

Certificate of Analysis

Name	Paeoniae lactiflorae, Radix
Pin Yin	Bai Shao Yao
Number of Product	1056
Charge	20031056
Lab.-No	LN-4517
Expiration date	30 May 2025
Galenic Form	Granules
Amount	200 g
No. of Certificate	154384_E.01
Issue Date	19 June 2020
Client	Medichin NV Groeningenweg 15 B-3590 Diepenbeek
Sample Receipt	28 May 2020

Identity

	Result
TLC-Identitiy	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	≤ 5.0 mg/kg ¹	0.085 mg/kg ²
Cadmium	0.010 mg/kg	≤ 1.0 mg/kg ¹	0.021 mg/kg ²
Mercury	0.010 mg/kg	≤ 0.1 mg/kg ¹	<0.010 mg/kg ²
Arsenic	0.040 mg/kg	≤ 2.0 mg/kg ¹	0.20 mg/kg ²

¹ According to the current edition of the European Pharmacopoeia.

² Determination according to the German Industry Standard (DIN) EN 15763 using ICP-MS.

Sample conforms to the current edition of the European Pharmacopoeia 10.1

Mycotoxine

	Limit of quantification	Specification	Result
Aflatoxin B1	0.05 µg/kg	≤ 2 µg/kg ¹	<0.050 µg/kg ²
Total Aflatoxin	-	≤ 4 µg/kg ¹	<0.200 µg/kg ²

¹ According to the current edition of the European Pharmacopoeia.

² Determination according to the German legislation § 64, Food and Feed Code of Law (LFGB) using UPLC-FLD.

Sample conforms to the current edition of the European Pharmacopoeia 10.1.

Pesticide residues

	Specification	Result
Pesticide residues	see footer ¹	not detectable ²

¹ According to the current edition of the European Pharmacopoeia 2.8.13. For substances not included in Table 2.8.13-1, maximum values apply as specified by Regulation (EC) No. 396/2005. For specific threshold values and approved pesticides see Appendix 1.

² Determination according to the German legislation § 64, Food and Feed Code of Law (LFGB) using GC-MS.

Sample conforms to the current edition of the European Pharmacopoeia 10.1 and the limits of Regulation (EC) No. 396/2005.

Microbial contamination

	Specification	Result
TAMC	$\leq 5 \cdot 10^5$ KBE/g ¹	$4 \cdot 10^2$ KBE/g ²
TYMC	$\leq 5 \cdot 10^4$ KBE/g ¹	$2 \cdot 10^1$ KBE/g ²
Bile-tolerant, gram(-) bacteria	$\leq 1 \cdot 10^4$ KBE/g ¹	$<1 \cdot 10^3$ KBE/g ²
Escherichia coli	Absence ¹	absent (KBE/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 and 2.6.31.

Sample conforms to the current edition of the European Pharmacopoeia 10.1.

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 (Certificate No. 506020). 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, 19 June 2020



Dr. Shu-Yuan Wang-Tschen
Qualified person

Attachement

TLC Fingerprint

Attachment of Certificate of Analysis

No. of Certificate	154384_E.01
Name	Paeoniae lactiflorae, Radix
Pin Yin	Bai Shao Yao
Number of Product	1056
Charge	20031056
Lab.-No	LN-4517

Chromatographic conditions

Stationary Phase	Silicagel 60 F254
Mobile Phase	27
Spray Reagent	2
Test Date	05.06.20

UV 254 nm



Sample 1056.20031056



Reference 8301/5

UV 366 nm



Sample 1056.20031056



Reference 8301/5

Visuelles Licht / Sprühreagenz



Sample 1056.20031056



Reference 8301/5

UV 366 nm / Sprühreagenz



Sample 1056.20031056



Reference 8301/5