**3 Determination of the mass contents of elements in glasses, glass ceramics, ceramics and other
anorganic materials, glass and ceramic raw materials**

3.1 Sampe preparation, digestion methods (open digestions, melting digestion techniques)²⁾

01_SOP_00556
2019-05 Separation of particles from solution by filtration and
analysis by SEM and EDS (qualitative analysis)

3.2 by Optical Emission Spectroscopy with Inductively Coupled Plasma (ICP-OES)³⁾

DIN 51086-2
2004-07

Testing of oxidic raw materials and materials for ceramics, glass and glazes - Part 2: Determination of Ag, As, B, Ba, Be, Bi, Ca, Cd, Ce, Co, Cr, Cu, Er, Eu, Fe, La, Mg, Mn, Mo, Nd, Ni, P, Pb, Pr, S, Sb, Se, Sn, Sr, Ti, V, W, Y, Yb, Zn, Zr by optical emission spectrometry with inductively coupled plasma (ICP-OES) -
(Modification: Determination of further elements)