SCHOTT

Accredited Testing Laboratories SCHOTT

Complete list of all accredited testing methods in the flexible scope according to the conformity assessment body D-PL-14645-01-00

The testing laboratory hereby publishes the list of all testing methods in the flexible scope of accreditation of the CAB with reference to
Working area FB 3.4 Medicine, pharmacy, non-active medical devices,
Partial certificate annex D-PL-14645-01-04

Coding:	01_LIST_00003 (Excerpt)
Version:	17.0
Issue date:	10-Dec-2025

Updates/changes are marked in **green**.
Newly introduced procedures according to category A, B or C are marked with [NEW in flexible scope] in column “Norm/Issue date/In-house procedure/Version".

Within the marked test scopes, the testing laboratory is permitted to do the following without having to inform and obtain prior approval from DAkkS:

[Flex A] The extension of the scope of accreditation by standardized or equivalent test methods with different issue dates within a defined testing scope.

[Flex B] Includes category A as well as the extension of the scope of accreditation by standardized or equivalent test methods within a defined test scope. Category B includes - where applicable - new specifications for test objects, provided that these can be determined using the procedure within the test scope.

[Flex C] Includes categories A and B as well as the extension of the scope of accreditation by modified as well as further and newly developed test methods (e.g. in-house procedures) within a defined test area.

The original complete certificate and the partial certificates issued by DAkkS for the above-mentioned conformity assessment body can be found at www.dakks.de, Accredited Bodies, D-PL-14645-01-00.
The testing procedures listed there are exemplary.

Tests are carried out in the following working areas:

Medicines and active ingredients

Locations:

SCHOTT AG
Otto-Schott-Straße 2, 55127 Mainz

SCHOTT AG
400 York Ave, Duryea/PA 18642 USA

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 for performing the conformity assessment activities listed in this annex. The testing laboratory fulfills any additional legal and normative requirements, including those in relevant sectoral programs, provided that these are expressly confirmed below.

The requirements for the management system are written in the relevant language and are fully compliant with the principles of DIN EN ISO 9001.

Medicines and active ingredients

Testing of primary pharmaceutical packaging materials

Test type: Determination of leakage [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
ISO 7886-1 2017-05 Annex D	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 11040-4 2024-06 Annex H Annex G2	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	Pharmaceutical primary packaging materials made of glass	MZ-OS
ISO 11040-6 2019-01 Annex H Annex G2	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 11608-3 2022-04 Section 5.1	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 21881 2019-10 Annex F	Package integrity leak test technologies	Pharmaceutical primary packaging materials made of glass	MZ-OS
USP <1207.2> 2016-08 Table 1, row 2 and Section 2.2	Package integrity leak test technologies	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Determination of residual emptying capacity

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
ISO 7886-1 2017-05 Annex C	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
01_SOP_00816 2025-09	Determination of the delivered dose of glass and plastic syringes	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Mechanical functional tests [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
ISO 8871-5 2016-10 Annex A	Elastomeric parts for parentals and for devices for pharmaceutical use - Part 5: Functional requirements and testing	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 11040-4 2024-06 Annex C1 Annex C2 Annex E Annex F Annex G1 Annex G3 Annex G6	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	Pharmaceutical primary packaging materials made of glass	MZ-OS
ISO 11040-6 2019-01 Annex C1 Annex C2 Annex E Annex G1 Annex G6	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 21881 2019-10 Annex D	Sterile packaged ready for filling glass cartridges	Pharmaceutical primary packaging materials made of glass	MZ-OS
USP <1207.3> 2016-08 Chapter 5	Package seal quality test technologies	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00817 2025-09	Needle penetration test for the closure systems of cartridges	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Chromatography (GC-MS, LC-MS) [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
USP <621> 2024-12	Chromatography	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00498 2025-09	Determination of plastic additives in and out of pharmaceutical packaging materials using gas chromatography - mass spectometry	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00684 2025-09	Gas chromatography - mass spectrometry for the analyses of extractable substances out of pharmaceutical packaging material	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00499 2025-09	Determination of leachable monomers from cured adhesives using liquid chromatography - mass spectrometry	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00685 2025-09	Liquid chromatography - mass spectrometry for the analyses of extractable substances out of pharmaceutical packaging material	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Extraction and leaching processes [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
Ph. Eur. 3.2.9 2023-04 Sample preparation of Solution S	European Pharmacopoeia - 3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Titrimetry [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
JP 18th edition 2021-06	Japanese Pharmacopoeia - 7. Test for Containers and Packing Materials - 7.01. Test for Glass Containers for Injections	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
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)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <660> 2023-10	USP <660>, Containers-Glass - Hydrolytic Resistance - Glass Grains Test - Surface Glass Test- Surface Etching Test	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Atomic absorption spectrometry (FAAS, HG-AAS) [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
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)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 3.2.9 2023-04 Extractable zinc	European Pharmacopoeia - 3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Optical emission spectrometry with Inductively Coupled Plasma (ICP-OES)/ Mass Spectrometry with Inductively Coupled Plasma [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
USP <730> 2018-05	Plasma spectrochemistry	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <233> 2018-05	Chemical Test and Assays: Elemental Impurities - Procedures	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00028 2025-08	Trace element analysis of aqueous extracts from glass, glass ceramics and pharmaceutical packaging with ICP-MS or ICP-OES	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 3.2.1 2019-01	European Pharmacopoeia - 3.2. Containers - 3.2.1. Glass containers for pharmaceutical use - Test A: Hydrolytic resistance of the inner surfaces of glass containers (Surface Test) - Test B: Hydrolytic resistance of glass grains (Glass Grains Test) - Test C: To determine whether the containers have been surface treated (Etching Test) - Annex - Test for surface hydrolytic resistance-determination by flame atomic absorption spectrometry (FAAS) (Modifikation: Bestimmung von weiteren Kationen mit ICP-OES oder ICP-MS)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 3749 2022-03	Glass syringes – Determination of extractable tungsten	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <660> 2023-10	USP <660>, Containers-Glass Hydrolytic Resistance Glass Grains Test Surface Glass Test Surface Etching Test (Modification: *Detection of cations with ICP-MS)*	Pharmazeutische Primärpackmittel aus Glas und Kunststoff	MZ-OS

Test type: Optical emission spectrometry with Inductively Coupled Plasma (ICP-OES) [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
USP <730> 2018-05	Plasma spectrochemistry	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA

Test type: UV-VIS spectrophotometry [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
ISO 8871-1 2003-10 Annex C	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 1: Extractables in aqueous autoclavates	Pharmaceutical primary packaging materials made of plastic	MZ-OS
JP 18th edition 2021-06 [NEW in flexible scope]	Japanese Pharmacopoeia Physical Methods Spectroscopic Methods 2.24 Ultraviolet-visible Spectrophotometry	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 3.2.1 2019-01 [NEW in flexible scope]	European Pharmacopoeia - 3.2. Containers - 3.2.1. Glass containers for pharmaceutical use - Spectral Transmission for Colored Glass Containers	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <660> 2023-10 [NEW in flexible scope]	USP <660>, Container Glass - Functionality - Spectral Transmission for Colored Glass Containers	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Infrared Spectroscopy (IR) [Flex A]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
ISO 8871-2 2020-05 Annex A	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Microscopy [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
ISO 8871-3 2003-08 Section 3	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released-particle count	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 8871-3 AMD 1 2018-01	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released-particle count; Amendment 1	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 8871-5 2016-10 Annex B	Elastomeric parts for parentals and for devices for pharmaceutical use - Part 5: Functional requirements and testing	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 11608-3 2022-04 Section 4.2.3 and Section 5.2	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 2.9.20 2020-01	European Pharmcopoeia 2.9.20 Particulate contamination: Visible Particles	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA
Ph. Eur. 3.2.9 2023-04	European Pharmacopoeia - 3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders Test: Appearance of solution S Test: Ammonium, Reference to Ph. Eur. 2.4.1 Method A Test: Extractable heavy metals, Reference to Ph. Eur. 2.4.8 Test A Test: Volatile sulfides	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <790> 2016-05	Visible particulates in injections	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA
01_SOP_00041 2025-09	Determination of delamination risk in primary packaging containers for storage of pharmaceutical products by Stereo-microscopy (Qualitative Analysis)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
USP <1181> 2014-12	Scanning Electron Microscopy	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA
01_SOP_00508 2025-09	Separation of particles from solution by filtration and suitable particle analyses	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA
ISO 11040-4 2024-06 Annex D2	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	Pharmaceutical primary packaging materials made of glass	MZ-OS
ISO 11040-6 2019-01 Annex D2	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 11608-3 2022-04 Annex A Table A1, row 3	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <788> 2013-01	Particulate matter in injections	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 2.9.19 2021-01	Particulate contamination: Sub-visible particles	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
DIN EN 843-6 2009-12	Advanced technical ceramics - Mechanical properties of monolithic ceramics at room temperature - Part 6: Guidance for fractographic investigation	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA
ASTM C 1256 2025-00a	Standard Practice for Interpreting Glass Fracture Surface Features	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA
01_SOP_00496 2025-09	Fractography/Fracture analysis on brittle materials	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
01_SOP_00501 2025-09	Sample characterization of glasses, glass ceramics, ceramics, metals, plastics, composite and solid materials by light microscopy	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA

Test type: Raman Spectroscopy [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
JIS K 0137 2010-05	General rules for Raman spectrometry	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00508 2025-09	Separation of particles from solution by filtration and suitable particle analyses	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA

Test type: pH-measurement [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
DIN 19268 2021-10	pH-measurement - pH-measurement of aqueous solutions with pH measuring chains with pH glass electrodes and evaluation of measurement uncertainty	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA