

# Deutsche Akkreditierungsstelle

## Annex to the Partial Accreditation Certificate D-PL-14170-01-06 according to DIN EN ISO/IEC 17025:2018

**Valid from:** 16.03.2023

**Date of issue:** 25.07.2023

This annex is a part of the accreditation certificate D-PL-14170-01-00.

Holder of partial accreditation certificate:

**GBA Gesellschaft für Bioanalytik mbH**  
**Goldtschmidtstraße 5**  
**21073 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 confirm generally with the principles of DIN EN ISO 9001.

Tests in the fields:

**Medicinal products and active ingredients**  
**Test areas: Chemical, physico-chemical and biological analysis of medicinal products, active ingredients and excipients**

*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

**Page 1 of 6**

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**Annex to the Partial Accreditation Certificate D-PL-14170-01-06**

Valid for the locations:

**Goldtschmidtstraße 5, 21073 Hamburg**  
**Am Werder 1, 21073 Hamburg**  
**Harburger Ring 17, 21073 Hamburg<sup>1)</sup>**  
**Flensburger Straße 15, 25421 Pinneberg**

<sup>1)</sup> Only administrative activities are carried out at this location and no laboratory activities are performed.

The test methods are marked with the following symbols for the locations at which they are carried out:

HHGS = Hamburg, Goldtschmidtstraße 5  
HHAW = Hamburg, Am Werder 1  
PI = Pinneberg

**Flexibility of the scope of accreditation**

**The testing laboratory is permitted to apply the listed standardised or equivalent test methods with different versions of the standards without obtaining prior notification and consent from DAkkS.**

**Within the specified test fields, the testing laboratory is permitted to do the following without obtaining prior notification and consent from DAkkS GmbH**

- \*) Freely select standard test methods or equivalent test methods.**
- \*\*\*) Modify test methods and develop new test methods.**

**The test methods listed are given by way of example.**

**The testing laboratory has an up-to-date list of all test methods within the flexible scope of accreditation.**

Valid from: 16.03.2023  
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**Annex to the Partial Accreditation Certificate D-PL-14170-01-06**

**1 Test area: Chemical analysis of medicinal products, active ingredients and excipients**

**Type of test: Basic wet chemical processes \***

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
Ph. Eur. 10 Monograph 0015 2021-01	Calcium chloride dihydrate by complexometric titration	Auxiliary and raw materials for pharmaceutical purposes	HHGS
Ph. Eur. 10 Monograph 0014 2021-01	calcium carbonate by complexometric titration	Auxiliary and raw materials for pharmaceutical purposes	HHGS
USP 41 <541> 2018-05	Titrimetry	Auxiliary and raw materials for pharmaceutical purposes	HHGS
Ph. Eur. 10 Monograph 1078 2017-01	Calcium hydroxide by titration	Auxiliary and raw materials for pharmaceutical purposes	HHGS
FCC IX Monograph CaO 2016	Calcium oxide by complexometric titration	Auxiliary and raw materials for pharmaceutical purposes	HHGS
Ph. Eur. 02 April 2014 2010-04	Sulphated ash	Solids for pharmaceutical purposes	HHGS

**2 Physico-chemical analysis of medicinal products, active ingredients and excipients**

**Type of test: Chromatography – Liquid chromatography (LC)\*\***

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
HH-MA-M 02-080 2020-01	Pharma pesticides LC-MS/MS – Agilent measurement (Processing: HHGS measurement: HHAW)	Raw materials for pharmaceutical purposes	HHGS, HHAW

Valid from: 16.03.2023

Date of issue: 25.07.2023

Page 3 of 6

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**Annex to the Partial Accreditation Certificate D-PL-14170-01-06**

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
HH-MA-M 02-101 2017-04	Purity and content testing of gluconic acid and 2-aminoethyl dihydrogen phosphate in medicinal products, active ingredients and excipients using HPLC-DAD/FLD	Solutions for pharmaceutical purposes	HHGS

**Type of test: Chromatography – Gas chromatography (GC)\*\***

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
HH-MA-M 03-023 2021-06	Dithiocarbamates with headspace and GC-MSD (Processing: HHGS measurement: HHAW)	Raw materials for pharmaceutical purposes	HHGS, HHAW
HH-MA-M 03-024 2020-02	Pharma pesticides GC-MS/MS measurement (Processing: HHGS measurement: HHAW)	Raw materials for pharmaceutical purposes	HHGS, HHAW

**Type of test: conductivity**

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
Ph. Eur. 2.2.38 2021-03	Electrical conductivity in ultrapure water with conductivity electrode	Aqua ad iniectabilia, Aqua purificata, pure steam condensate	HHGS

**Type of test: Spectrometry – Optical emission spectrometry with inductively coupled plasma (ICP-OES)\***

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
Ph. Eur. 2.2.22 2008-01	Atomic emission spectrometry with inductively coupled plasma (processing: only: HHGS; processing and measurement: PI)	Raw materials for pharmaceutical purposes	HHGS, PI

Valid from: 16.03.2023

Date of issue: 25.07.2023

Page 4 of 6

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**Type of test: Spectroscopy – Infrared spectroscopy (IR)**

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
Ph. Eur. 2.2.44 2008-01	Total organic carbon in water for pharmaceutical use	Aqua ad iniectabilia, Aqua purificata, pure steam condensate	HHGS
USP 41 <643> Version 36 2013	Total organic carbon	Aqua ad iniectabilia, Aqua purificata, pure steam condensate	HHGS

**3 Test area of analysis of medicinal products, active ingredients and excipients**

**Type of test: Microbiological testing of non-sterile products\***

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
Ph. Eur. 2.6.12 2010-07	Enumeration of microorganisms capable of reproduction in non-sterile products	Auxiliary and raw materials for pharmaceutical purposes	HHGS
Ph. Eur. 2.6.13 2010-04	Detection of specific microorganisms in non-sterile products	Auxiliary and raw materials for pharmaceutical purposes	HHGS
Ph. Eur. 2.6.31 2014-01	Microbiological examination of herbal medicinal products for oral use	Herbal medicinal products for oral use	HHGS

**Type of test: Test for bacterial endotoxins\***

Standard/date of issue In-house method/version	Title of standard or in-house procedure (indicate deviations/modifications from standard methods where applicable)	Test item	Location
Ph. Eur. 2.6.14 2014	Bacterial endotoxins in medicinal products, active ingredients and excipients	Auxiliary and raw materials for pharmaceutical purposes	HHGS

**Abbreviations used**

DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization)
EN	European standard
GW	Raw and groundwater
In-house method ST-MA-M xx-yyy	In-house method of GBA Gesellschaft für Bioanalytik mbH
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
Ph. Eur.	European Pharmacopoeia
USP	U.S. Pharmacopeial Convention