

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: 15.0

Issue date: 28-Oct-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	Sterile hypodermic syringes for single	Pharmaceutical	MZ-OS
2017-05	use - Part 1: Syringes for manual use	primary packaging	
Annex D		materials made of glass	
		and plastic	
ISO 11040-4	Prefilled syringes - Part 4: Glass	Pharmaceutical	MZ-OS
2024-06	barrels for injectables and sterilized	primary packaging	
Annex H	subassembled syringes ready for	materials made of glass	
Annex G2	filling		
ISO 11040-6	Prefilled syringes - Part 6: Plastic	Pharmaceutical	MZ-OS
2019-01	barrels for injectables and sterilized	primary packaging	
Annex H	subassembled syringes ready for	materials made of	
Annex G2	filling	plastic	
ISO 11608-3	Needle-based injection systems for	Pharmaceutical	MZ-OS
2022-04	medical use - Requirements and test	primary packaging	
Section 5.1	methods - Part 3: Containers and	materials made of glass	
	integrated fluid paths	and plastic	
ISO 21881	Package integrity leak test	Pharmaceutical	MZ-OS
2019-10	technologies	primary packaging	
Annex F		materials made of glass	
USP <1207.2>	Package integrity leak test	Pharmaceutical	MZ-OS
2016-08	technologies	primary packaging	
Table 1, row 2 and		materials made of glass	
Section 2.2		and plastic	

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	Sterile hypodermic syringes for single	Pharmaceutical	MZ-OS
2017-05	use - Part 1: Syringes for manual use	primary packaging	
Annex C		materials made of glass	
		and plastic	

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	Determination of the delivered dose	Pharmaceutical	MZ-OS
2025-09	of glass and plastic syringes	primary packaging	
		materials made of glass	
		and plastic	

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 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 <621>	Chromatography	Pharmaceutical	MZ-OS
2024-12		primary packaging materials made of glass and plastic	
01_SOP_00498	Determination of plastic additives in	Pharmaceutical	MZ-OS
2025-09	and out of pharmaceutical packaging	primary packaging	
	materials using gas chromatography -	materials made of glass	
	mass spectometry	and plastic	
01_SOP_00684	Gas chromatography - mass	Pharmaceutical	MZ-OS
2025-09	spectrometry for the analyses of	primary packaging	
	extractable substances out of	materials made of glass	
	pharmaceutical packaging material	and plastic	
01_SOP_00499	Determination of leachable	Pharmaceutical	MZ-OS
2025-09	monomers from cured adhesives	primary packaging	
	using liquid chromatography - mass	materials made of glass	
	spectrometry	and plastic	
01_SOP_00685	Liquid chromatography - mass	Pharmaceutical	MZ-OS
2025-09	spectrometry for the analyses of	primary packaging	
	extractable substances out of	materials made of glass	
	pharmaceutical packaging material	and plastic	

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	European Pharmacopoeia - 3.2.9	Pharmaceutical	MZ-OS
2023-04	Rubber closures for containers for	primary packaging	
Sample preparation of	aqueous parenteral preparations, for	materials made of glass	
Solution S	powders and for freeze-dried	and plastic	
	powders		

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	Japanese Pharmacopoeia - 7. Test for	Pharmaceutical	MZ-OS
18th edition	Containers and Packing Materials -	primary packaging	
2021-06	7.01. Test for Glass Containers for	materials made of glass	
	Injections	and plastic	
Ph. Eur. 3.2.1	European Pharmacopoeia - 3.2.	Pharmaceutical	MZ-OS
2019-01	Containers - 3.2.1. Glass containers	primary packaging	
	for pharmaceutical use - Test A:	materials made of glass	
	Hydrolytic resistance of the inner	and plastic	
	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)		
USP <660>	USP <660>, Containers-Glass -	Pharmaceutical	MZ-OS
2023-10	Hydrolytic Resistance - Glass Grains	primary packaging	
	Test - Surface Glass Test- Surface	materials made of glass	
	Etching Test	and plastic	

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	European Pharmacopoeia - 3.2.	Pharmaceutical	MZ-OS
2019-01	Containers - 3.2.1. Glass containers	primary packaging	
	for pharmaceutical use - Annex - Test	materials made of glass	
	for surface hydrolytic resistance-	and plastic	
	determination by flame atomic		
	absorption spectrometry (FAAS) -		
	Arsenic (HGAAS)		
Ph. Eur. 3.2.9	European Pharmacopoeia - 3.2.9	Pharmaceutical	MZ-OS
2023-04	Rubber closures for containers for	primary packaging	
Extractable zinc	aqueous parenteral preparations, for	materials made of glass	
	powders and for freeze-dried	and plastic	
	powders		

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>	Plasma spectrochemistry	Pharmaceutical	DY-YA
2018-05		primary packaging	
		materials made of glass	
		and plastic	

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	Elastomeric parts for parenterals and	Pharmaceutical	MZ-OS
2003-10	for devices for pharmaceutical use -	primary packaging	
Annex C	Part 1: Extractables in aqueous	materials made of	
	autoclavates	plastic	
JP 18th edition	Japanese Pharmacopoeia Physical	Pharmaceutical	MZ-OS
2021-06	Methods Spectroscopic Methods	primary packaging	
	2.24 Ultraviolet-visible	materials made of glass	
[NEW in flexible scope]	Spectrophotometry	and plastic	
Ph. Eur. 3.2.1	European Pharmacopoeia - 3.2.	Pharmaceutical	MZ-OS
2019-01	Containers - 3.2.1. Glass containers	primary packaging	
	for pharmaceutical use - Spectral	materials made of glass	
[NEW in flexible scope]	Transmission for Colored Glass	and plastic	
	Containers		
USP <660>	USP <660>, Container Glass -	Pharmaceutical	MZ-OS
2023-10	Functionality - Spectral Transmission	primary packaging	
	for Colored Glass Containers	materials made of glass	
[NEW in flexible scope]		and plastic	

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	Elastomeric parts for parenterals and	Pharmaceutical	MZ-OS
2020-05	for devices for pharmaceutical use -	primary packaging	
Annex A	Part 2: Identification and	materials made of glass	
	characterization	and plastic	

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

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	Sample characterization of glasses,	Pharmaceutical	DY-YA
2025-09	glass ceramics, ceramics, metals, plastics, composite and solid materials by light microscopy	primary packaging materials made of glass and plastic	

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	General rules for Raman	Pharmaceutical	MZ-OS
2010-05	spectrometry	primary packaging	
		materials made of glass	
		and plastic	
01_SOP_00508	Separation of particles from solution	Pharmaceutical	MZ-OS
2025-09	by filtration and suitable particle	primary packaging	DV VA
	analyses	materials made of glass	DY-YA
		and plastic	

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	pH-measurement - pH-measurement	Pharmaceutical	DY-YA
2021-10	of aqueous solutions with pH	primary packaging	
	measuring chains with pH glass	materials made of glass	
	electrodes and evaluation of	and plastic	
	measurement uncertainty		