

Certificate of Analysis

Sample name	Dioscoreae oppositae Rhizoma
Pin Yin	Shan Yao
Product no.	1019
Batch	25031019
Sample no.	LN-9387
Expiration date	30. April 2030
Galenic form	Granules
Amount	200 g
Certificate no.	159842_E.01
Client	Medichin NV, Groeningenweg 15, B-3590 Diepenbeek
Sample receipt	2. May 2025
Issue date	21. May 2025

Identity

	Result
TLC-Identity	conforms ¹

¹ Determination according to SOP 3.2.3 Thin-Layer Chromatography.

Sample conforms to the current edition of the Pharmacopoeia of the People's Republic of China and/or other relevant literature concerning TCM such as the European Pharmacopoeia.

Heavy metals

	Limit of quantification	Specification	Result
Lead	0.020 mg/kg	$\leq 5.0 \text{ mg/kg}^1$	0.12 mg/kg ³
Cadmium	0.010 mg/kg	$\leq 1.0 \text{ mg/kg}^1$	0.14 mg/kg ³
Mercury	0.010 mg/kg	$\leq 0.1 \text{ mg/kg}^1$	< 0.010 mg/kg ³
Arsenic	0.040 mg/kg	$\leq 2.0 \text{ mg/kg}^2$	0.15 mg/kg ³

¹ According to the current edition of the European Pharmacopoeia.

² According to the customer's specification.

³ Determination according to the German Industry Standard (DIN) EN 15763 using ICP-MS.^{EXT}

Sample conforms to the current edition of the European Pharmacopoeia.

Mycotoxins

	Limit of quantification	Specification	Result
Aflatoxin B1	0.05 µg/kg	$\leq 2 \text{ µg/kg}^1$	0.29 µg/kg ²
Total Aflatoxin	-	$\leq 4 \text{ µg/kg}^1$	< 0.440 µg/kg ²

¹ According to the current edition of the European Pharmacopoeia.

² Determination using LC-MS/MS.^{EXT}

Sample conforms to the current edition of the European Pharmacopoeia.

Pesticide residues

	Specification	Result
Pesticide residues	see footer ¹	positive ²
Carbendazim and benomyl (sum)	$\leq 0.1 \text{ mg/kg}^1$	0.016 mg/kg ²

¹ According to the current edition of the European Pharmacopoeia 2.8.13. For substances not included in Table 2.8.13-1, the Regulation (EC) No. 396/2005 applies.

² Determination according to § 64 of the Food and Feed Code of Law (LFGB; Germany) using LC-MS/MS and GC-MS/MS. ^{EXT}

Sample conforms to the current edition of the European Pharmacopoeia and the limits of Regulation (EC) No. 396/2005.

Microbial contamination

	Specification	Result
TAMC	$\leq 5 \cdot 10^5$ KBE/g ¹	$< 1 \cdot 10^1$ KBE/g ²
TYMC	$\leq 5 \cdot 10^4$ KBE/g ¹	$< 1 \cdot 10^1$ KBE/g ²
Bile-tolerant, gram(-) bacteria	$\leq 1 \cdot 10^4$ KBE/g ¹	$< 1 \cdot 10^1$ KBE/g ²
Escherichia coli	Absence ¹	absent (g) ²
Salmonella	Absence ¹	absent (25g) ²

¹ According to the current edition of the European Pharmacopoeia 5.1.8; Category C.

² Determination according to the current edition of the European Pharmacopoeia 2.6.12, 2.6.13 and 2.6.31. ^{EXT}

Sample conforms to the current edition of the European Pharmacopoeia.

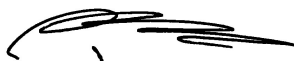
Abbreviations:

EXT: accredited external laboratory

This Certificate of Analysis is based on the German Ordinance on the Operation of Pharmacies (Apothekenbetriebsordnung (ApBetrO) §§ 6 + 11) according to the Mutual Recognition Agreement (MRA, Chapter 15) between the European Union and Switzerland.

Phytax GmbH is a GMP-certified analytical laboratory and is regularly inspected on behalf of Swissmedic (Permit No. 512882-102708829). We hereby confirm that the commissioned analyses were performed according to approved pharmaceutical regulations. The concluding result applies exclusively to the received sample and the commissioned analyses. Further analyses were not performed.

Schlieren, 21. May 2025



Dr. Peter Staub
Responsible Person