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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 23-Apr-2020 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 6.0, 21-Aug-2020

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;

Strenth tests and determination of micro- and nano-hardness and elastic characteristics 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

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 area.

Abbreviations used: see last page

Contact person for quality management matters of the accredited testing laboratories of SCHOTT AG:

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

1 Determination of the mass contents 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, specical steels) in combination 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 (*withdrawn standard*)
DIN 52340-3 1990-07	Testing of glass Chemical analysis of colorless soda-lime-glass with SiO_2, CaO, MgO and Na_2O 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_2O_3, Fe_2O_3 and TiO_2 as well as CaO, MgO, Na_2O and K_2O (Modification: *Application for further oxides*)
SCHOTT_CA_0007 2016-10	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: *Digestion, no reprecipitation*)
SCHOTT_CA_0008 2016-10	Titrimetric determination of main and minor components in glasses, glass ceramics and raw materials

1.2.2 by Gravimetry [2)]

ISO 247 2006-09	Rubber - Determination of ash
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: *material-related tempartures, sample amounts*)
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 *(withdrawn standard*)
Ph.Eur. 3.2.9 2017-07	European Pharmacopoeia 3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders Test: Residue on evaporation
SCHOTT_CA_0009 2016-10	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_2O_3, Fe_2O_3, Cr_2O_3 content by flame atomic absorption spectrometry (FAAS) and Na_2O and K_2O by flame atomic emission spectrometry (FAES) (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_2O and K_2O (*standard withdr*awn) (Modification: *Detection with ICP-OES or FAAS*)
SCHOTT_CA_0010 2016-10	Determination of alkaline and alkaline earth oxides in raw materials and materials by flame atomic absorption spectrometry (FAAS)
SCHOTT_CA_0011 2016-10	Determination of traces and ultratraces in glasses, glass ceramics and raw materials after digestion and/or extraction by graphite furnace-AAS (GFAAS)
ICG/TC 2 Handbook of recommended analytical methods ISBN 92-95041-01-01 p. 23ff	Determination of mercury in glass by cold vapour atomic absorption spectrometry (CVAAS)

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

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 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 (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
SCHOTT_CA_0012 2016-10	Semi-quantitatve trace analysis of glasses, glass ceramics, raw materials and materials, dusts after sample digestion by ICP-MS

1.3.4 UV-VIS-Spectrophotometry [2)]

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)
SCHOTT_CA_0013 2016-10	Spectrophotometric determination of halides and arsenic in glasses, glass ceramics, raw materials and refractory materials
SCHOTT_CA_0014 2016-10	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 solution*s)
DIN EN ISO 14911 1999-12	Water quality - Determination of dissolved Li^+, Na^+, NH^{4+}, K^+, Mn^{2+}, Ca^{2+}, Mg^{2+}, Sr^{2+}, und Ba^{2+} using ion chromatography – Method for water and waste water (Modification: *Determination in aqueous extracts and digestion solutions*)
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 2003-08 and Supplement to DIN 51001 2010-05	Testing of oxidic raw materials and basic materials – General bases of work for X-ray fluorescence method (XRF) 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
SCHOTT_CA_0015 2016-10	Semi-quantitative determination of the composition of unknown glasses, glass ceramics, raw materials and materials, dusts, pigments, metals and residues by WD-XRF

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

SCHOTT_CA_0016 2016-10	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 51085 2015-01	Testing of oxidic raw and basic materials – Determination of total sulphur content
SCHOTT_CA_0017 2016-10	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 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 2017-07	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> 2017-12	Evaluation of the inner surface durability of glass containers
SCHOTT_CA_0001 2016-10	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 (in accordance with DIN EN ISO 4802-1, 2012-12)
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
Ph. Eur. 3.2.1 2017-07	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) 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
JP 17th edition 2016-03	Japanese Pharmacopoeia 7. Test for Containers and Packing Materials 7.01. Test for Glass Containers for Injections

USP <660> 2017-12	USP <660>, Containers-Glass Chemical Resistance Glass Grains Test Surface Glass Test Surface Etching Test

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 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 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 2017-07	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)

SCHOTT_CA_0002 2016-10	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 ICPMS*)
ISO 7086-1 2000-03	Glass hollowware in contact with food - Release of lead and cadmium - Part 1: Test method (Modification: *Detection with ICP-OES or ICP-MS*)
DIN EN ISO 11885 (E 22) 2009-09	Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)
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 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: *Determination of further cations with ICP-OES or ICP-MS*)
Ph. Eur. 3.2.1 2017-07	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: *Determination of further cations with ICP-OES or ICP-MS*)
USP <233> 2017-12	Chemical Test and Assays: Elemental Impurities - Procedures
USP <660> 2017-12	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)*
SCHOTT_CA_0003 2016-10	Trace analysis of aqueous extracts of glasses, glass ceramics and 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: *Determination of further cations with ICP-OES or ICPMS*)
ISO 7086-1 2000-03	Glass hollowware in contact with food - Release of lead and cadmium - Part 1: Test method (Modification: *Detection with ICP-OES or ICP-MS*)
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 2017-07	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: *Determination of further cations with ICP-OES or ICP-MS*)
USP <233> 2017-12	Chemical Test and Assays: Elemental Impurities - Procedures
USP <660> 2017-12	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)*
SCHOTT_CA_0003 2016-10	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 10304-1 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 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)
SCHOTT_CA_0004 2016-10	Determination of the chemical resistance of glasses, glass ceramics and other materials after chemical stresses by differential weighing and visual inspection

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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> 2017-12	Arsenic <211> Method I
SCHOTT_CA_0005 2016-10	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 2011-08	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)
SCHOTT_CA_0006 2016-10	Determination of the resistance of glasses, glass ceramics and composites with these materials after stresses by alternating climate and gases

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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
ISO 7991 1998-02	Glass; Determination of coefficient of mean linear thermal expansion
SCHOTT_PA_0001 2016-10	Determination of the static and dynamic thermal expansion behaviour of solids by dilatometry
SCHOTT_PA_0002 2016-10	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 10^0-$5 \cdot 10^{13}$ dPa s [2)]

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

SCHOTT_PA_0003 2016-10	Determination of the viscosity properties of glasses by beam bending, fibre elongation and rotation viscosimeters

3.3 Determination of density as well as the electric resistivity of glasses, glass ceramics, ceramics and other materials [2)]

ISO 2781 2008-05 with Ammendment 1 2010-07	Rubber, vulcanized or thermoplastic – Determination of density Precision data
DIN 52326 1986-05	Testing of glass; Determination of electrical resistivity (*withdrawn standard*)
ASTM C 693 1993 (reapproved 2008)	Standard Test Method for Density of Glass by Buoyancy (Modification: *Use of a surfactant additive as well as smaller sample mass*)
SCHOTT_PA_0004 2016-10	Determination of the specific electric volume resistance of glasses and glass ceramics by current and voltage measurements

3.4 Thermodynamic Measurements, especially differential thermal analysis (DTA), differential scanning calorimetry (DSC) and calorimetry (specific heat) on glasses, glass ceramics, ceramics and raw materials (powders) [2)]

DIN 51004 1994-06	Thermal analysis (TA) - Determination of melting temperatures of crystalline materials by differential thermal analysis (DTA)
DIN 51006 2005-07	Thermal analysis (TA) - Thermogravimetry (TG) - Principles
DIN 51007 1994-06	Differential thermal analysis (DTA) - Principles
SCHOTT_PA_0005 2017-08	Determination of the true and average specific heat capacity of solids by calorimetric methods
SCHOTT_PA_0006 2017-08	Thermal analysis of solids by differential thermal analysis (DTA), differential scanning calorimetry (DSC) and thermogravimetric analysis (TGA) as well as simultaneous DTA-TGA

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3.5 Determination 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 (*withdrawn standard*) (Modification: *measuring location near the sealing line*)

3.6 Determination of crystallization properties of glasses by gradient furnace method [2)]

ASTM C 829 1981	Standard Practices for Measurement of Liquidus Temperature of Glass by the Gradient Furnace Method
SCHOTT_PA_0007 2016-10	Determination of the crystallization properties of glasses and glass ceramics by the gradient furnace method

3.7 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 D 4093 1995	Test Method for Photoelastic Measurements of Birefringence and Residual Strains in Transparent or Translucent Plastic Materials
ASTM C 1422/C 1422 M 2010-02	Standard Specification for Chemically Strengthened Flat Glass (*withdrawn standard*)
SCHOTT_PA_0008 2016-10	Determination of mechanical tensions, birefringence and stress-optical coefficient of transparent solids by polarization-optical measurement methods

3.8 Determination of Young`s Modulus, Shear Modulus and Poisson`s constant of glass, glass ceramic and ceramic by resonance method [2)]

ASTM C 1259 2015	Standard Test Method for Dynamic Youngs Modulus, Shear Modulus, and Poissons Ratio for Advanced Ceramics by Impulse Excitation of Vibration

SCHOTT_PA_0009 2016-10	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 Determination of optical properties (Transmission, Reflection, Remission, scattered light/haze, solarization, spectral color measurement, refractive index and dispersion, fluorescence) of glasses, glass ceramics, liquids by spectroscopy [2)]

ISO 15368 2001-08	Optics and optical instruments - Measurement of reflectance of plane surfaces and transmittance of plane parallel elements
Ph. Eur. 3.2.9 2017-07	European Pharmacopoeia 3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders Test: Absorbance, Reference to EP 2.2.25 Test A: Infrared absorption spectrometry, Reference to EP 2.2.24
SCHOTT_PA_0010 2016-10	Determination of spectral transmission, remission, reflection, scattering, color value and solarization of solids, especially glasses and glass ceramics, plastics and liquids by optical spectroscopy
SCHOTT_PA_0011 2016-10	Determination of refractive index and dispersion of glasses, glass ceramics, plastics and solids by prism coupler method
SCHOTT_PA_0012 2016-10	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

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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	Standard Guide for Specimen Preparation and Mounting in Surface Analysis
SCHOTT_OF_0001_EN 2016-10	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 2004-01	Guide to Scanner and Tip Related Artifacts in Scanning Tunneling Microscopy and Atomic Force Microscopy
SCHOTT_OF_0002 2016-10	Topographic determination on glasses, glass ceramics, ceramics, metals, plastics and composite materials by white-light interference microscopy
SCHOTT_OF_0004 2016-10	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 2013-05	Steels - Micrographic determination of the apparent grain size
ASTM E 112 2013-04	Standard Test Methods for Determining Average Grain Size

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SCHOTT_OF_0003_EN 2016-10	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 2011-05	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 2009-01	Standard Guide for Interpretation of Mass Spectral Data Acquired with Time-of-Flight Secondary Ion Mass Spectroscopy
SCHOTT_OF_0005 2016-10	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 2010-05	General rules for Raman spectrometry
USP <1854> 2017-12	Mid-infrared spectroscopy - Theory and practice

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

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
SCHOTT_ZL_0001 2016-10	Determination of the strength of brittle materials, plastics and composite materials by tensile and pressure tests with universal testing machines

7 Determination of microhardness and nanohardness as well as plastic/elastic parameters of glasses, glass ceramics, plastics and composite materials by penetrant testing, Determination of material and product properties [2)]

DIN EN ISO 4545-1 2006-03	Metallic materials - Knoop hardness test Part 1: Test method
DIN EN ISO 6507-1 2006-03	Metallic materials - Vickers hardness test Part 1: Test method
DIN EN ISO 14577-1 2015-11	Metallic materials - Instrumented indentation test for hardness and materials parameters - Part 1: Test method
DIN ISO 9385 1991-01	Glass and glass-ceramics; Knoop hardness test
SCHOTT_ZL_0002 2016-10	Determination of mechanical parameters (strength, stiffness and elastic behavious) of brittle materials, plastics, composite materials and coatings by indentation test

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8 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 (reapproved 2003)	Standard Practice for Interpreting Glass Fracture Surface Features
PDA-TR 43 2013	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
SCHOTT_ZL_0003_EN 2016-10	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 spectroscopy

SCHOTT_BA_0001 2016-10	Determination of volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by mass spectrometry
SCHOTT_BA_0002 2016-10	Determination of volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by Raman spectroscopy
JIS K 0137 2010-05	General rules for Raman spectrometry

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

10.1 by gas chromatography (GC-MS) [2)]

USP <621> 2017-12	Chromatography

USP <1663> 2017-12	Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems
USP <1664> 2017-12	Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems
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
SCHOTT_PS_0001_EN 2016-10	Determination of plastic additives in and out of polymer materials using gas chromatography - mass spectrometry

10.2 by Liquid Chromatography (HPLC-MS-IT-TOF) [2)]

USP <621> 2017-12	Chromatography
USP <1663> 2017-12	Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems
USP <1664> 2017-12	Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems
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
SCHOTT_PS_0002_EN 2016-10	Determination of leachable monomers from cured adhesives using liquid chromatography - mass spectrometry

10.3 by Inductively Coupled Plasma (ICP-OES) [2)]

ICH Q3D Guideline 2014-12	Guideline for Elemental Impurities
USP <730> 2017-12	Plasma spectrochemistry
USP <233> 2017-12	Chemical Test and Assays: Elemental Impurities - Procedures

USP <1660> 2017-12	Evaluation of the inner surface durability of glass containers
USP <1663> 2017-12	Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems
USP <1664> 2017-12	Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems
SCHOTT_CA_0003 2016-10	Trace analysis of aqueous extracts of glasses, glass ceramics and pharmaceutical packaging by ICP-MS or ICP-OES

10.4 by Inductively Coupled Plasma (ICP-MS) [2)]

ICH Q3D Guideline 2014-12	Guideline for Elemental Impurities
USP <730> 2017-12	Plasma spectrochemistry
USP <233> 2017-12	Chemical Test and Assays: Elemental Impurities - Procedures
USP <1660> 2017-12	Evaluation of the inner surface durability of glass containers
USP <1663> 2017-12	Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems
USP <1664> 2017-12	Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems
SCHOTT_CA_0003 2016-10	Trace analysis of aqueous extracts of glasses, glass ceramics and pharmaceutical packaging by ICP-MS or ICP-OES

10.4 by UV-VIS-Spectrophotometry [3)]

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

10.5 by Infrared Spectroscopy (IR) [3)]

DIN EN ISO 8871-2 2014-08 Annex A	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization (text in German and English)

10.6 by Visual Inspection and optical microscopy [1)]

DIN EN ISO 8871-3 2004-09 Section 3	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 2017-07	European Pharmacopoeia 2.9.20 Particulate contamination: Visible Particles
Ph. Eur. 3.2.9 2017-07	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 EP 2.4.8 Test A Test: Volatile sulfides
PDA-TR 43 2013	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> 2017-12	Visible particulates in injections
USP <1660> 2017-12	Evaluation of the inner surface durability of glass containers

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

ASTM F 1877 2016	Standard Practice for Characterization of Particles
USP <1660> 2017-12	Evaluation of the inner surface durability of glass containers

USP <1181> 2017-12	Scanning Electron Microscopy
SCHOTT_PS_0003_EN 2016-10	Separation of particles from liquids by filtration and analysis by SEM and EDS (qualitative analysis)

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)]

DIN 51045-1 2005-08	Determination of the thermal expansion of solids - Part 1: Basic rules
ISO 7991 1998-02	Glass; Determination of coefficient of mean linear thermal expansion
SCHOTT_PA_0001 2016-10	Determination of the static and dynamic thermal expansion behaviour of solids by dilatometry

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 2001-08	Optics and optical instruments - Measurement of reflectance of plane surfaces and transmittance of plane parallel elements
SCHOTT_PA_0010 2016-10	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
SCHOTT_OM_0001 2016-10	Determaination of the refractive index and dispersion of glasses with standard and/or precision accuracy by optical refractography

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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	Standard Guide for Specimen Preparation and Mounting in Surface Analysis
SCHOTT_OF_0001_EN 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 (reapproved 2003)	Standard Practice for Interpreting Glass Fracture Surface Features
SCHOTT_OF_0003_EN 2018-02	Sample characterization of glasses, glass ceramics, ceramics, metals, plastics, composite and solid materials by light microscopy
SCHOTT_ZL_0003 2018-02	Fractography / fracture analysis on brittle materialsby 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 2017-07	European Pharmcopoeia 2.9.20 Particulate contamination: Visible Particles
PDA-TR 43 2013	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> 2019-05	Visible particulates in injections
USP <1660> 2019-05	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	Standard Practice for Characterization of Particles
USP <1660> 2019-05	Evaluation of the inner surface durability of glass containers
USP <1181> 2019-05	Scanning Electron Microscopy
SCHOTT_PS_0003_EN 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> 2019-05	Plasma spectrochemistry
USP <1660> 2019-05	Evaluation of the inner surface durability of glass containers

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

3.1 Sample preparation, digestion methods (open digestions, melting digestion techniques)

SCHOTT_CC_0001_EN 2019-05	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)]

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*)

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
EP	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

IC	Ion chromatography
ICG/TC 2	International Commission on Glass/ Technical Committee 2
ICP-AES	Inductively Coupled Plasma Optical Emission Spectrometry
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
ICP-OES	Inductively Coupled Plasma Optical Emission Spectrometry
IR	Wavelength range of infrared light
KL	Cathode luminescence
LA-ICP-MS	Laser Ablation - Inductively Coupled Plasma - Mass Spectrometry
LC	Liquid chromatography
MS	Mass spectrometry
OINDP	Orally inhaled and nasal drug products
PDA	Photodiode array detector
PQRI	Product Quality Research Institute
RTCA	Radio Technical Commission for Aeronautics
SEM	Scanning Electron Microscopy
SCHOTT_...	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
XRF	X-ray Fluorescence