DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

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

Eurofins Dr. Specht Laboratorien GmbH
Am Neuländer Gewerbepark 2, 21079 Hamburg

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 17.12.2024 with accreditation number D-PL-14198-01.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 4 pages.

Registration number of the partial accreditation certificate: **D-PL-14198-01-02**
It is a part of the accreditation certificate: D-PL-14198-01-00.

Berlin, 17.12.2024
Andrea Gabler
Head of Technical Unit

Translation issued:
18.03.2025
Andrea Gabler
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

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10117 Berlin

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60327 Frankfurt am Main

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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 Partial Accreditation Certificate D-PL-14198-01-02 according to DIN EN ISO/IEC 17025:2018

Valid from: **17.12.2024**

Date of issue: 17.12.2024

This annex is a part of the accreditation certificate D-PL-14198-01-00.

Holder of partial accreditation certificate:

Eurofins Dr. Specht Laboratorien GmbH
Am Neuländer Gewerbepark 2, 21079 Hamburg, Germany

with the location

Eurofins Dr. Specht Laboratorien GmbH
Am Neuländer Gewerbepark 2, 21079 Hamburg, Germany

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.

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.

Annex to the Partial Accreditation Certificate D-PL-14198-01-02

Tests in the fields:

Pharmaceutical products and active ingredients

Flexible scope of accreditation:

Within the marked testing fields, the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS

[Flex B] the free choice of standard or equivalent testing methods.

[Flex C] the modification, development and refinement of testing methods.

The test methods listed are given by way of example. The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation. The list is publicly available on the website of the testing laboratory.

1 Pharmaceutical products and active ingredients

1.1 Physical and physico-chemical analysis of pharmaceutical products, active ingredients and excipients

1.1.1 Gas chromatography [Flex C]

Standard/Issue date In-house method/Version	Title of standard or in-house method (indicate deviations/modifications from standard methods where applicable)	Test item
DIN EN 13191-2 2000-10	Non-fatty foods – Determination of bromide residues – Part 2: Determination of inorganic bromide (Modification: *Application to pharmaceutical raw materials, pollen*)	Pharmaceutical raw materials
DIN EN 15662 2018-07	Foods of plant origin – Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE – Modular QuEChERS-method *(Modification: Slightly modified dispersive SPE where applicable, additional clean-up with toluene)*	Pharmaceutical raw materials
ASU L 00.00-34 2010-09	Analysis of foodstuffs – Modular multi-method for the determination of plant protection product residues in foodstuffs (extended revision of DFG Method S 19) (Modification: *Application on waxes, shellac resins and other pharmaceutical raw materials, for complex oils 2D-GPC and clean-up on multisorbent*)	Pharmaceutical raw materials

Standard/Issue date In-house method/Version	Title of standard or in-house method (indicate deviations/modifications from standard methods where applicable)	Test item
P-14.089.6 2024-07	Gas chromatographic determination of organotin compounds in selected plant and animal materials by GC-MSD	Pharmaceutical raw materials
P-14.098.6 2024-07	Gas chromatographic determination of phenoxy alkane carboxylic acids in selected foodstuffs, feedstuffs and pharmaceutical raw materials by GC-MSD or GC-MS/MS	Pharmaceutical raw materials
P-14.139.6 2023-02	Determination of hydrogen phosphide in selected plant and animal-based foodstuffs by GC-HS-FPD	Pharmaceutical raw materials

1.1.2 Liquid chromatography [Flex C]

Standard/Issue date In-house method/Version	Title of standard or in-house method (indicate deviations/modifications from standard methods where applicable)	Test item
DIN EN 15662 2018-07	Foods of plant origin – Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE – Modular QuEChERS-method (Modification: *Application to pharmaceutical raw materials, slightly modified dispersive SPE where applicable*)	Pharmaceutical raw materials
P-14.179.2 2018-01	Determination of pesticides in selected plant-based foodstuffs (citrus oils) by LC-MS/MS	Pharmaceutical raw materials
P-14.185.4 2024-04	Determination of plant protection product residues in vegetable oils and fats, egg and egg products and in capsicum oleoresin by LC-MS/MS after acetonitrile extraction/partitioning and EMR lipid clean-up	Pharmaceutical raw materials
P-14.190.5 2024-03	Determination of ETU/PTU in selected plant and animal-based foodstuffs and pharmaceutical raw materials by LC-MS/MS	Pharmaceutical raw materials

1.1.3 Photometry [Flex B]

Standard/Issue date In-house method/Version	Title of standard or in-house method (indicate deviations/modifications from standard methods where applicable)	Test item
DIN EN 12396-1 1998-12	Non-fatty foods – Determination of dithiocarbamate and thiuram disulfide residues – Part 1: Spectrophotometric method	Pharmaceutical raw materials

Annex to the Partial Accreditation Certificate D-PL-14198-01-02

Standard/Issue date In-house method/Version	Title of standard or in-house method (indicate deviations/modifications from standard methods where applicable)	Test item
DIN EN 12396-3 2000-10	Non-fatty foods – Determination of dithiocarbamate and thiuram disulfide residues – Part 3: UV spectrophotometric xanthate method	Pharmaceutical raw materials

Abbreviations used:

ASU	Amtliche Sammlung von Untersuchungsverfahren nach § 64 Lebensmittel- und Futtermittelgesetzbuch (LFGB) (Official Collection of Test Methods on the basis of § 64 German Food and Feed Act)
DFG	Deutsche Forschungsgemeinschaft (German Research Foundation)
DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization)
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
P-XX.XXX.X	In-house method of Eurofins Dr. Specht Laboratorien GmbH