Translation of

Annex to Accreditation Certificate D-PL-14645-01-00 according to DIN EN ISO/IEC 17025:2018

The analytical testing laboraties of SCHOTT AG Mainz are accredited under the terms of DIN EN ISO/IEC 17025:2018.

The original accreditation certificate with the accreditation number D-PL-14645-01-00 is valid from 10-Feb-2022 and is published on the homepage of Deutsche Akkreditierungsstelle (DAkkS) in the internet under www.dakks.de, Akkreditierte Stellen.

It comprises the cover sheet, the reverse side of the cover sheet and the following annex. This paper shall only apply in connection with the original documents issued by DAkkS in German language.

Abbreviations used: see last page

Version 7.0, 01-Apr-2022

The services of the **Accredited Testing Laboratories of SCHOTT AG**

are carried out at three locations:

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

Tests are carried out in the following fields:

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 oft he 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 oft he 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) on 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

Within the marked testing areas the laboratory has authorization,

without prior information or approval of German accreditation body (DAkkS),

- ¹⁾ for free choice of standardised methods or procedures equal to them
- ²⁾ for modification of methods as well as developments of methods
- ³⁾ the use of standardised methods or procedures equal to them with different issue dates.

The listed methods are examplarily. The laboratory has an actual list of all testing procedures within the flexible accreditation scope.

The requirements for the management system in DIN EN ISO/IEC 17025 are written in a language relevant for testing laboratories and are overall in accordance with the principles of DIN EN ISO 9001.

The certificate including the certificate annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of the Deutsche Akkreditierungsstelle GmbH (DAkkS). https://www.dakks.de/content/datenbank-akkreditierter-stellen

Contact person for quality management matters of the Accredited Testing Laboratories of SCHOTT AG:

Christine Strubel Head of "Management Systems Quality & EHS"

Hattenbergstrasse 10 TSA-Q/Ma 2.85 55122 Mainz phone: +49 (0)6131/ 66 - 7458 Email: christine.strubel@schott.com

Contents

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

1 Determination of the concentrations and valence states of elements in glasses, a ceramics, ceramics and other anorganic materials, glass- and ceramic raw mater		
	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, noble	e
	metals) in combination with glass production	. 6
1.1	Sample preparation, digestion methods (open digestions, melting digestion techniques,	
	digestions in closes 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 (ICP-MS) ²⁾	9
1.3.4	UV-VIS-Spectrophotometry ²)	9
1.4	by Ion Chromatography (IC) ¹⁾	.10
1.5	Solid state methods (XRF, Laser-ICP-MS, VGA/TGHE)	.10
1.5.1	X-Ray Fluorescence-Analysis (XRF) ²	.10
1.5.2	Laser Ablation-Inductively Coupled Plasma-Mass Spectrometry (LA-ICP-MS) ²	.11
1.5.3	Combustion Analysis/ Carrier gas hot extraction (VGA/TGHE) ²	.11
2	Determination of the chemical resistance of glasses, glass ceramics, decorations on	
	glasses or glass ceramics and other materials	11
2.1	Determination of resistance to liquid media	.11
2.1.1	Ionic release of surface	.11
2.1.1.1	Sample preparation by extraction and leaching procedures ²⁾	.11
2.1.1.2	by Titrimetry ¹⁾	.12
2.1.1.3	by Atomic Absorption Spectrometry (FAAS, HG-AAS, GFAAS) ²⁾	.13
2.1.1.4	by Inductively Coupled Plasma (ICP-OES) ²⁾	.14
2.1.1.5	by Inductively Coupled Plasma with mass-selective detection (ICP-MS) ²⁾	.16
2.1.1.6	by electrode measurement ¹⁾	.17
2.1.1.7	by ion chromatography (IC) ³⁾	.18
2.1.2	Mass loss and/or time needed for defined removal in μm by differential weighing and	
	visual inspection ²⁾	.18
2.1.3	Staining, Color and Gloss changes, Abrasion Resistence	.19
2.1.3.1	Visual Inspection ²⁾	.19
2.1.3.2	Differential weighing and visual inspection ¹⁾	.19
2.2	Determination of the resistance against changing climate (humidity, temperature) by	
	climate test chamber ²	.19
3	Thermal Characterization of glasses, glass ceramics, ceramics, sinter glasses, composite	es
	with glass or glass ceramic as well as raw materials of glass industry	20
3.1	Testing of thermal expansion (static, dynamic) of glasses, glass ceramics and plastics by	
	inductive and ontical methods for a temperature range of -180°C to 1300°C $^{2)}$	20

3.2	Determination of viscosity of glasses for a viscosity range of 10^{0} -5 \cdot 10 ¹³ dPa s ²)20
3.3	Determination of rheological parameters on solids, suspensions and
	highly viscous liquids ²)
3.4	Determination of density of glasses, glass ceramics, ceramics and other materials ² ,21
3.5	Thermodynamic Measurements (differential thermal analysis (DTA), differential scanning
	calorimetry (DSC) and calorimetry (specific heat)) on glasses, glass ceramics, ceramics and
	raw materials (powders) ²⁾ 21
3.6	Determination of the thermal diffusity of solids by flash method and calculation of the
	thermal conductivity21
3.7	Determination of seal stress in glass by polarization microscopy ³)
3.8	Determination of crystallization properties of glasses by gradient furnace method ²)22
3.9	Determination of Young`s Modulus, Shear Modulus and Poisson`s constant of glass,
	glass ceramic and ceramic by resonance method ²⁾ 22
3.10	Determination of the electric resistivity of glasses, glass ceramics, ceramics and other
	materials ²⁾ 22
4	Optical Characterization of glasses, glass ceramics, sintered glasses and composites
	with glass or glass ceramics as well as raw materials of the glass industry
4.1	Determination of transmission, reflection, remission, scattered light/haze, solarization,
	spectral color measurement, refractive index and dispersion, fluorescence of glasses,
	glass ceramics and liquids by spectroscopy ²⁾ 23
4.2	Ellipsometric characterization of coatings and uncoated materials ²⁾ 23
4.3	Stress measurements and stress-optical coefficient ²⁾
5	Characterization of glasses, glass ceramics, ceramics, metals, plastics and composite
	materials in micro and surface area24
5.1	by Scanning Electron Microscopy/Energy Dispersive X-ray spectroscopy (SEM/EDX) ²⁾ 24
5.2	by topographic methods (WLI, AFM) ²⁾ 24
5.3	by Light Microscopy ²⁾ 25
5.4	by Time-of-Flight-Secondary Ion Mass Spectrometry (ToF-SIMS) ²⁾
5.5	by Vibrational Spectroscopy ³)
6	
	Strength tests on glasses, glass ceramics, plastics and composites. Determination of
	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9 9.1	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9 9.1 9.2 9.2	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9 9.1 9.2 9.3	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9 9.1 9.2 9.3 9.4 0.5	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9 9.1 9.2 9.3 9.4 9.5 0.6	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾
7 8 9 9.1 9.2 9.3 9.4 9.5 9.6 0.7	Strength tests on glasses, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile tests ²⁾

9.8	by Visual Inspection and optical microscopy ¹⁾	30
9.9	by Scanning Electron Microscopy/ Energy Dispersive X-ray spectroscopy (SEM/EDX) ²⁾	30
9.10	by Raman spectroscopy ³⁾	31

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⁾
2	Determination of optical properties (transmission and derived parameters, refractive index and dispersion) preferably on glasses by optical spectroscopy and optical
	refractography ²⁾
3	Determination of density of glasses, glass ceramics, ceramics and other materials ³⁾ 31

Laboratory site 400 York Ave, Duryea/PA, 18642 USA

1	Characterization of glasses, glass ceramics, ceramics, metals, plastics and compo materials in micro and surface area	osite
	Fracture analysis (fractography)	32
1.1	by Scanning Electron Microscopy/Energy Dispersive X-ray spectroscopy	
	(SEM/EDX) ²)	32
1.2	by Light Microscopy Methods ²⁾	32
2 Analysis of pharmaceutical packaging and their components regarding contaminat		ations
	and corrosion products	32
2.1	by Visual Inspection ¹⁾	
2.2	by Scanning Electron Microscopy/Energy Dispersive X-ray spectroscopy	
	(SEM/EDX) ²⁾	
2.3	by optical emission spectroscopy with inductively coupled plasma	
	(ICP-OES) ²⁾	33
3	Determination of the mass contents of elements in glasses, glass ceramics, cerar	nics and
	other anorganic materials, glass and ceramic raw materials	
3.1	Sample preparation, digestion methods (open digestions, melting digestion technic	iques) .34
3.2	by optical emission spectroscopy with inductively coupled plasma (ICP-OES) ²)	34

Laboratory site Otto-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, noble metals) in combination with glass production
- **1.1** Sample preparation, digestion methods (open digestions, melting digestion techniques, digestions in closes systems)²⁾

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
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
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
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 Al ₂ O ₃ , Fe ₂ O ₃ and TiO ₂ as well as CaO, MgO, Na ₂ O and K ₂ O (Modification: <i>Application for further oxides</i>)
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 Titrimetry ²⁾

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: <i>Digestion, no reprecipitation</i>)
YBB00232003-2015 2015-00	Determination of Boron Oxide

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

1.2.2 by Gravimetry ²⁾

ISO 247 2018-07	Rubber - Determination of ash – Part 1: Combustion method
DIN EN ISO 8871-2 2014-08	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: <i>material-related tempartures, sample amounts</i>)
DIN 52340-2 1974-01	Testing of glass Chemical analysis of colorless soda-lime-glass with SiO2, CaO, MgO and Na2O as main constituents - Part 2: Determination SiO ₂
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⁾

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 colourless soda-lime-glass - Part 11: Determination of BaO, CaO, MgO, Al ₂ O ₃ , Fe ₂ O ₃ , Cr ₂ O ₃ content by flame atomic absorption spectrometry (FAAS) and Na ₂ O and K ₂ O by flame atomic emission spectrometry (FAES) (Modification: <i>Applicatin on special glasses and glass ceramics,</i> <i>further elements, AAS-detection</i>)
DIN 52341 1993-10	Testing of glass - Chemical analysis of lead crystal glass and crystal glass (Modification: <i>Application on special glasses and glass ceramics,</i> <i>further elements</i>)
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 (Modification: <i>Detection with ICP-OES or FAAS</i>)
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. 23ff 2009-02	Determination of mercury in glass by cold vapour atomic absorption spectrometry (CVAAS)

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

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)
Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES) (Modification: <i>Application on digestion solutions, further elements</i>)
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)

1.3.3 by Inductively Coupled Plasma (ICP-MS)²⁾

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: <i>Application on digestion solutions</i>)
01_SOP_00478 2018-02	Semi-quantitatve 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⁾

DIN EN ISO 14719 2012-03	Chemical analysis of refractory material glass and glazes - Determination of Fe^{2+} and Fe^{3+} 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⁾

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 Solid state methods (XRF, Laser-ICP-MS, VGA/TGHE)

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

DIN EN ISO 12677 2013-02	Chemical analysis of refractory products by X-ray fluorescence (XRF) Fused cast-bead method
DIN 51001	Testing of oxidic raw materials and basic materials –
2003-08 and	General bases of work for X-ray fluorescence method (XRF)
Supplement to DIN 51001 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 fluorescense 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 Spectroemtry (LA-ICP-MS)

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

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
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	Investigration of solids - Temperature-dependent differentiation of total carbon (TOC400, ROC, TIC900)
DIN 51085 2015-01	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 Ionic release of surface
- **2.1.1.1** Sample preparation by extraction and leaching procedures ²)

DIN EN 12457-2	Characterization of waste – Leaching;
2003-01	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: <i>Application on glass</i>)
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 Titrimetry ¹⁾

ISO 4802-1 2016-06	Glassware - Hydrolytic resistance of the interior surfaces of glass containers - Part 1: Determination by titration method and classification
DIN ISO 719 1989-12	Glass: Hydrolytic resistance of glass grains at 98 °C; Method of test and classification
DIN ISO 720 1989-12	Glass: Hydrolytic resistance of glass grains at 121 °C; Method of test and classification
JP	Japanese Pharmacopoeia
17th edition 2016-04	7. Test for Containers and Packing Materials7.01. Test for Glass Containers for Injections
Ph. Eur. 3.2.1	European Pharmacopoeia
2019-01	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 wether 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 Interíor Surfaces at 121°C
YBB00252003-2015 2015-00	Tests and Classification for Hydrolytic Resistance of Glass Grains at 121°C
YBB00362004-2015 2015-00	Tests 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
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
DIN EN ISO 4531 2018-12	Vitreous and porcelain enamels - Release from enamelled articles in contact with food - Methods of test and limits
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: <i>Determination of further cations with ICP-OES or</i> <i>ICP-MS</i>)
ISO 7086-1 2019-08	Glass hollowware in contact with food - Release of lead and cadmium - Part 1: Test method (Modification: <i>Detection with ICP-OES or ICP-MS</i>)
ISO 6486-1 2019-08	Glass hollowware in contact with food – Release of lead and cadmium – Part 1: Method of test (Modification: Detection with ICP-OES or ICP-MS)
DIN EN ISO 11885 2009-09	Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)

DIN EN ISO 4531 2018-12	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: <i>Detection with ICP-OES or ICP-MS</i>)
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: <i>Detection with ICP-OES or ICP-MS</i>)
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 (Modification: <i>Determination of further cations with ICP-OES or ICP-</i> <i>MS</i>)
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 wether the containers have been surface treated (Etching Test) Annex - Test for surface hydrolytic resistance-determination by flame atomic absorption spectrometry (FAAS) (Modification: <i>Determination of further cations with ICP-OES or ICP-MS</i>)
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: <i>Detection of cations with ICP-OES or ICP-MS)</i>

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

2.1.1.5 by Inductively Coupled Plasma with mass-selective detection (ICP-MS)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: <i>Determination of further cations with ICP-OES or</i> <i>ICP-MS</i>)
ISO 7086-1 2019-08	Glass hollowware in contact with food - Release of lead and cadmium - Part 1: Test method (Modification: <i>Detection with ICP-OES or ICP-MS</i>)
ISO 6486-1 2019-08	Glass hollowware in contact with food – Release of lead and cadmium – Part 1: Method of test (Modification: Detection with ICP-OES or ICP-MS)
DIN EN ISO 4531 2018-12	Vitreous and porcelain enamels - Release from enamelled articles in contact with food - Methods of test and limits
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: <i>Detection with ICP-OES or ICP-MS</i>)
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: <i>Detection with ICP-OES or ICP-MS</i>)
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: <i>Determination of further cations with ICP-OES or</i> <i>ICP-MS</i>)

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 wether the containers have been surface treated (Etching Test) Annex - Test for surface hydrolytic resistance-determination by flame atomic absorption spectrometry (FAAS) (Modification: <i>Determination of further cations with ICP-OES or ICP-MS</i>)
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: <i>Detection of cations with ICP-OES or ICP-MS</i>)
YBB00372004-2015 2015-00	Tests for release of arsenic antimony, lead and cadmium
01_SOP_00028 2020-10	Trace analysis of aqueous extracts of glasses, glass ceramics and pharmaceutical packaging by ICP-MS or ICP-OES

2.1.1.6 by electrode measurement ¹⁾

DIN 19268 2007-05	pH-measurement - pH-measurement of aqueous solutions with pH measuring chains with pH glass electrodes and evaluation of measurement uncertainty
DIN EN 27888 (C 8) 1993-11	Water quality - determination of electrical conductivity

2.1.1.7 by ion chromatography (IC) ³⁾

DIN EN ISO 10304-1Water quality - Determination of dissolved anions by liquid2009-07chromatography 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 μ m by differential weighing and visual inspection ²⁾

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
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 Attackof 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 Resistence

2.1.3.1 Visual Inspection ²⁾

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 resistence of glasses, glass ceramics and other materials after chemical stresses by visual inspection

2.1.3.2 Differential weighing and visual inspection ¹⁾

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
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 chamber ²⁾

RTCA DO-160G 2017-12	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°C ²⁾

DIN 51045-1 2005-08	Determination of the thermal expansion of solids - Part 1: Basic rules
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
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 10⁰-5·10¹³ dPa s²)

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

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

3.3 Determination of rheological parameters on solids, suspensions and highly viscous liquids ²⁾

01_SOP_00671	Determination of the rheological parameters of solids, slurries and
2021-05	highly viscous liquids using rheometric measurement techniques in
	rotational and oscillation mode

3.4 Determination of density of glasses, glass ceramics, ceramics and other materials²⁾

ISO 2781 2018-06	Rubber, vulcanized or thermoplastic – Determination of density
ASTM C 693	Standard Test Method for Density of Glass by Buoyancy
1993-00	(Modification: <i>Use of a surfactant additive as well as smaller sample mass</i>)

3.5 Thermodynamic Measurements (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 2018-02	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 diffusity of solids by flash method and calculation of the thermal conductivity

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

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 Determinatio	n of seal stress in glass by polarization microscopy ³⁾
DIN 52327-1 1977-11	Testing of glass; Determination of stresses in glass-to-glass sealings (<i>withdrawn standard</i>) (Modification: <i>measuring location near the sealing line</i>)
3.8 Determinatio	n of crystallization properties of glasses by gradient furnace method ²⁾
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 ceramic and c	n of Young`s Modulus, Shear Modulus and Poisson`s constant of glass, glass eramic by resonance method ²⁾
ASTM C 1259 2015-00	Standard Test Method for Dynamic Youngs Modulus, Shear Modulus, and Poissons Ratio for Advanced Ceramics by Impulse Excitation of Vibration
01_SOP_00502 2018-02	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
3.10 Determination materials ²⁾	n of the electric resistivity of glasses, glass ceramics, ceramics and other
DIN 52326 1986-05	Testing of glass; Determination of electrical resistivity (<i>withdrawn standard</i>)
01_SOP_00511 2018-02	Determination of the specific electric volume resistance of glasses and glass ceramics by current and voltage measurements

- 4 Optical Characterization of glasses, glass ceramics, sintered glasses and composites with glass or glass ceramics as well as raw materials of the glass industry
- 4.1 Determination of transmission, reflection, remission, scattered light/haze, solarization, spectral color measurement, refractive index and dispersion, fluorescence of glasses, glass ceramics and liquids by spectroscopy ²)

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 2018-07	Determination of 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 refractive index and dispersion of glasses, glass ceramics, plastics and solids by prism coupler method
01_SOP_00490 2018-02	Determination of 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	Recommendations for Fluorescence Instrument qualification: The new ASTM Standard Guide Paul de Rose, Ute Resch-Genger

4.2 Ellipsometric characterization of coatings and uncoated materials²⁾

DIN 50989-1	Ellipsometry - Part 1: Principles
2018-03	
01_SOP_00538	Ellipsometric characterization of coatings and uncoated materials
2021-06	

4.3 Stress measurements and stress-optical coefficient ²⁾

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

ISO 11455 1995-03	Raw optical glass - Determination of birefringence
ASTM C 1422/C 1422 Ma 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 stress- optical coefficient of transparent solids by polarization-optical measurement methods

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

5.1 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 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

5.2 by topographic methods (WLI, AFM)²⁾

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

01_SOP_00489 2018-04	Topographic determination on glasses, glass ceramics, ceramics, metals, plastics and composite materials by white-light interference microscopy
01_SOP_00537 2020-01	High-resolution determination of the surface topography of glasses, glass ceramics, ceramics, metals, plastics and composite materials and solids by atomic force microscopy

5.3 by Light Microscopy ²⁾

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

5.4 by Time-of-Flight-Secondary Ion Mass Spectrometry (ToF-SIMS)²⁾

ISO 13084 2018-11	Surface chemical analysis - Secondary-ion mass spectrometry - Calibration of the mass scale for a time-of-flight secondary-ion mass spectrometer
ISO 18116 2005-08	Surface chemical analysis - Guidelines for preparation and mounting of specimens for analysis
ASTM E 2695 2009-00	Standard Guide for Interpretation of Mass Spectral Data Acquired with Time-of-Flight Secondary Ion Mass Spectroscopy
01_SOP_00493 2019-10	Qualitative analysis of the surface composition of glasses, glass ceramics, ceramics, metals, plastics, composite materials and solids by ToF-SIMS

5.5 by Vibrational Spectroscopy ³⁾

JIS K 0137	General rules for Raman spectrometry
2010-05	

USP <1858>	R
2020-11	

6	Strength tests on glasses, glass ceramics, plastics and composites,
	Determination of material and product properties by pressure and tensile tests ²⁾

ISO 14704 2016-04	Fine ceramics (advanced ceramics, advanced technical ceramics) – Test method for flexural strength of monolithic ceramics at room temperature
DIN EN ISO 7458 2004-05	Glass containers - Internal pressure resistance - Test methods
DIN EN ISO 8113 2004-05	Glass containers - Resistance to vertical load - Test method
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
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)
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
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

7 Fracture analysis (fractography) on glasses, glass ceramics, ceramics and plastics by light microscopic methods ²⁾

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

8 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)

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

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

9	9.1 Sample preparation ³⁾	
	DIN EN ISO 10993-12 2012-10	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>	Assessment of Drug Product Leachables Associated with
2015-08	Pharmaceutical Packaging/Delivery Systems

9.2 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 polymer materials using gas chromatography - mass spectrometry
01_SOP_00684 2021-08	Gas chromatography – massspectrometry for the analyses of extractable substances out of pharmaceutical packaging material

9.3 by Liquid Chromatography (HPLC-MS-IT-TOF)²⁾

USP <621> 2017-12	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_00499 2018-02	Determination of leachable monomers from cured adhesives using liquid chromatography - mass spectrometry
01_SOP_00685 2021-08	Liquid chromatography – mass spectrometry for the analyses of extractable substances out of pharmaceutical packaging material

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

ICH Q3D Guideline	Guideline for Elemental Impurities
2019-03	
USP <730>	Plasma spectrochemistry
2018-05	

USP <233> 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 analysis of aqueous extracts of glasses, glass ceramics and pharmaceutical packaging by ICP-MS or ICP-OES

9.5 by Inductively Coupled Plasma (ICP-MS)²⁾

ICH Q3D Guideline 20142019-03	Guideline for Elemental Impurities
USP <730> 2018-05	Plasma spectrochemistry
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 analysis of aqueous extracts of glasses, glass ceramics and pharmaceutical packaging by ICP-MS or ICP-OES

9.6 by UV-VIS-Spectrophotometry ³⁾

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

9.7 by Infrared Spectroscopy (IR) ³⁾

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

9.8 by Visual Inspection and optical microscopy ¹⁾

DIN EN ISO 8871-3 2019-08	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released-particle count
Section 3	(text German and English)
Ph. Eur. 2.9.20	European Pharmacopoeia
2020-01	2.9.20 Particulate contamination: Visible Particles
Ph. Eur. 3.2.9 2020-12	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 EP 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

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

ASTM F 1877 2016-00	Standard Practice for Characterization of Particles
USP <1660> 2013-12	Evaluation of the inner surface durability of glass containers
USP <1181> 2014-12	Scanning Electron Microscopy
01_SOP_00508 2018-02	Separation of particles from liquids by filtration and analysis by SEM and EDS (qualitative analysis)

9.10 by Raman spectroscopy ³⁾

JIS K 0137 2010-05

General rules for Raman spectrometry

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°C²⁾

DIN 51045-1 2005-08	Determination of the thermal expansion of solids - Part 1: Basic rules
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 refractography²⁾

ISO 15368 2021-03	Optics and optical instruments - Measurement of reflectance of plane surfaces and transmittance of plane parallel elements
01_SOP_00487 2018-07	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 2018-08	Determaination of the refractive index and dispersion of glasses with standard and/or precision accuracy by optical refractography

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

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

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)
- 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 Methods ²⁾

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 materialsby 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 ²⁾

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

PDA-TR 43	Technical Report No. 43 (Revised 2013)
2013-00	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 optical emission spectroscopy with inductively coupled plasma (ICP-OES)¹⁾

USP <730> 2018-05	Plasma spectrochemistry
USP <1660> 2013-12	Evaluation of the inner surface durability of glass containers

3	Determination of the mass contents of elements in glasses, glass ceramics, ceramics and othe anorganic materials, glass and ceramic raw materials		
3.1	3.1 Sample preparation, digestion methods (open digestions, melting digestion techniques) ²⁾		
01_ 20	_SOP_00556 19-05	Special digestion procedures for glasses, glass ceramics, ceramics, raw materials and other materials	
3.2 by optical emission spectroscopy with inductively coupled plasma (ICP-OES) ³⁾			
DII 20	N 51086-2 D4-07	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)

Abbreviations Used:

AAW/SOP	Standard Operation Procedure, in-house method of the chemical and physical testing laboratories of SCHOTT AG, complements national and/ or international standards (ASTM, DIN, ISO,) AAW: language German SOP: language English
AFM	Atomic Force Microscopy
CV-AAS	Cold Vapour - Atomic Absorption Spectrometry
DSC	Difference Scanning Calorimetry
DTA	Difference thermal analysis
EDS, EDX	Energy Dispersive X-ray spectroscopy
Ph.Eur.	European Pharmacopoeia
FAAS	Flame Atomic Absorption Spectrometry
FDA	Food and Drug Administration
FID	Flame ionization detector
GC	Gas chromatography
GFAAS	Graphite Furnace Atomic Absorption Spectrometry
HG-AAS	Hydride Generation - Atomic Absorption Spectrometry

ICG/TC 2International Commission on Glass/ Technical Committee 2ICP-AESInductively Coupled Plasma Optical Emission SpectrometryICP-MSInductively Coupled Plasma Mass SpectrometryICP-OESInductively Coupled Plasma Optical Emission SpectrometryIRWavelength range of infrared lightJISJapanese Industrial StandardJPJapanese PharmacopoeiaLA-ICP-MSLaser Ablation - Inductively Coupled Plasma - Mass SpectrometryICLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
ICP-AESInductively Coupled Plasma Optical Emission SpectrometryICP-MSInductively Coupled Plasma Mass SpectrometryICP-OESInductively Coupled Plasma Optical Emission SpectrometryIRWavelength range of infrared lightJISJapanese Industrial StandardJPJapanese PharmacopoeiaLA-ICP-MSLaser Ablation - Inductively Coupled Plasma - Mass SpectrometryLCLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
ICP-MSInductively Coupled Plasma Mass SpectrometryICP-OESInductively Coupled Plasma Optical Emission SpectrometryIRWavelength range of infrared lightJISJapanese Industrial StandardJPJapanese PharmacopoeiaLA-ICP-MSLaser Ablation - Inductively Coupled Plasma - Mass SpectrometryLCLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
ICP-OESInductively Coupled Plasma Optical Emission SpectrometryIRWavelength range of infrared lightJISJapanese Industrial StandardJPJapanese PharmacopoeiaLA-ICP-MSLaser Ablation - Inductively Coupled Plasma - Mass SpectrometryLCLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
IRWavelength range of infrared lightJISJapanese Industrial StandardJPJapanese PharmacopoeiaLA-ICP-MSLaser Ablation - Inductively Coupled Plasma - Mass SpectrometryLCLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
JISJapanese Industrial StandardJPJapanese PharmacopoeiaLA-ICP-MSLaser Ablation - Inductively Coupled Plasma - Mass SpectrometryLCLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
JPJapanese PharmacopoeiaLA-ICP-MSLaser Ablation - Inductively Coupled Plasma - Mass SpectrometryLCLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
LA-ICP-MSLaser Ablation - Inductively Coupled Plasma - Mass SpectrometryLCLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
LCLiquid chromatographyMSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	/
MSMass spectrometryOINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
OINDPOrally inhaled and nasal drug productsPDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
PDAPhotodiode array detectorPQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
PQRIProduct Quality Research InstituteRTCARadio Technical Commission for AeronauticsSEMScanning Electron Microscopy	
RTCA Radio Technical Commission for Aeronautics SEM Scanning Electron Microscopy	
SEM Scanning Electron Microscopy	
SOP In-house method of SCHOTT AG	
TGHE Carrier gas hot extraction	
Tof-SIMS Time of flight – Secondary Ion Mass Spectrometry	
USP United States Pharmacopoeia	
UV Ultra Violet = Wavelength range of ultra violet light	
UV-VIS Photometric method of the area "Chemical Analysis"	
VGA Combustion gas analysis	
VIS Visible = Wavelength of visible	
YBB Abbreviation for Chinese Pharmacopoeia regulation	
XRF X-ray Fluorescence	