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Deutsche Akkreditierungsstelle (German Accreditation Body)

German Accreditation Body (Deutsche Akkreditierungsstelle)

Annex to the accreditation certificate D-PL-14508-01-03 according to DIN EN ISO/IEC 17025:2018

Valid from: **27 November 2025**

Date of issue: 27 November 2025

This annex to the certificate is part of the accreditation certificate D- PL-14508-01-00.

Owner of the accreditation certificate:
Quality Services International GmbH
Flughafendamm 9a, 28199 Bremen

Please select
Quality Services International GmbH
Flughafendamm 9a, 28199 Bremen

The testing laboratory fulfils the requirements according to DIN EN ISO/IEC 17025:2018 to perform the conformity assessment activities specified in this annex. The testing laboratory may also meet additional legal and normative requirements, including those in relevant sectoral programs, provided these are expressly confirmed below.

The requirements for the management system in DIN EN ISO/IEC 17025 are written in a language that is relevant to testing laboratories and are generally in agreement with the principles of DIN EN ISO 9001.

Testing in the following area:
Medicinal Products

Flexible accreditation area:

This annex to the certificate was issued by the German Accreditation Body Ltd. and is digitally sealed. It is only valid in conjunction with the written certificate and reflects the status at the date of issue. The respective current status of a valid and monitored accreditation can be found in the database of accredited entities of the German Accreditation Body (www.dakks.de).

Acronyms used: see last page

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The testing laboratory is authorized to perform testing within the designated testing areas without requiring prior notification of and approval from DAkkS.

[Flex B] The free choice of standardized or equivalent testing methods is permitted.

[Flex C] Modification, further development, and new development of testing methods are permitted.

The testing procedures listed are examples. The testing laboratory has an up-to-date list of all testing procedures in the flexible accreditation area. The list is publicly available on the testing laboratory's website.

Medicinal products

Pharmacognosy [Flex B]

Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures).	Test object
Ph. Eur. 2.8.15 11th edition 2023-01	Bitterness value	Raw materials for medicinal products
Ph. Eur. 2.8.2 11th edition 2023-01	Foreign matter; visual inspection	Raw materials for medicinal products
Ph. Eur. 2.8.23 11th edition 2023-01	Microscopic examination of herbal drugs	Raw materials for medicinal products
Ph. Eur. 2.8.1 11th edition 2023-01	Ash insoluble in hydrochloric acid	Pharmaceutical ingredients and additives
Ph. Eur. 2.8.13 11th edition 2023-01	Pesticide residues, LC-MS/MS	Herbal drugs
Ph. Eur. 2.8.18 11th edition 2023-01	Determination of aflatoxin B1, B2, G2, LC-MS/MS	Herbal drugs
Ph. Eur. 2.8.22 11th edition 2023-01	Determination of ochratoxin A, LC-MS/MS	Herbal drugs
Ph. Eur. 2.8.13 11th edition 2023-01	Pesticide residues, GC-MS/MS	Herbal drugs
Ph. Eur. 2.8.9 11th edition 2023-01	Residue on evaporation of essential oils	Pharmaceutical ingredients and additives
Ph. Eur. 2.8.16 11th edition 2023-01	Dry residue of extracts	Pharmaceutical ingredients and additives

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Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures).	Test object
Ph. Eur. 2.8.12 11th edition 2023-01	Essential oils in herbal drugs – steam distillation	Herbal drugs

Physical and physicochemical analyses [Flex C]

Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures).	Test object
Ph. Eur. 2.2.32 11th edition 2023-01	Loss on drying	Pharmaceutical ingredients and additives
Ph. Eur. 2.2.25 11th edition 2023-01	Absorption spectrophotometry, ultraviolet and visible	Pharmaceutical ingredients and additives
Ph. Eur. 2.2.3 11th edition 2023-01	Potentiometric determination of the pH value	Pharmaceutical ingredients and additives
Ph. Eur. 2.2.20 11th edition 2023-01	Potentiometry (potentiometric titration)	Pharmaceutical ingredients and additives
Ph. Eur. 2.2.38 9th edition 2017-12	Conductivity	Pharmaceutical ingredients and additives
Ph. Eur. 2.2.27 11th edition 2023-01	Thin-layer chromatography	Raw materials for medicinal products
Ph. Eur. 2.2.29 11th edition 2023-01	Liquid chromatography (HPLC)	Raw materials for medicinal products
Ph. Eur. 2.2.28 11th edition 2023-01	Gas chromatography	Raw materials for medicinal products
Ph. Eur. 2.2.5 11th edition 2023-01	Relative density	Liquid raw materials for medicinal products
Ph. Eur. 2.2.6 11th edition 2023-01	Refractive index	Liquid raw materials for medicinal products
Ph. Eur. 2.2.7 11th edition 2023-01	Optical rotation	Liquid raw materials for medicinal products
Ph. Eur. 2.2.8 11th edition 2023-01	Viscosity	Liquid raw materials for medicinal products

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Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures).	Test object
Ph. Eur. 2.2.9 11th edition 2023-01	Capillary viscometer method	Liquid raw materials for medicinal products
Ph. Eur. 2.2.10 11th edition 2023-01	Viscosity - rotating viscometer method	Liquid raw materials for medicinal products
Ph. Eur. 2.2.11 11th edition 2023-01	Distillation range	Liquid raw materials for medicinal products
Ph. Eur. 2.2.12 11th edition 2023-01	Boiling point	Liquid raw materials for medicinal products
Ph. Eur. 2.2.13 11th edition 2023-01	Analysis of water by distillation	Liquid raw materials for medicinal products
Ph. Eur. 2.2.14 11th edition 2023-01	Melting temperature, capillary method (modification: *only for the range < 95 degrees*)	Raw materials for medicinal products
Ph. Eur. 2.2.15 11th edition 2023-01	Rising melting point - method with open capillary	Raw materials for medicinal products
Ph. Eur. 2.2.17 11th edition 2023-01	Dripping point	Raw materials for medicinal products
Ph. Eur. 2.2.18 11th edition 2023-01	Freezing point	Raw materials for medicinal products
Ph. Eur. 2.2.49 11th edition 2023-01	Falling ball and automatic rolling ball viscometer methods	Raw materials for medicinal products
DGF-M-V 6 (57) 1957-03	Total hydrocarbons (gravimetric method)	Pharmaceutical ingredients and additives
IUPAC-Method 2.611 1992-06	Thin-layer chromatography (deviation: jojoba oil matrix)	Raw materials for medicinal products

Limit tests [Flex B]

Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures)	Test object
Ph. Eur. 2.4.14 11th edition 2023-01	Sulfated ash	Pharmaceutical ingredients and additives

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Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures).	Test object
Ph. Eur. 2.4.16 11th edition 2023-01	Ash	Pharmaceutical ingredients and additives
Ph. Eur. 2.4.2 9th edition 2017-12	Arsenic	Raw materials for pharmaceuticals
Ph. Eur. 2.4.4 9th edition 2017-12	Chloride	Raw materials for pharmaceuticals
Ph. Eur. 2.4.13 9th edition 2017-12	Sulfate	Raw materials for pharmaceuticals

Assay determination [Flex B]

Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures).	Test object
Ph. Eur. 2.5.7 11th edition 2023-01	Unsaponifiable components	Pharmaceutical ingredients and additives
Ph. Eur. 2.5.1 11th edition 2023-01	Acid number	Pharmaceutical ingredients and additives
Ph. Eur. 2.5.2 11th edition 2023-01	Ester number	Pharmaceutical ingredients and additives
Ph. Eur. 2.5.3 11th edition 2023-01	Hydroxyl number	Pharmaceutical ingredients and additives
Ph. Eur. 2.5.4 11th edition 2023-01	Iodine number	Pharmaceutical ingredients and additives

Pharmaceutical technological tests [Flex B]

Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures).	Test object
Ph. Eur. 2.9.12 11th edition 2023-01	Sieve analysis	Pharmaceutical ingredients and additives

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Identity reactions [Flex C]

Standard/issue date internal method/version	Title of the standard or internal methods (if necessary, specify deviations from/ modifications of standard procedures).	Test object
VA 1103 2011-08	Identity verification flavonoids, thin-layer chromatography	Raw materials for medicinal products

Acronyms used:

DGF	Standard methods of Deutsche Gesellschaft für Fettwissenschaft e.V. (German Society for Fat Science DGF)
DIN	Deutsches Institut für Normung e.V. [German Institute for Standardisation e.V.]
EN	Europäische Norm [European Standard]
IEC	International Electrotechnical Commission –[Internationale Elektrotechnische Kommission]
ISO	International Organization for Standardisation - [Internationale Organisation für Normung]
IUPAC	International Union of Pure and Applied Chemistry –[Internationale Union für reine und angewandte Chemie]
Ph. Eur.	Pharmacopoeia Europaea; European Pharmacopoeia [Europäisches Arzneibuch]
VA XXXXX	Hausverfahren der [Internal Method of] Quality Services International GmbH

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I HEREBY CERTIFY THAT THIS IS A TRUE AND COMPLETE TRANSLATION OF THE ORIGINAL GERMAN DOCUMENT PRESENTED TO ME.

Göttingen, 22 February 2026

Vom Landgericht Hannover beeidigte Dolmetscherin u. ermächtigte Übersetzerin – allgemein für die englische Sprache – Lucie Hamdi M.A.

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