

### Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

### Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the testing laboratory

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

is competent under the terms of DIN EN ISO/IEC 17025:2018 to carry out tests in the following fields:

physical, physico-chemical, chemical, visual, microscopic, microbiological and selected molecular biological studies of plant-based foodstuffs and feedstuffs;

Pharmaceutical products and active ingredients

Test areas:

Physical, physical-chemical and chemical as well as microbiological and molecular-biological analysis of drugs, active ingredients and auxiliaries.

The accreditation certificate shall only apply in connection with the notice of accreditation of 26.11.2019 with the accreditation number D-PL-19308-02. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 16 pages.

Registration number of the certificate: D-PL-19308-02-00

Berlin, 26.11.2019 Dipl.-Ing. Andrea Valbuena Head of Division Translation issued: 21.04.2020

Head of Division

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH. https://www.dakks.de/en/content/accredited-bodies-dakks

This document is a translation. The definitive version is the original German accreditation certificate. See notes overleaf.



### Deutsche Akkreditierungsstelle GmbH

# Annex to the Accreditation Certificate D-PL-19308-02-00 according to DIN EN ISO/IEC 17025:2018

Valid from: 26.11.2019

Date of issue: 21.04.2020

Holder of certificate:

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

Tests in the fields:

physical, physico-chemical, chemical, visual, microscopic, microbiological and selected molecular biological studies of plant-based foodstuffs and feedstuffs;

Pharmaceutical products and active ingredients

Test areas:

Physical, physical-chemical and chemical as well as microbiological and molecular-biological analysis of drugs, active ingredients and auxiliaries.

Within the given testing field marked with \*/\*\*, the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following:

- \*) the free choice of standard or equivalent testing methods.
- \*\*) the modification, development and refinement of testing methods.

The listed testing methods are exemplary.

The testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use standards or equivalent testing methods listed here with different issue dates.

The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH. https://www.dakks.de/en/content/accredited-bodies-dakks



#### 1 Plant-based foodstuffs and plant-based feedstuffs

#### 1.1 Physical, physico-chemical and chemical analysis

#### 1.1.1 Gravimetric determination of dry substance \*\*

DIN 10800 Analysis of tea - Determination of loss in mass of unground tea at 103 °C

2016-07 (Modification: also in other selected plant-based foodstuffs and

feedstuffs, single determination only)

DIN 10806 Analysis of tea - preparation of ground sample of defined dry matter

2016-07 content (gravimetry)

(Modification: also in other selected plant-based foodstuffs and

feedstuffs, single determination only)

USP 41 <731> Loss on drying

2018 (Modification: in selected plant-based foodstuffs and feedstuffs)

PV 304110 Determination of dry residue (gravimetry) of glycolic extracts

2016-03

#### 1.1.2 Determination of water content by titrimetric investigation \*

Ph. Eur. 9.4 2.5.12 Semi-microdetermination of water, Karl Fischer method

Methode A (Modification: also in other selected plant-based foodstuffs and

(Woulder all of the Selected plant based jobastajjs a

2018 feedstuffs)

Ph. Eur. 9.4 2.5.32 Micro determination of water - coulometric titration

2018 (Modification: also in selected plant-based foodstuffs and feedstuffs)

#### 1.1.3 Determination of water content by distillation \*

ISO 939 Spices and condiments - Determination of moisture content -

1980-05 Entrainment method

Ph. Eur. 9.0, 2.2.13 Determination of water by distillation

2016 (Modification: also in selected plant-based foodstuffs and feedstuffs)

-Translation-



#### 1.1.4 Determination of volatile oils by steam distillation \*

**DIN EN ISO 6571** 

2018-03

Spices, condiments and herbs - Determination of volatile oil content

(steam distillation method)

(Modification: Determination of the loss of mass (gravimetry) of unground tea at 103 °C according to DIN 10800:2016-07, PV 304000 (method 304450), adaptation of distillation times and weights to Ph.Eur., also in other selected plant-based foodstuffs and feedstuffs)

Ph. Eur. 9.8 2.8.12

2018

Determination of the volatile oil content in drugs (steam distillation)

(Modification: to be indicated in % m/V, based on the dried or anhydrous

drug, also in other selected plant-based foodstuffs and feedstuffs)

#### 1.1.5 Determination of radioactivity by gamma spectroscopy

PV 804200

2019-05

Determination of total radioactivity, expressed as Cs-137 equivalent (gamma spectroscopy, sodium iodine detector) in selected plant-based

products

#### 1.1.6 Photometric determination of ingredients and residues \*\*

DIN ISO 14502-1

2007-11

Determination of substances characteristic for green and black tea -

Part 1: Content of total polyphenols in tea - Colorimetric method using

Folin-Ciocalteu reagent.

(Modification: also in other selected plant-based foodstuffs and

feedstuffs)

DIN EN 12396-3

2000-10

Non-fatty foods - Determination of dithiocarbamate and thiuram

disulfide residues-

Part 3: UV-spectrometric xanthogenate method

(Modification: only in selected plant-based foodstuffs and feedstuffs)

PV 608063

2018-09

Determination of total flavonoids (colorimetric method using Folin-

Ciocalteu reagent) in green and black tea

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#### 1.1.7 Determination of identity and purity by thin layer chromatography \*\*

PV 203900 Determination of identity of selected foodstuffs by thin layer chromatography

PV 203950 Determination of identity from volatile oil in selected plant-based foodstuffs by thin layer chromatography

PV 309900 Determination of purity of selected plant-based foodstuffs by thin layer chromatography

# 1.1.8 Determination of ingredients and organic contaminations by liquid chromatography with standard detectors (UV, Fluorescence) \*\*

| Ph. Eur. 9.0/0277<br>Licorice root<br>2016 | Glycyrrhizinic acid relative to the dried drug (HPLC-UV) in licorice root (Modification: in selected plant-based foodstuffs and feedstuffs)      |
|--|--|
| Ph. Eur. 9.0/1523<br>Ginseng root<br>2016  | Ginsenoside Rg 1 and Rb 1 relative to the dried drug (HPLC-UV) in ginseng root (Modification: in selected plant-based foodstuffs and feedstuffs) |
| PV 403073<br>2014-02                       | Determination of cumarin (HPLC-UV) in cinnamon and cinnamon extracts   |
| PV 605410<br>2014-02                       | Determination of ginsenoside content (HPLC-UV), calculated as Rg 1 and Rb 1, in ginseng extract $$   |
| PV 805021<br>2014-12                       | Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant-based products (matrix group I)                     |
| PM 805023<br>2018-11                       | Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant-based products (matrix group II)                    |
| PV 805025<br>2015-01                       | Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant-based products (matrix group III)                   |
| PM 805091<br>2019-04                       | Identification and determination of ochratoxin A (HPLC fluorescence) in plant-based products   |

-Translation-



## 1.1.9 Determination of ingredients, organic contaminants and pesticide residues by liquid chromatography with mass-selective detectors (MS, MS/MS) \*\*

ASU L 00.00-115

2018-10

Investigation of foodstuffs - Multimethod for the determination of pesticide residues in plant-based foodstuffs by GC or LC following acetonitrile extraction/partitioning and purification by dispersive SPE in plant-based foodstuffs - Modular QuEChERS method (adoption of the

standard DIN EN 15662, July 2018)

(Modification: only LC-MS/MS, different weights, extraction mixture of acetonitrile/methanol, chromatography modified, only with selected

plant-based foodstuffs and feedstuffs)

PV 504870 2017-12 Determination of anisatin (LC-MSD) in star anise and star anise oil

PV 720724 2018-08

Determination of nicotine (LC-MS/MS) in selected plant-based products

PV 720728

Determination of phenoxy alkane carboxylic acids (LC-MS/MS) in

2018-04

selected plant-based products

PV 804920 2017-12 Determination of acrylamide (LC-MS/MS) in selected plant-based

products

PV 805163

Determination of ochratoxin A, based on dry matter, (LC-MS/MS) in

2018-12 selected plant products

PM 805521

2017-01

Determination of pyrrolizidine alkaloids and their N-oxides (LC-MS/MS)

in selected plant products

## 1.1.10 Determination of ingredients, organic contaminants and pesticide residues by gas chromatography with standard detection (FID, FPD, ECD, NPD) \*\*

**DIN EN ISO 9832** 

2003-12

Animal and vegetable fats and oils - Determination of residual technical

hexane content

(Modification: adaption to state of the art of technology, sample

preparation and measurement (headspace), only in plant-based fats and

oils)

ASU L 00.00-34

2010-09

Investigation of foodstuffs- Modular multimethod for the determination of pesticide residues in plant-based foodstuffs (extended revised version

of the DFG method, page 19)

(Modification: limited to the components D1, D2, E1, E2, E3, E6, E7, E9,

only in selected plant-based foodstuffs and feedstuffs)

-Translation-



| ASU L 53.00-1<br>1999-11                    | Investigation of foodstuffs - Gas chromatographic determination of ethylene oxide and 2-chloroethanol in spices (Modification: Six-point calibration with internal standard 1-bromo-2-propanol, reduced concentration of the sodium iodide and sodium thiosulfate solution, the ISTD is added before extraction, shake once, also in other selected plant based foodstuffs and feedstuffs) |
|---|--|
| Ph. Eur. 9.7/0405<br>Peppermint oil<br>2019 | Determination of purity (GC) on the basis of oil components in peppermint oil (Modification: also in selected plant-based foodstuffs and feedstuffs)   |
| PV 403310<br>2017-03                        | Content of ethanol (GC) in liquid plant-based products   |
| PV 730271<br>2014-08                        | Determination of phosphine (Headspace GC) in selected plant-based products   |
| PV 805762<br>2017-03                        | Determination of residual solvents (Headspace GC) in % in selected plant-based products  |
| PV 805763<br>2017-03                        | Determination of residual solvents (Headspace GC) in mg/kg in selected plant-based products  |

# 1.1.11 Determination of organic contaminants and pesticide residues by gas chromatography with mass-selective detectors (MS, MS/MS) \*\*

| ASU L 00.00-34<br>2010-09 | Investigation of foodstuffs - Modular multimethod for the determination of pesticide residues in foodstuffs (extended version of the DFG method, page 19) (Modification: limited to the component D4, measurement with GC-MS/MS, only in selected plant-based foodstuffs and feedstuffs) |
|---------------------------|--|
| ASU L 47.08-02<br>2004-12 | Investigation of foodstuffs - Determination of estragole in tea infusion by GC-MS (Modification: sample weight and extraction volume reduced, single-point calibration, also in extract mixtures of several components)  |
| ASU L 47.08-03<br>2006-09 | Investigation of foodstuffs - Determination of estragole in infusions of fennel and other tea-like products - GC-MS method (Modification: infusion preparation also according to specification, single-point calibration)  |

-Translation-



| PV 720470<br>2015-12 | Screening of pesticide residues (GC-MS/MS) in selected plant products   |
|----------------------|---|
| PV 720546<br>2017-03 | Determination of pesticide residues: Glyphosate and aminomethylphosphonic acid (AMPA) by GC-MS in selected plant products |
| PV 730110<br>2017-04 | Determination of pesticide residues:<br>Phenylureas and their anilines by GC-MS in selected plant products                |
| PV 800809<br>2015-12 | Sample preparation for the determination of polycyclic aromatic hydrocarbons (PAHs) in selected plant products by GC-MS   |
| PV 800812<br>2015-12 | Determination of polycyclic aromatic hydrocarbons (PAHs) in selected plant-based products by GC-MS                        |
| PV 800817<br>2015-12 | Determination of polycyclic aromatic hydrocarbons (PAHs) relative to the fat content in cocoa by GC-MS                    |

#### 1.1.12 Determination of elements by atomic absorption spectroscopy \*

Ph. Eur. 9.0, 2.4.27

2016

Heavy metals in plant-based drugs and drug preparations; lead,

cadmium, mercury and nickel via AAS

(Modification: also in selected plant-based foodstuffs and feedstuffs)

### 1.1.13 Determination of anions and elements by mass spectrometry with inductively coupled plasma \*\*

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 closet, sample filtration with C18 column instead of membrane filters, upper and lower endpoints of calibration range extended, only in selected plant-based

foodstuffs and feedstuffs)

Ph. Eur. 9.0, 2.4.27

2016

Determination of lead, cadmium, mercury (ICP-MS) in herbal drugs and

drug preparations

(Modification: also for elements other than those mentioned in the monograph and in selected plant-based foodstuffs and feedstuffs)

PV 730207 2017-05

Determination of inorganic bromide, calculated as bromide ion (ICP-MS)

in selected plant products

-Translation-



PV 811100 2016-12 Determination of aluminium (ICP-MS) in selected plant products

PV 812300 2016-12

Determination of sodium (ICP-MS) in mg/kg in selected plant products

#### 1.2 Determination of bacteria, moulds and yeasts using cultural microbiological methods \*

ISO 21527-2 2008-07 Microbiology of foodstuffs and feedstuffs - Horizontal method for the enumeration of yeasts and moulds. - Colony count technique - Part 2:

Products with a water activity equal to or less than 0,95

(Modification: single approach for quantitative methods according to

DIN EN ISO 7218)

ISO 21528-2 2017-06 Microbiology of the food chain - Horizontal method for the detection and enumeration of Enterobacteriaceae - Part 2: Colony counting

method

(Modification: single approach for quantitative methods according to

DIN EN ISO 7218)

**DIN EN ISO 6888-1** 

2003-12

Microbiology of foodstuffs and feedstuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 1: Method using Baird-Parker agar (withdrawn

standard)

(Modification: single approach for quantitative methods according to DIN

EN ISO 7218)

**DIN EN ISO 7932** 

2005-03

Microbiology of foodstuffs and feedstuffs - Horizontal method for counting presumptive Bacillus cereus - Colony counting method at 30 °C (Modification: single approach for quantitative methods according to

**DIN EN ISO 7218)** 

#### 1.2 Molecularbiology

Du Pont BAX® System PCR AssAy for Screening Salmonella (D11000133) 2019-03 Method for the detection of Salmonella spp. in foodstuffs and feedstuffs

using the BAX PCR system

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#### 1.3 Visual inspections

#### 1.3.1 Verification of identity by simple visual inspections \*\*

PV 201900

Verification of identity by simple visual examination (macroscopic, magnifying glass) for selected plant raw materials and monoproducts

2019-04

Verification of identity by simple visual examination (macroscopic,

PV 204000 2017-05

magnifying glass) of selected plant mixtures

#### 1.3.2 Verification of Identity by Microscopy

PV 202900 2019-08 Verification of identity by microscopy for selected plant products

- 2 Pharmaceuticals and active ingredients (herbal pharmaceuticals and preparations of herbal pharmaceuticals, homeopathic pharmaceutical products and preparations)
- 2.1 Physical, physical-chemical and chemical analysis of drugs, active ingredients and auxiliaries

#### 2.1.1 Type of testing: Gravimetry \*\*

Ph. Eur. 9.8, 2.2.32

Loss on drying (gravimetry), method d)

2019

Ph. Eur. 9.0, 2.8.17

Loss on drying (gravimetry), extracts

2016

USP 41 <731>

Loss on drying

2018

HAB H 2.2.6

Determination of the dry matter residue (gravimetry) of liquid

2015

substances

PV 304110 2016-03

Determination of the dry matter residue (gravimetry) of glycolic extracts

-Translation-



#### 2.1.2 Type of testing: Titrimetry \*

Ph. Eur. 9.4 2.5.12,

Semi-microdetermination of water by the Karl Fischer method

Methode A

2018

Ph. Eur. 9.4 2.5.32

Mikrodetermination of water - Coulometric titration

2018

#### 2.1.3 Type of testing: Distillation \*

ISO 939

Spices and condiments - Determination of moisture content -

1980-05 Entrainment method

(Modification: also in plant-based pharmaceutic raw materials)

Ph. Eur. 9.0, 2.2.13

2016

Determination of water by distillation

#### 2.1.4 Type of testing: Steam Distillation\*

**DIN EN ISO 6571** 

2018-03

Spices, condiments and herbs - Determination of volatile oil content

(Hydro-distillation method)

(Modification: Determination of mass loss (gravimetry) of unground tea at 103 °C according to DIN 10800:2016-07, PV 304000 (method 304450), adaptation of distillation times and weights to Ph.Eur., also in selected

vegetable pharmaceutical raw materials)

Ph. Eur. 9.8 2.8.12

2019

Determination of volatile oil content in drugs (steam distillation)

(Modification: expressed in % m/v, based on the dried or anhydrous

drug)

#### 2.1.5 Type of testing: Gamma spectroscopy

PV 804200

2019-05

Determination of total radioactivity expressed as CS-137 equivalents (gamma spectroscopy, sodium iodide detector) in selected plant-based

foodstuffs

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#### 2.1.6 Type of testing: Photometry \*\*

DIN EN 12396-3

2000-10

Low-fat foodstuffs; Determination of dithiocarbamate and thiuram

disulphide residues - Part 3: UV-spectrophotometric xanthogenate

method

(Modification: also in selected plant-based pharmaceutical raw

materials)

Ph. Eur. 9.0/0206

Senna leaves

2016

Hydroxyanthracene glycosides, calculated as sennoside B, relative to

the dried drug (spectral photometry) in senna leaves

Ph. Eur. 9.0/0207

Alexandrine senna pods

2016

Hydroxyanthracene glycosides, calculated as sennoside B, relative to

the dried drug (spectral photometry) in alexandrine senna pods

Ph. Eur. 9.0/1261

Standardized senna leaf dry

extract

Hydroxyanthracene glycosides, calculated as sennoside B, relative to the dried extract (spectral photometry) in standardized senna leaf dry

extract

2016

(Modification: without reference to the dried extract)

PV 608063

Determination of total flavonoids (colorimetric with Folin-Ciocalteu

2018-09

reagent), in black and green tea

#### 2.1.7 Type of testing: Thin layer chromatography\*\*

PV 203900

Determination of identity in selected plant-based products by thin-layer

2019-04

chromatography

PV 203950

Determination of identity from volatile oil in selected plant-based

2019-04

products by thin-layer chromatography

PV 309900

Determination of purity of selected plant-based foodstuffs by thin-layer

#### 2019-04

-04 chromatography

#### 2.1.8 Type of testing: High performance liquid chromatography (UV, Fluorescence) \*\*

Ph. Eur. 9.0/0277

Licorice root

2016

Glycyrrhizic acid, based on dried drug (HPLC-UV) in licorice root

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| Ph. Eur. 9.0/1523<br>Ginseng root<br>2016 | Ginsenosides Rg 1 and Rb 1, based on the dried drug (HPLC-UV) in ginseng root   |
|---|---|
| PV 403073<br>2014-02                      | Determination of cumarin (HPLC-UV) in cinnamon and cinnamon extracts  |
| PV 605410<br>2014-02                      | Determination of ginsenoside content (HPLC-UV), calculated as Rg1 and Rb1 in ginseng extract                            |
| PV 805021<br>2014-12                      | Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant products (matrix group I)  |
| PM 805023<br>2018-11                      | Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant products (matrix group II) |
| PV 805025<br>2015-01                      | Identification and determination of aflatoxin B1, B2, G1 and G2 (HPLC fluorescence) in plant products (matrix group II) |

Identification and determination of ochratoxin A (HPLC fluorescence) in

#### 2.1.9 Type of testing: High performance liquid chromatography (MS, MS/MS) \*\*

plant products

| ASU L 00.00-115<br>2018-10 | Investigation of foodstuffs - Multimethod for the determination of pesticide residues with GC and LC after acetonitrile extraction/distribution and purification with disperse SPE in plant-based foodstuffs - Modular QuEChERS method (adoption of the standard DIN EN 15662, July 2018) (Modification: only LC-MS/MS, differing weights, extraction mixture of acetonitrile/methanol, chromatography modified, also in selected plant-based pharmaceutical raw materials) |
|----------------------------|---|
| PV 504870<br>2017-12       | Determination of anisatin (LC-MSD) in star anise and star anise oil   |
| PV 720724<br>2018-08       | Determination of nicotine (LC-MS/MS) in selected plant-based products   |
| PV 720728<br>2018-04       | Determination of phenoxyalkanoic acids (LC-MS/MS) in selected plant-based products  |
| PV 804920<br>2017-12       | Determination of acrylamide (LC-MS/MS) in selected plant products   |

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PM 805091

2019-04



PV 805163 2018-12 Determination of ochratoxin A, relative to dry matter (LC-MS/MS) in

selected plant-based products

PM 805521 2017-01

Determination of pyrrolizidine alkaloids and their N-oxides (LC-MS/MS)

in selected plant-based products

2.1.10 Type of testing: Gaschromatography (FID, FPD, ECD, NPD) \*\*

**DIN EN ISO 9832** 

2003-12

Animal and vegetable fats and oils - Determination of the content of

technical residual hexane

(Modification: adaptation to the state of the art, sample preparation and measurement (headspace), only in plant-based fats and oils, also in

selected plant-based raw materials for pharmaceuticals)

ASU L 00.00-34

2010-09

Analysis of foodstuffs - Modular multimethod for the determination of

pesticide residues in foodstuffs

(Modification: restricted to building blocks D1, D2, E1, E2, E3, E6, E7, E9,

also in selected plant-based raw materials for pharmaceuticals)

Ph. Eur. 9.7, 0405

Peppermint oil

2019

Determination of purity (GC) via oil components in peppermint oil

PV 403310

2017-03

Ethanol content (GC) in liquid plant-based products

PV 730271

2014-08

Determination of phosphine (Headspace-GC) in selected plant-based

products

PV 805762

2017-03

Determination of residual solvents (Headspace-GC) in % in selected

plant-based products

PV 805763

2017-03

Determination of residual solvents (Headspace-GC) in mg/kg in selected

plant-based products

2.1.11 Type of testing: Gas chromatography (MS, MS/MS) \*\*

ASU L 00.00-34

2010-09

Analysis of foodstuffs - Modular multimethod for the determination of

pesticide residues in foodstuffs

(Modification: Restricted to module D4, measurement with GC-MS/MS,

also in selected plant-based raw materials for pharmaceuticals)

-Translation-

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ASU L 47.08-02 2004-12

Analysis of foodstuffs - Determination of estragole in tea infusions by

GC-MS

(Modification: weighing and extraction volume reduced, single-point calibration; also in extract mixtures of several components, also in

selected plant-based raw materials for pharmaceuticals)

ASU L 47.08-03

2006-09

Analysis of foodstuffs - Determination of estragole in infusions of fennel

and other tea-like products - GC-MS method

(Modification: infusion preparation also according to specification,

calibration, also in selected plant-based raw materials for

pharmaceuticals)

PV 720470

2015-12

Screening of pesticide residues (GC-MS/MS) in selected plant products

PV 720546

2017-03

Determination of pesticide residues: Glyphosate and

aminomethylphosphonic acid (AMPA) by GC-MS in selected plant

products

PV 730110

2017-04

Determination of pesticide residues: Phenylureas and their anilines by

GC-MS in selected plant products

PV 800808

2015-12

Sample preparation for the determination of polycyclic aromatic

hydrocarbons (PAHs) by GC-MS in tea infusions

PV 800813 2015-12

Determination of polycyclic aromatic hydrocarbons (PAHs) by GC-MS in

tea infusions

#### 2.1.12 Type of testing: Atomic absorption spectroscopy \*

Ph. Eur. 9.0, 2.4.27

2016

Heavy metals in herbal drugs and drug preparations; lead, cadmium,

mercury and nickel via AAS

#### 2.1.13 Type of testing: Mass Spectrometry with inductively coupled plasma (ICP-MS) \*\*

**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 closet, sample filtration with C18 columns instead of membrane filters, upper and lower endpoints of calibration range extended, also in selected plant-based

raw materials for pharmaceuticals)

-Translation-



Ph. Eur. 9.0, 2.4.27

2016

Determination of lead, cadmium, mercury (ICP-MS) in herbal drugs and

drug preparations

(Modification: also for elements other than those mentioned in the

monograph)

PV 730207

Determination of inorganic bromide, calculated as bromide ion (ICP-MS)

2017-06

in selected plant-based products

PV 811100 2016-12 Determination of aluminium (ICP-MS) in selected plant-based products

#### 2.2 Analysis of biological pharmaceuticals, active ingredients and auxiliaries

#### 2.2.1 Type of testing: Microbiological testing of non-sterile products \*\*

Ph. Eur. 9.0, 2.6.12

2016

Microbiological examination of non-sterile products: Counting of microorganisms in pharmaceuticals and their initial and intermediate

products:

Total number of aerobic germs, counting on agar plates and total

number of yeasts and moulds, counting on agar plates

Ph. Eur. 9.0, 2.6.13

2016

Microbiological examination of non-sterile products: Tests for certain

microorganisms in pharmaceuticals and their raw materials and

intermediate products:

Bile salt-tolerant, Gram-negative bacteria, quantitative testing

Escherichia coli, testing for absence/quantitative testing

Salmonella, check for absence

Staphylococcus aureus, check for absence

Pseudomonas aeruginosa, examination for absence

Ph. Eur. 9.0, 2.6.31

2016

Microbiological testing in herbal pharmaceuticals and their initial and

intermediate products

#### 2.2.2 Type of testing: Amplification of nucleic acids (PCR) \*

Du Pont BAX® System

PCR AssAy for Screening Salmonella (D11000133)

2019-03

Method for the detection of Salmonella spp. in drugs using the BAX PCR

system

-Translation-



#### 2.3 Optical sensor technology

#### 2.3.1 Type of testing: Visual analysis \*\*

PV 201900

Verification of identity by means of simple visual examination

2019-04

(macroscopic, magnifying glass) for selected plant-based raw materials

and monoproducts

PV 204000

Verification of identity by simple visual examination (macroscopic,

2017-05

magnifying glass) of selected plant-based mixtures

#### 2.3.2 Type of testing: Microscopy \*\*

PV 202900

Verification of identity by microscopy for selected plant-based products

2019-08

#### Abbreviations used:

ASU Official collection of testing methods in accordance with § 64 LFGB

DIN German Standards Institute

EN Europäische Standard

HAB Homeopathic Pharmacopoeia

IEC International Electrotechnical Commission
ISO International Organization for Standardization

TS Technical Specification
Ph. Eur. Pharmacopoea Europaea

PM test method (Prüfmethode) PhytoLab GmbH & Co. KG

PV In-house test method (Prüfvorschrift) PhytoLab GmbH & Co. KG

USP United States Pharmacopeia

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