CERTIFIED TRANSLATION FROM GERMAN

Deutsche Akkreditierungsstelle (German Accreditation Body)

Annex to the partial accreditation certificate D-PL-14508-01-03 according to DIN EN 1SO/IEC 17025:2018

Valid from: **26.06.2024**

Date of issue: 26.06.2024

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

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

The owner of the partial accreditation certificate:

Quality Services International GmbH
Flughafendamm 9 a, 28199 Bremen

with the location

Quality Services International GmbH
Flughafendamm 9 a, 28199 Bremen

fulfils the requirements according to DIN EN ISO/IEC 17025:2018 for the conformity assessment activities specified in more detail in the annex to this certificate. As the case may be, the testing laboratory also includes existing legal and normative requirements for the testing laboratory, including those in relevant sectoral programs, insofar as these are expressly confirmed in the annex to this certificate.

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

Fields of testing:
sensory, chemical, chemo-physical, physical, and microscopic testing of pharmaceutical raw material.

Within the testing field marked with *, the testing laboratory is permitted to freely select standardized or equivalent testing methods without the need for prior information and approval by DAkkS.

Within the testing field marked with **, the testing laboratory is permitted to modify, further develop and develop new testing methods without the need for prior information or approval of DAkkS.

This annex to the certificate is only valid together with the certificate issued in writing and reflects the status at the time of issue. The respective current status of valid and supervised 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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Within the accreditation fields marked with *, the testing laboratory is permitted to use the standardized or equivalent testing methods listed here with different release statuses without the need for prior information and approval by DAkkS.**

The testing methods listed are exemplary. The testing laboratory has a current list of all testing methods in the flexible accreditation area.

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1 Pharmaceuticals and Active Ingredients

1.1 Sensory testing of pharmaceutical raw material***

Ph. Eur. 2.2.1 9th edition 2017-12	Clarity and opalescence of liquids, visual
Ph. Eur. 2.2.2 9th edition 2017-12	Colouring of liquids, visual
Ph. Eur. 2.8.2 9th edition 2017-12	Methods of pharmacognosy, foreign matter, visual
Ph. Eur. **2.8.8** 9th edition 2017-12	Methods of pharmacognosy, appearance, colour and smell of essential oils, sensory
Ph. Eur. 2.8.15 9th edition 2017-12	Sensory testing methods, bitter value

1.2 Microscopic testing of pharmaceutical raw material***

Ph. Eur. 2.8.2 9th edition 2017-12	Methods of pharmacognosy, stomata and stomatal index, microscopic
Ph. Eur. 2.8.3 9th edition 2017-12	Microscopic testing of herbal drugs
Ph. Eur. 2.8.23 9th edition 2017-12	Foreign matter

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1.3 Physical, physico-chemical and chemical testing of pharmaceutical raw material

1.3.1 Gravimetric determination of ingredients and additives*

Ph. Eur. 2.2.32 9th edition 2017-12	Loss of mass by drying; gravimetric, air-oven method
Ph. Eur. 2.4.14 9th edition 2017-12	Limit testing, sulphated ash, gravimetric
Ph. Eur. 2.4.16 9th edition 2017-12	Limit testing, ash, gravimetric
Ph. Eur. 2.5.7 9th edition 2017-12	Method of content determination, unsaponifiable matter, gravimetric
Ph. Eur. 2.8.1 9th edition 2017-12	Methods of pharmacognosy of hydrochloric acid insoluble ash, gravimetric
Ph. Eur. 2.8.9 9th edition 2017-12	Methods of pharmacognosy, evaporation residue of essential oils, gravimetric
Ph. Eur. 2.8.16 9th edition 2017-12	Methods of pharmacognosy, dry residue of extracts, gravimetric
Ph. Eur. 2.9.12 9th edition 2017-12	Methods of pharmaceutical technology, sieve analysis, gravimetric
DGF-M-V 6 {57) 1957-03	Total hydrocarbons (gravimetric method)

1.3.2 Titrimetric determination of ingredients and additives*

Ph. Eur. 2.5.1 9th edition 2017-12	Method of content determination, acid value, titrimetric
Ph. Eur. 2.5.2 9th edition 2017-12	Method of content determination, ester value, titrimetric

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Ph. Eur. 2.5.3 9th edition 2017-12	Method of content determination, hydroxyl value, titrimetric
Ph. Eur. 2.5.4 9th edition 2017-12	Method of content determination, iodine value, titrimetric/iodometry
Ph. Eur. 2.5.5 9th edition 2017-12	Method of content determination, peroxide value, titrimetric/iodometry
Ph. Eur. 2.5.6 9th edition 2017-12	Method of content determination, saponification value, titrimetric
Ph. Eur. 2.5.12 9th edition 2017-12	Method of content determination, semi-micro determination of water - Karl-Fischer-Method, titration

1.3.3 Photometric determination of ingredients and additives ***

Ph. Eur. 2.2.25 9th edition 2017-12	UV-Vis-spectroscopy, photometer

1.3.4 Determination of parameters by means of electrochemical analyses ***

Ph. Eur. 2.2.3 9th edition 2017-12	pH-value, potentiometric method
Ph. Eur. 2.2.20 9th edition 2017-12	Potentiometry, potentiometer
Ph. Eur. 2.2.38 9th edition 2017-12	Conductivity, conductometer

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1.3.5 Detection of ingredients by means of thin-layer chromatography (TLC) in pharmaceutical raw materials **

IUPAC-Method 2.611 1992-06	Testing for paraffins, thin-layer chromatography (deviation: *Matrix jojoba oil)*
Ph. Eur. 2.2.27 9th edition 2017-12	Thin-layer chromatography, capillary chromatography
VA 1103 (TLC)2011-08	Identity testing flavonoids, thin-layer chromatography

1.3.6 Detection of ingredients by means of high-performance liquid chromatography (HPLC) in pharmaceutical raw material ***

Ph. Eur. 2.2.29 9th edition 2017-12	Ingredients of pharmaceutical raw material, liquid chromatography (HPLC)

1.3.7 Detection of ingredients by means of gas chromatography (GC) with standard detectors in pharmaceutical raw material ***

Ph. Eur. 2.2.28 9th edition 2017-12	Ingredients of pharmaceutical raw material, gas chromatography (GC)

1.3.8 Determination of ingredients and additives by means of wet chemical analysis of pharmaceutical raw material ***

Ph. Eur. 2.4.1 9th edition 2017-12	Limit testing, ammonium, wet chemical
Ph. Eur. 2.4.2 9th edition 2017-12	Limit testing, arsenic, wet chemical
Ph. Eur. 2.4.4 9th edition 2017-12	Limit testing, chloride, wet chemical

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Ph. Eur. 2.4.8 9th edition 2017-12	Limit testing, heavy metals, wet chemical
Ph. Eur. 2.4.13 9th edition 2017-12	Limit testing, sulphate, wet chemical
Ph. Eur. 2.4.19 9th edition 2017-12	Limit testing, alkaline reacting substances in fatty oils, wet chemical

1.3.9 Further physical, physico-chemical and chemical analyses of pharmaceutical raw material***

Ph. Eur. 2.2.5 9th edition 2017-12	Relative density, densitometer (oscillating U-tube), liquid pharmaceutical raw material
Ph. Eur. 2.2.6 9th edition 2017-12	Refractive index, refractometer, liquid pharmaceutical raw material
Ph. Eur. 2.2.7 9th edition 2017-12	Optical rotation, polarimeter, liquid pharmaceutical raw material
Ph. Eur. 2.2.8/9 9th edition 2017-12	Viscosity, capillary viscosimeter
Ph. Eur. 2.2.11 9th edition 2017-12	Distillation range, determination of the temperature range, liquid pharmaceutical raw material
Ph. Eur. 2.2.12 9th edition 2017-12	Boiling temperature, determination of the temperature, liquid pharmaceutical raw material
Ph. Eur. 2.2.13 9th edition 2017-12	Analysis of water through distillation, volumetric. liquid pharmaceutical raw material

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Ph. Eur. 2.2.14 9th edition 2017-12	Melting temperature, capillary method (modification: *only for the range < 95 degrees*)
Ph. Eur. 2.2.15 9th edition 2017-12	Clear melting point, method with open capillary
Ph. Eur. 2.2.17 9th edition 2017-12	Dropping point, dropping point thermometer
Ph. Eur. 2.2.18 9th edition 2017-12	Solidification temperature, thermometer
Ph. Eur. 2.2.49 9th edition 2017-12	Viscosity, falling sphere viscometer, liquid pharmaceutical raw material
Ph. Eur. 2.8.12 9th edition 2017-12	Methods of pharmacognosy, content determination of essential oil in drugs, steam distillation

Acronyms used:

DGF	Standard methods of the German Society for Fat Science e.V.)
DIN	German Institute for Standardization e.V.
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied
Ph. Eur.	Chemistry Pharmacopoea Europaea;
USP	European Pharmacopoeia United States Pharmacopeia
VA XXXXX	In-house testing method of Quality Services International GmbH

I hereby certify that this is a true and complete translation of the German original document presented to me. This translation comprises 8 pages.

Göttingen, 13 September 2024

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

Lucie Hamdi – Generally sworn interpreter and authorised translator, District Court of Hanover

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