DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that the testing laboratory

Evonik Operations GmbH
Rellinghauser Straße 1-11, 45128 Essen

meets the requirements of DIN EN ISO/IEC 17025:2018 for the conformity assessment activities specified in the following partial accreditation certificates. This includes additional existing legal and normative requirements for the testing laboratory, including those in relevant sectoral schemes, provided that these are explicitly confirmed in the annexes to the partial accreditation certificates listed below.

D-PL-21594-04-01
D-PL-21594-04-02

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This accreditation certificate consists of this cover sheet, the reverse side of the cover sheet and the following annex. It only applies in connection with the partial accreditation certificates listed above and the notices referred to there.

Registration number of the certificate: **D-PL-21594-04-00**

Berlin, 26.01.2023 Dr. rer. nat. Olga Lettau
Head of Technical Unit

Translation issued:
07.10.2024 Dr. rer. nat. Olga Lettau
Head of Technical Unit

The certificate together with the annex reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf

Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

Office Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Office Braunschweig
Bundesallee 100
38116 Braunschweig

The Deutsche Akkreditierungsstelle GmbH (DAkkS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkkS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

DAkkS is a signatory to the multilateral agreements for mutual recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Co-operation (ILAC).

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-21594-04-00 according to DIN EN ISO/IEC 17025:2018

Valid from: **26.01.2023**

Date of issue: 23.06.2023

Holder of accreditation certificate:

Evonik Operations GmbH
Rellinghauser Straße 1-11, 45128 Essen

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed in the annexes to the partial accreditation certificates listed below.

D-PL-21594-04-01

D-PL-21594-04-02

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de.

DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

The Deutsche Akkreditierungsstelle attests with this **Partial Accreditation Certificate** that the testing laboratory

Evonik Operations GmbH
Rellinghauser Straße 1-11, 45128 Essen

meets the requirements according to DIN EN ISO/IEC 17025:2018 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the testing laboratory, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This partial accreditation certificate only applies in connection with the notice of 26.01.2023 with accreditation number D-PL-21594-04.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 12pages.

Registration number of the partial accreditation certificate: **D-PL-21594-04-01**
It is a part of the accreditation certificate: D-PL-21594-04-00.

Berlin, 26.01.2023 — Dr. rer. nat. Olga Lettau, Head of Technical Unit

Translation issued: 07.10.2024 — Dr. rer. nat. Olga Lettau, Head of Technical Unit

The certificate together with the annex reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf

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Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

DAkkS is a signatory to the multilateral agreements for mutual recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Co-operation (ILAC).

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ILAC: www.ilac.org
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Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-21594-04-01 according to DIN EN ISO/IEC 17025:2018

Valid from: **26.01.2023**

Date of issue: 13.06.2023

This annex is a part of the accreditation certificate D-PL-21594-04-00.

Holder of partial accreditation certificate:

Evonik Operations GmbH
Rellinghauser Straße 1-11, 45128 Essen

with the location

Evonik Operations GmbH
Product Line Analytik
Paul-Baumann-Straße 1, 45764 Marl

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

Testing for the following areas:

physical, physical-chemical and chemical investigations of inorganic and organic chemicals, pharmaceuticals, cosmetics, rubber, plastics, plastic additives, fibers, foils, dyes, pigments, emulsifiers, additives, surfactants, waxes and resins, ceramics, coal, minerals, other solids, Semi-finished products, semi-finished products, consumer goods, commodities, (compressed) gases, combustible gases, metals, alloys, solders, catalysts and exhaust gas catalysts, semiconductors, ceramic colors, carbon black, silicas, pyrogenic oxides, metallic materials and surfaces;

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de.

Within the testing areas marked with **, the testing laboratory is permitted, without being required to inform and obtain prior approval from Deutsche Akkreditierungsstelle GmbH, to modify, further develop, and develop new testing procedures.

The listed test procedures are examples only.
The laboratory has an up-to-date list of all test procedures in the flexible accreditation area.

Valid for the location(s):

Rodenbacher Chaussee 4, 63457 Hanau
Paul-Baumann-Straße 1, 45764 Marl

The test procedures are marked with the following symbols of the locations where they are carried out:

M = Marl, W = Hanau-Wolfgang

1 Physical, physical-chemical and chemical analysis of ingredients and contaminants in chemical raw materials, intermediate and end products

1.1 Structural analysis of organic compounds using NMR spectroscopy **

SOP 0558 Version 09 06.02.2020	^{13}C-NMR-Spectroscopy Recording and analyzing nuclear magnetic resonance spectra	M
SOP 0565 Version 07 06.02.2020	^{1}H-NMR-Spectroscopy Recording and analyzing nuclear magnetic resonance spectra	M
SOP 0565 Method 008, Version 03 11.05.2016	NMR spectroscopic examination of (product name), (product name) and (product name) of the syringe A	M
SOP 0565 Method 015e, Version 05 28.01.2019	Determination of modification degree of (API) hydrogels (product name) by means of ^{1}H NMR spectroscopy	M
SOP 0565 Method 021e, Version 01 28.02.2019	Assay determination of EDTA and citric acid in (API) by means of ^{1}H NMR spectroscopy	M
SOP 1999, Version 01 16.05.2017	Method of weight percent ethylene oxide of (product name) by NMR (USP-NF- and EP-modified)	M

SOP NMR-024, Version 03 11.11.2016	Assay determination using NMR spectroscopy	M/W
SOP NMR-024 Method 014, Version 04 22.05.2017	Identity verification and determination of the salary of (product name) using ^{1}H-NMR spectroscopy	W
SOP NMR 1995, Version 01 08.09.2015	Determination of percentage α 1,6-branching in (product name) by ^{13}C-NMR spectroscopy	M
SOP NMR-021 Version 02 09.07.2015	Evaluation of NMR spectra	M/W
SOP NMR-021 E Method 024 E, Version 01 13.08.2013	Identity and impurity profile of phosphoramidites by ^{31}P-NMR spectroscopy	W

1.2 Photometric analysis of organic and inorganic compounds using UV/VIS and colorimetry **

SOP 0190 Version 03 30.07.2004	Measurement of UV/VIS spectra	M
QK TM 25109e/07	Determination of total phosphorous content in (product name) and (product name)	M
Ph.Eur. 0204 (10.0)	Sucrose: Sulfites	M
Ph.Eur. 30209 (10.0)	Rubber closures for containers for aqueous parenteral preparations for powders and for freeze dried powders: Absorbance	M

1.3 Investigations or product identifications using infrared spectroscopy (FT-IR) **

AN-SOP 0188, Version 05 07.12.2012	measuring IR spectra	M
AN-SOP 0188 Method 04, Version 01 27.02.2019	measuring IR spectra Identity verification of (product name), (product name), (product name) and (product name) using IR spectroscopy	M
SOP 0188 Method 003, Version 04 09.05.2016	FT-IR identity verification of (product name), (product name) and (product name) syringe B	M

SOP 2059, Version 02 08.04.2019	Determination of the degree of siliconization of rubber parts by means of IR spectroscopy	M
SOP IR-011, Version 06 17.10.2018	Identity verification using IR spectroscopy	W
SOP IR-011 Method 054, Version 01 29.02.2012	Identity verification using IR spectroscopy Determining the identity of (product name) using ATR-IR spectroscopy	W
SOP IR-011 Method 055, Version 02 19.12.2019	Identity verification using IR spectroscopy Determining the identity of (product name)	W
SOP IR-011 Method 080, Version 01 29.11.2012	Identity verification using IR spectroscopy Determining the identity and comparing the chromatographic gels of the type (product name) using ATR-IR spectroscopy	W
SOP IR-011 Method 081, Version 01 21.12.2018	Identity verification using IR spectroscopy Determining the identity and comparing the chromatographic gels of the type (product name) using ATR-IR spectroscopy	W

1.4 Investigations of ingredients and contaminants using liquid chromatographic with mass spectrometric detection (HPLC-ESI-MS, APCI-MS coupling techniques) **

SOP LCMS-016 Version 05 18.07.2019	Determination of degradation products in (API) tablets of (company name)	W
SOP LCMS-020 Version 01 02.06.2015	Determination of peak E in tryptophan	W
SOP LCMS-023 Version 01 05.10.2011	Mass spectrometric limit test for genotoxic 4-fluoroaniline in (product name) from (company name)	W
SOP LCMS-028 Version 01 27.05.2014	Determination of impurity E in (product name) from (company name) by HPLC-MS	W
SOP LCMS-034 Version 01 18.01.2017	Mass spectrometric limit test for bromoacetic acid in (product name)	W
SOP LCMS-041 Version 03 02.12.2019	Quantification of histamine in (API) using LC-MS	W

1.5 Gas chromatographic analysis of organic and inorganic substances (GC-FID, HSGC-FID, GC-WLD) **

AN-SOP 1946, Version 01 12.12.2013	Determination of the residual solvents ethylene glycol, acetic acid and 2-propanol in (product name) and (product name) as a limit test	M
SOP 2060e, Version 02 01.02.2019	Determination of monomer lactide in (product name) and in (product name) using gas chromatography	M
SOP 2077, Version 01 22.02.2019	Determination of ethylene oxide, propylene oxide and 1,4 dioxane in (product name) by HS-GC on the basis of the USP monograph poloxamer (USP 41/NF 36)	M
SOP 2107e, Version 01 29.08.2019	Limit test of residual solvents ethanol and 2-propanol in (API) based on USP General Chapter <467> for water-insoluble substances Procedure A	M
Ph.Eur. 0428 (10.0)	Polysorbate 80: Composition of fatty acids	M
Ph.Eur. 1497 (10.0)	Castor oil, hydrogenated: Composition of fatty acids	M
AN-SOP 1665 Method 03, Version 02 08.07.2008	Determination of the content and identity of nitrogen	M
AN-SOP 1665 Method 08, Version 01 26.03.2015	Determination of argon, oxygen and nitrogen in air and gas mixtures using capillary separation columns	M
AN-SOP 1599 Method 01, Version 03 21.04.2016	Determination of gas samples for trace amounts of carbon monoxide with a specification ≤ 10 ml/m3	M
AN-SOP 1599 Method 02, Version 01 26.04.2019	Determination of gas samples for traces of carbon monoxide, methane and carbon dioxide	M
SOP 1993, Version 01 26.03.2015	Determination of the content of pure nitrogen according to USP	M
SOP 2020, Version 02 14.04.2020	Determination of the content of sick matter in pure nitrogen by means of gas chromatography according to EP 1247	M

1.6 Liquid chromatographic analysis of organic substances using HPLC (HPLC-DAD, HPLC-RID, HPLC-UVD, HPLC-FLD, HPLC-ELSD) **

SOP 1366_e Version 02 06.02.2014	Determination of the assay of lactose monohydrate by means of HPLC	M
SOP 1368_e Version 04 06.02.2014	Determination of the related substances in lactose monohydrate by means of HPLC	M
SOP 1968, Version 01 16.08.2016	Determination of related compounds in aspartic acid according to USP 38 2nd supplement	M
SOP 2062e, Version 01 01.02.2018	Determination of the related compounds in Methionine according to USP 40 NF 35s1	M
SOP HPLC-1082 Version 06 28.09.2017	HPLC method for the simultaneous determination of (API) and (API) impurities in doped bone cement	W
USP 41 NF 36	Glycine: Related compounds	M

1.7 Ion chromatographic analysis of organic and inorganic substances (IC-LFD, IC-AMP, IC-UV) **

SOP 2104, Version 03 16.09.2019	Determination of chloride, nitrite and nitrate in (product name) by ion chromatography	M
SOP STT-ASA-001 Method ASA-0008 Version 09 25.07.2019	Implementation of an amino acid analysis with the amino acid analyzer S433 of the company Sykam: Determination of "Ninhydrin-positive substances and ammonium" according to Ph.Eur. and of "physiological amino acids" using the method "ASA-0008_Ver09_Lithium"	W
Ph.Eur. 1562 (10.0)	Silica dental type: Chlorides, sulfates	M
Ph.Eur. 0910 (10.0)	Histidine hydrochloride monohydrate: Ninhydrin-positive substances	W

1.8 Gas chromatographic analysis of organic compounds with mass spectrometric detection (GC-MS, Thermodesorption-GC-MS, HSGC-MS) **

AN-SOP 1842-e Version 02 10.08.2010	Methyl methane sulphonate and ethyl methane sulphonate in (product name) by GC/MS	M
AY-001892 Version 4 19.10.2021	Determination of benzene and toluene in adhesive layer of (product name) and (product name) by headspace-GCMS	M
SOP GCMS-021 Version 02 19.10.2017	Determination of hexachlorbenzene in (product name) and (product name) samples by GCMS	W
SOP GCMS-022 Version 01 27.03.2018	Quantification of cyclic polymethylsiloxanes Polymethylsiloxanen (Si_4 – Si_6) in fumed and precipitated silica by HR-GC/MS coupling	W
SOP GCMS-024 Version 02 25.05.2020	GC-HRMS determination of specific nitrosamines in dichlormethane extracts from aqueous hydrogen peroxide solutions	W

1.9 1.9 Titration of inorganic and organic compounds by potentiometric, coulometric and visual endpoint determination **

SOP AOAN-036 Version 01 02.12.2019	Determination of fluoride (E552) in (product name) by ion selective electrode	W
SOP EA1-079 Version 03 21.03.2019	Quantitative determination of Chloride in synthetic silica by argentometric titration after dissolving in sodium hydroxide solution	W
Ph.Eur. 20512 (10.0)	Water: Semi-micro determination	M
Ph.Eur. 20532 (10.0)	Water: Micro determination	M

1.10 Determination of physical key figures of inorganic and organic substances by using conventional methods**

SOP 1566 Method 01e, Version 01 30.01.2018	Determination of the inherent viscosity of (product name)	M

SOP 1566 Method 02e, Version 01 23.01.2019	Determination of the inherent viscosity of (product name)	M
SOP 1825 Version 01 03.02.2009	Determination of the refractive index of transparent liquids by using of a Abbé Refractometer	M
SOP 1879 Version 01 26.05.2011	Determination of the melting behavior (melting point and melting range) using the capillary tube method analogous to DIN EN ISO 3146, method A using the melting point device M-565 (Büchi)	M
SOP STO-051 Method 005, Version 01 17.01.2014	Determination of rheological properties with the rheometer MCR 101 Determination of Complex Viscosity of (Product Name)	W

1.11 Determination of elements by using atomic absorption spectroscopy (FI-AAS, CV-AAS, GF-AAS) **

SOP AAS-051 Version 01 22.11.2019	Determination of lead (Pb) in zinc sulfate-7-hydrate by graphite tube AAS after dissolving for (company name)	W
SOP AAS-052 Version 01 22.11.2019	Determination of lead (Pb) in zinc chloride by graphite tube AAS after dissolving for (company name)	W

1.12 Determination of elements by plasma atomic spectrometry (ICP-OES) **

SOP ICPO-055 Version 02 20.04.2018	Quantitative determination of sulfur in (product name) by ICP-OES by using pressure digestion (TW) "Project (Product Name)"	W
SOP ICPO-059 Version 01 20.04.2018	Quantitative determination of Pd and Cu in (product name) after pressure digestion (ultraclave (UC)) using ICP-OES for (company name)	W
SOP ICPO-060 Version 02 15.05.2019	Limit value testing of Ni and Pd in (API) using ICP-OES after pressure digestion (UC) for the company (company name)	W
SOP ICPO-062 Version 02 03.01.2020	Quantitative determination of Pd in (product name) after pressure digestion (ultraclave (UC)) using ICPOES for the company (company name)	W

1.13 Determination of elements by plasma mass spectrometry (ICP-MS, GD-MS) **

SOP GDMS-036 Version 07 09.01.2020	Semi-quantitative survey analysis of Ag, In, Cd using GDMS	W
SOP GDMS-049 Version 06 13.08.2019	Semi-quantitative overview and multi-element analysis of flat Cu and Cu alloys at the Finnigan ELEMENT GD	W
SOP GDMS-052 Version 03 09.03.2017	Semi-quantitative overview and multi-element analysis of flat Ni and Ni alloys at Finnigan ELEMENT GD	W
SOP SPEA-102 Version 02 07.02.2014	Quantitative determination of Pb, and Ni in different types of sugars by ICP-MS after dissolution	W
SOP SPEA-141 Version 01 11.07.2019	Determination of As, Cd, Pb, and Hg by ICP-MS after pressure digestion (MW) and Hg by DMA in (product name) and (product name) (SiO2 content (hydrate form) ≥ 94%) for (company name)	W
SOP SPEA-142 Version 01 14.11.2019	Determination of As, Cd, Pb, and Hg (E 551) by using ICP-MS after dissolution and Hg by DMA in (product name) (pyrogenic silica; SiO2 content (after annealing) ≥ 99%) for (company name)	W
SOP EA1-047 Version 03 17.10.2019	Determination of H, N, C, F, Cl, B, Al2O3 content and impurities in Al_2O_3	W

1.14 Elemental analysis after combustion (detection principle: IR, WLD, IC-LFD) **

SOP 1875 Method 3, Version 05 09.09.2019	Determination of CHNS C, H, N-determination in (product name) by using elemental analysis (vario-EL-cube)	M
SOP 1875 Method 6, Version 01 29.08.2019	Determination of CHNS N-determination in (product name) by using elemental analysis (elemental vario-EL-cube)	M
SOP AOAN-029 Method EA-0011, Edition 03 03.08.2018	Determination of C, H, N, S by the elemental analyzer Eurovector EA3000 Parameters for the elemental analysis of (API)	W
SOP ELA-013, Version 01 04.10.2019	Quantitative determination of carbon and sulfur in metals, metal oxides and inorganic matrices	W

SOP ELA-016, Version 01 04.10.2019	Quantitative determination of hydrogen, nitrogen and oxygen in metals, metal oxides and inorganic matrices	W

1.15 X-ray diffraction analysis (RBA) for the characterization and phase determination of inorganic and organic materials **

AN-SOP 0637 Method 53, Version 1 (EN) 17.10.2018	Characterisation of (API) using X-ray powder diffraction Crystallinity detection of (API) in 20 mg and 30 mg tablets	W
AN-SOP 0637 Method 55, Version 2 (EN) 29.08.2019	Characterisation of (API) using X-ray powder diffraction Determination of crystal modification of the active pharmaceutical ingredient by X-ray Powder Diffraction	W
AN-SOP 0637 Method 56, Version 1 (EN) 03.09.2019	Characterisation of (API) using X-ray powder diffraction Determination of crystal modification of the (API) in 100 mg, 200 mg and 300 mg tablets by X-ray Powder Diffraction	W
SOP 0637 Method 57, Version 2 29.03.2019	Characterisation of (API) using X-ray powder diffraction Determination of crystal modification of and detection of Forms II and III contaminants in Form I by X-ray Powder Diffraction	W
AN-SOP 0637 Method 44, Version 01 17.01.2018	Wide-angle X-ray diffraction to characterize the morphology of drugs Quantitative determination of phase composition of (product name) according to ASTM F2024-10	W
SOP ROE-045, Version 01 28.10.2019	Quantitative detection of crystalline fractions in amorphous silica by XRD after enrichment	W

1.16 Determination of thermal properties of inorganic and organic compounds by using thermal analysis (differential scanning calorimetry DSC, thermogravimetric analysis TGA) **

SOP TA-002 Version 06 08.02.2018	Differential dynamic calorimetry with DSC modules from Mettler Toledo	W
SOP TA-028 Version 01 18.09.2008	Differential dynamic calorimetry with the TM-DSC 204 F1 Phoenix	W

SOP TA-028 Method 001, Version 01 09.05.2014	Dynamic difference calorimetry with the DSC 204 F1 by Netzsch Determination of melt peak of (product name)	W
SOP TA-028 Method 002, Version 02 12.07.2018	Dynamic difference calorimetry with the DSC 204 F1 by Netzsch Melting point determination of L-lactide, TMX, D-lactide, glycolide and D,L-lactide	W

1.17 Determination of the particle size distribution of inorganic and organic materials by laser diffraction, light scattering **

SOP KORN-050 Method 015, Version 03 05.06.2018	Determination of particle size distribution using the Coulter LS 13320 Particle Size Analyzer Determination of particle size distribution of (product name)	W
SOP KORN-050 Method 017, Version 01 31.01.2013	Determination of particle size distribution using the Coulter LS 13320 Particle Size Analyzer Determination of particle size distribution of (product name)	W
SOP KORN-050 Method 018, Version 01 12.12.2013	Determination of particle size distribution using the Coulter LS 13320 Particle Size Analyzer Determination of particle size distribution of (product name)	W
SOP KORN-054 Method 001, Version 02 29.10.2018	Determination of particle size distribution using the AccuSizer 780 SIS optical single-particle counter Determination of particulate impurities on (product name) products	W

1.18 Determination of sorption properties and pore volume of solids by sorption, desorption of test gases **

SOP SOR-024 Method 022e, Version 01 27.01.2017	Determination of N2 sorption isotherms using the TRISTAR sorption measuring instrument Determination of the specific surface area of (product name) as per EP2.9.26	W

SOP SOR-024 Method 016, Version 01 17.01.2014	Determination of N2 sorption isotherms using the TRISTAR sorption meter Determination of the specific surface area of magnesium stearate according to USP 846	W
SOP SOR-024 Method 017, Version 01 05.08.2014	Determination of N2 sorption isotherms using the TRISTAR sorption meter Determination of the specific surface area of silica according to USP 846	W
SOP SOR-024 Method 018, Version 01 05.08.2014	Determination of N2 sorption isotherms using the TRISTAR sorption meter Determination of the specific surface area of silica according to USP 846	W
SOP SOR-024 Method 019, Version 01 05.08.2014	Determination of N2 sorption isotherms using the TRISTAR sorption meter Determination of the specific surface area of (API) according to USP 846	W

1.19 Determination of convention parameters on organic and inorganic substances by gravimetry **

Ph.Eur. 0738 (10.0)	Substances soluble in hydrochloric acid	M
USP NF	Silicon Dioxide, Assay	M
JECFA FAO Monographs	Calcium Silicate: LOD, LOI	W
JECFA FAO Monographs	Silicon Dioxide Amorphous: LOD, LOI, Si-Assay	W

Abbreviations used:

API	Active Pharmaceutical Ingredient (Pharmazeutischer Wirkstoff)
DIN	German Institute for Standardization (Deutsches Institut für Normung e.V.)
EN	European standards (Europäische Norm)
IEC	International Electrotechnical Commission
ISO	International Standards Organization
SOP	Standard operating procedure (in-house method)
VIS	visible

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-21594-04-02 according to DIN EN ISO/IEC 17025:2018

Valid from: **26.01.2023**

Date of issue: 13.06.2023

This annex is a part of the accreditation certificate D-PL-21594-04-00.

Holder of partial accreditation certificate:

Evonik Operations GmbH
Rellinghauser Straße 1-11, 45128 Essen

with the location

Evonik Operations GmbH
Product Line Analytik
Paul-Baumann-Straße 1, 45764 Marl

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

Testing for the following areas:

Analysis of hazardous substances (gases, dusts, gas enrichments and aerosols) in air samples (workplace measurements)

Within the testing areas marked with **, the testing laboratory is permitted, without being required to inform and obtain prior approval from Deutsche Akkreditierungsstelle GmbH, to modify, further develop, and develop new testing procedures.

The listed test procedures are examples only.
The laboratory has an up-to-date list of all test procedures in the flexible accreditation area.

Valid for the location(s):

Paul-Baumann-Straße 1, 45764 Marl

The test procedures are marked with the following symbols of the locations where they are carried out:

1 Analysis of hazardous substances (gases, dusts, gas enrichments and aerosols) in air samples (workplace measurements)

1.1 Determination of organic air components using gas chromatography (GC-FID, HSGC-FID, GC-WLD, GC-MS) **

SOP 1656, Version 02 02.08.2019	Gas chromatographic determination of methanol and acetone after collection of adsorption tubes, desorption with dimethylacetamide/water (9:1) and evaluation against an internal standard
SOP 2030, Version 01 05.01.2017	Determination of 2-butanone oxime in air using GCMS
SOP 2082 Method 01, Version 01 26.03.2019	Gas chromatographic determination of trace amounts of hazardous substances in air after thermal desorption Brief description for the determination of ethanol after thermodesorption of Tenax adsorption tubes
SOP 2082 Method 03, Version 01 24.01.2019	Gas chromatographic determination of trace amounts of hazardous substances in air after thermal desorption Short description of the determination of isotridecanol after thermal desorption of Tenax adsorption tubes
SOP 2082 Method 04, Version 01 04.03.2019	Gas chromatographic determination of trace amounts of hazardous substances in air after thermal desorption Brief description of the determination of 1-pentanol after thermal desorption of Tenax adsorption tubes

SOP 2082 Method 05, Version 01 20.03.2019	Gas chromatographic determination of trace amounts of hazardous substances in air after thermal desorption Brief description of the determination of aromatic compounds after thermal desorption of Carbopak:B adsorption tubes
SOP 2082 Method 06, Version 01 04.03.2019	Gas chromatographic determination of trace amounts of hazardous substances in air after thermal desorption Brief description of the determination of tetrahydrofuran after thermal desorption of Carbosieve/Tenax adsorption tubes

1.2 Determination of organic air components using HPLC (HPLC-DAD, HPLC-RID, HPLC-UVD, HPLC-FLD, HPLC-ELSD) **

SOP 2081, Version 01 04.12.2018	Determination of valeraldehyde/isovaleraldehyde in the trace amounts in air after collection on impregnated silica gel and quantification using HPLC
SOP 2084, Version 02 18.02.2019	Determination of i-butyraldehyde in the trace amounts in air after collection on impregnated silica gel and quantification by HPLC
AN-SOP 1906, Version 001 15.01.2013	Determination of aldehydes in trace amounts in air after collection and derivatization on impregnated silica gel cartridges and quantification using HPLC analysis

Abbreviations used:

API	Active Pharmaceutical Ingredient (Pharmazeutischer Wirkstoff)
DIN	German Institute for Standardization (Deutsches Institut für Normung e.V.)
EN	European standards (Europäische Norm)
IEC	International Electrotechnical Commission
ISO	International Standards Organization
SOP	Standard operating procedure (in-house method)
VIS	visible

DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

The Deutsche Akkreditierungsstelle attests with this **Partial Accreditation Certificate** that the testing laboratory

Evonik Operations GmbH
Rellinghauser Straße 1-11, 45128 Essen

meets the requirements according to DIN EN ISO/IEC 17025:2018 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the testing laboratory, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This partial accreditation certificate only applies in connection with the notice of 26.01.2023 with accreditation number D-PL-21594-04.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 03 pages.

Registration number of the partial accreditation certificate: **D-PL-21594-04-02**
It is a part of the accreditation certificate: D-PL-21594-04-00.

Berlin, 26.01.2023 — Dr. Haiko Blumental, Head of Technical Unit

Translation issued: 07.10.2024 — Dr. rer. nat. Olga Lettau, Head of Technical Unit

The certificate together with the annex reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf

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The Deutsche Akkreditierungsstelle GmbH (DAkkS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkkS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

DAkkS is a signatory to the multilateral agreements for mutual recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Co-operation (ILAC).

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu