DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

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

PhytoLab GmbH & Co. KG
Dutendorfer Straße 5 - 7, 91487 Vestenbergsgreuth

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-19308-02.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 11 pages.

Registration number of the partial accreditation certificate: **D-PL-19308-02-01**
It is a part of the accreditation certificate: D-PL-19308-02-00.

Berlin, 17.12.2024 — Andrea Gabler, Head of Technical Unit

Translation issued: 09.09.2025 — 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).

See notes overleaf

Deutsche Akkreditierungsstelle GmbH

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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

DAkkS Deutsche Akkreditierungsstelle

Deutsche Akkreditierungsstelle

Annex to the Partial Accreditation Certificate D-PL-19308-02-01 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-19308-02-00.

Holder of partial accreditation certificate:

PhytoLab GmbH & Co. KG
Dutendorfer Straße 5 - 7, 91487 Vestenbergsgreuth

with the location

PhytoLab GmbH & Co. KG
Dutendorfer Straße 5 - 7, 91487 Vestenbergsgreuth

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.

Tests in the fields:

Pharmaceutical products and active ingredients

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.

Abbreviations used: see last page

Flexible scope of accreditation:

Within the indicated test areas the testing laboratory is permitted without being required to prior inform and obtain approval from DAkkS

[Flex B] to have the free choice from standardised or equivalent test methods.

[Flex C] to modify, develop or further develop test methods.

The test methods listed are examples. The testing laboratory has an up-to-date list of all test methods within the flexible scope of accreditation. The list is publicly available on the website of the testing laboratory.

Pharmaceutical products and active ingredients

1 Physical, physico-chemical and chemical analysis of medicinal products, active ingredients and excipients

1.1 Type of test: Gravimetry [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house method (specify deviations/modifications of standard methods if necessary)	Test item
Ph. Eur. 11.0, 01/2008:20232	Loss on drying	Plant-based raw materials, preparations, active ingredients and medicinal products
Ph. Eur. 11.0, 01/2008:20817	Loss on drying of dry extracts	Plant-based raw materials, preparations, active ingredients and medicinal products
USP 41 <731> 2018	Loss on drying	Plant-based raw materials, preparations, active ingredients and medicinal products
HAB H 2.2.6 2015	Determination of dry residue (gravimetry) of liquid substances	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 304110 2016-03	Determination of dry residue (gravimetry) of glycolic extracts	Plant-based raw materials, preparations, active ingredients and medicinal products

1.2 Type of test: Titrimetry [Flex B]

Standard / issue date in-house method / version	Title of standard or in-house method (specify deviations/modifications of standard methods if necessary)	Test item
Ph. Eur. 11.0, 04/2018:20512 method A	Semi-micro determination of water - Karl Fischer method	Plant-based raw materials, preparations, active ingredients and medicinal products
Ph. Eur. 11.0, 07/2019:20532	Semi-microdetermination of water - coulometric titration	Plant-based raw materials, preparations, active ingredients and medicinal products

1.3 Type of test: Distillation [Flex B]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
ISO 939 2021-01	Spices and condiments - Determination of moisture content - Entrainment method	Plant-based raw materials, preparations, active ingredients and medicinal products
Ph. Eur. 11.0, 01/2008:20213	Determination of water by distillation	Plant-based raw materials, preparations, active ingredients and medicinal products

1.4 Type of test: Hydrodistillation [Flex B]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
DIN EN ISO 6571 2018-03	Spices, condiments and herbs – Determination of volatile oil content (hydrodistillation method) (Modification: Determination of loss in mass (gravimetry) of unground tea at 103 °C according to DIN 10800:2016-07, PV 304000 (Method 304450), adaptation of distillation times and sample weights to Ph. Eur., also in selected plant-based pharmaceutical raw materials)	Unground tea
Ph. Eur. 11.0, 07/2019:20812	Essential oils in herbal drugs (Modification: Specified in % m/V)	Dried or anhydrous drug

1.5 Type of test: Photometry [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
DIN EN 12396-3 2000-10	Non-fatty foods – Determination of dithiocarbamate and thiuram disulphide residues – Part 3: UV-spectrometric xanthogenate method (Modification: Also in selected plant-based pharmaceutical raw materials)	Plant-based pharmaceutical raw materials
Ph. Eur. 11.0, 01/2015:0206	Hydroxyanthracene glycosides (UV/VIS), expressed as sennoside B, with reference to the dried drug	Senna leaves
Ph. Eur. 11.0, 01/2015:0207	Hydroxyanthracene glycosides (UV/VIS), expressed as sennoside B, with reference to the dried drug, monograph Senna pods, alexandrian	Alexandrian senna pods
Ph. Eur. 11.0, 07/2015:1261	Hydroxyanthracene glycosides (UV/VIS), expressed as sennoside B, monograph Senna leaf dry extract, standardised	Senna leaf dry extract
PV 608063 2018-09	Determination of total flavonoids (colorimetric with Folin-Ciocalteu reagent), in black and green tea	Black and green tea

1.6 Type of test: Thin-layer chromatography [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
PV 203900 2019-04	Test for identity using thin layer chromatography for selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 203950 2019-04	Test for identity from the essential oil using thin-layer chromatography for selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 309900 2019-04	Test for purity using thin layer chromatography for selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products

1.7 Type of test: High performance liquid chromatography (HPLC-UV, HPLC fluorescence) [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
Ph. Eur. 11.0, 01/2012:0277	18-beta-glycyrrhizic acid (HPLC-UV), with reference to dried drug, monograph Liquorice root	Liquorice root
Ph. Eur. 11.0, 07/2019: 1523	Ginsenosides (HPLC-UV), with reference to dried drug, monograph Ginseng	Ginseng root
PV 403073 2014-02	Determination of coumarin (HPLC-UV) in cinnamon and cinnamon extracts	Cinnamon and cinnamon extracts
PV 605410 2014-02	Determination of the content (HPLC-UV) of ginsenosides, calculated as Rg1 and Rb1 in ginseng extract	Ginseng root extracts
PV 805021 2014-12	Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant-based products	Mother tinctures (matrix group I)
PM 805023 2018-11	Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant-based products	Fruits, seeds, roots (matrix group II)
PV 805025 2015-01	Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant-based products	Herbs, leaves, flowers (matrix group III)
PM 805091 2019-04	Identification and determination of ochratoxin A (HPLC fluorescence) in plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products

1.8 Type of test: High performance liquid chromatography (HPLC-MS, HPLC-MS/MS) [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
ASU L 00.00-115 2018-10	Analysis of foodstuffs – Multiple analytical method for the determination of pesticide residues using GC and LC after acetonitrile extraction/partitioning and clean-up by dispersive SPE in plant-based foodstuffs – Modular QuEChERS method (adoption of standard of the same name DIN EN 15662, July 2018) (Modification: Only LC-MS/MS, different sample weight, extraction mixture of acetonitrile/methanol, chromatography modified, also in selected plant-based pharmaceutical raw materials)	Plant-based pharmaceutical raw materials
PV 504870 2017-12	Determination of anisatin (LC-MSD) in star anise and star anise oil	Star anise, star anise oil
PV 720724 2018-08	Determination of nicotine (LC-MS/MS) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 720728 2018-04	Determination of phenoxy alkane carboxylic acids (LC-MS/MS) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 804920 2017-12	Determination of acrylamide (LC-MS/MS) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 805163 2018-12	Determination of ochratoxin A, based on dry substance (LC-MS/MS) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PM 805521 2017-01	Determination of pyrrolizidine alkaloids and their N-oxides (LC-MS/MS) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products

1.9 Type of test: Gas chromatography (GC-FID, FPD, ECD, NPD) [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
DIN EN ISO 9832 2003-12	Animal and vegetable fats and oils – Determination of residual technical hexane content (Modification: Adaptation to state-of-the-art technology, sample preparation and measurement (headspace), only in vegetable fats and oils, also in selected plant-based pharmaceutical raw materials)	Pharmaceutical raw materials
ASU L 00.00-34 2010-09	Analysis of foodstuffs – Modular multiple analytical method for the determination of plant protection product residues in foodstuffs (Modification: Restriction to modules D1, D2, E1, E2, E3, E6, E7, E9, also in selected plant-based pharmaceutical raw materials)	Pharmaceutical raw materials
Ph. Eur. 11.0, 04/2019:0405	Chromatographic profile (GC-FID), (mod.) monograph Peppermint oil	Peppermint oil
PV 403310 2017-03	Ethanol content (GC) in liquid plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 730271 2014-08	Determination of phosphine (headspace GC) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 805762 2017-03	Determination of residual solvents (headspace GC) in % in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 805763 2017-03	Determination of residual solvents (headspace GC) in mg/kg in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products

1.10 Type of test: Gas chromatography (GC-MS, GC-MS/MS) [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
ASU L 00.00-34 2010-09	Analysis of foodstuffs – Modular Multiple analytical method for the determination of plant protection product residues in foodstuffs (restriction to module D4, measurement with GC-MS/MS, also in selected plant-based pharmaceutical raw materials)	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 511322 2021-05	Analysis of foodstuffs – Determination of estragole in tea infusion using GC-MS (Modification: Sample weight and extraction volume reduced, single-point calibration; also in extract mixtures of several components, also in selected plant-based pharmaceutical raw materials)	Water-soluble plant-based raw materials, preparations, active ingredients and medicinal products and essential oils
PV 512005 2015-06	Analysis of foodstuffs – Determination of estragole in infusions of fennel and other tea-like products – GC-MS method (Modification: Infusion preparation also according to specifications, calibration, also in selected plant-based pharmaceutical raw materials)	Infusion of tea
PV 720470 2015-12	Screening of plant protection product residues (GC-MS/MS) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 720546 2017-03	Determination of plant protection product residues: glyphosate and aminomethylphosphonic acid (AMPA) by GC-MS in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 730110 2017-04	Determination of plant protection product residues: phenylureas and their anilines by GC-MS in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 800808 2015-12	Sample preparation for the determination of polycyclic aromatic hydrocarbons (PAHs) by GC-MS in tea infusions	Tea
PV 800813 2015-12	Determination of polycyclic aromatic hydrocarbons (PAHs) by GC-MS in tea infusions	Tea

1.11 Type of test: Atomic absorption spectrometry (AAS) [Flex B]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
Ph. Eur. 11.0, 07/2014:20427	Heavy metals in herbal drugs and herbal drug preparations Lead, Cadmium, Mercury, Nickel	Plant-based drugs, drug preparations

1.12 Type of test: Inductively coupled plasma mass spectrometry (ICP-MS) [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
DIN EN 15111 2007-06	Foodstuffs – Determination of trace elements – Determination of iodine by ICP-MS (inductively coupled plasma mass spectrometry) (Modification: Digestion in microwave instead of drying cabinet, sample filtration with C18 columns instead of membrane filters, calibration range extended downwards and upwards, also in selected plant-based pharmaceutical raw materials)	Plant-based pharmaceutical raw materials
Ph. Eur. 11.0, 07/2014:20427	Heavy metals in herbal drugs and herbal drug preparations Lead, Cadmium, Mercury, Nickel	Plant-based drugs, drug preparations
PV 730207 2017-06	Determination of inorganic bromide, calculated as bromide ion (ICP-MS) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 811100 2016-12	Determination of aluminium (ICP-MS/MS) in selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products

2 Biological analysis of medicinal products, active ingredients and excipients

2.1 Type of test: Microbiological testing of non-sterile products [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
Ph. Eur. 11.0, 01/2021:20612	Microbiological examination of non-sterile products: microbial enumeration tests Membrane filtration, pour-plate method and surface spatula method	Plant-based raw materials, preparations, active ingredients and medicinal products
Ph. Eur. 11.0, 04/2010:20613	Microbiological examination of non-sterile products: test for specified micro-organisms Bile salt tolerant gram-negative bacteria, *Escherichia coli*, Salmonella, *Staphylococcus aureus, Pseudomonas aeruginosa*	Plant-based raw materials, preparations, active ingredients and medicinal products
Ph. Eur. 11.0, 01/2014:20631	Microbiological examination of herbal medicinal products for oral use and extracts used in their preparation Salmonella, *Escherichia coli*, bile salt tolerant gram-negative bacteria	Plant-based medicinal products and their starting materials and intermediate products
Ph. Eur. 11.0, 04/2022:50103	Efficacy of antimicrobial preservation	Plant-based raw materials, preparations, active ingredients and medicinal products

2.2 Type of test: Method for amplification of nucleic acids [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
PV 803031 2022-06	Method for identification/confirmation of Salmonella spp in medicinal products using the BAX® System Q7 PCR assay for Salmonella 2 *Part KIT 2011 (D14368501) 2019-08*	Plant-based raw materials, preparations, active ingredients and medicinal products

2.3 Type of test: Macroscopic testing [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
PV 201900 2020-06	Test for identity testing by simple visual inspection (macroscopic, magnifying glass) for selected plant-based raw materials and mono-products	Plant-based raw materials, preparations, active ingredients and medicinal products
PV 204000 2020-06	Test for identity testing by simple visual inspection (macroscopic, magnifying glass) for selected plant-based mixtures	Plant-based raw materials, preparations, active ingredients and medicinal products

2.4 Type of test: Microscopic testing [Flex C]

Standard / issue date in-house method / version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item
PV 202900 2019-08	Test for identity using microscopy for selected plant-based products	Plant-based raw materials, preparations, active ingredients and medicinal products

Abbreviations used:

DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization)
EN	European standard
HAB	Homoeopathic Pharmacopoeia
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
Ph. Eur.	Pharmacopoeia Europaea
PV XXXX	In-house method (test specification) of PhytoLab
TS	Technical Specification
USP	United States Pharmacopeia