

Certificate of Analysis

Name	Paeoniae lactiflorae, Radix
Pin Yin	Bai Shao Yao
Number of Product	1056
Charge	18051056
Lab.-No	LN-2864
Expiration date	30 July 2023
Galenic Form	Granules
Amount	200 g
No. of Certificate	152495_E.01
Issue Date	29 August 2018
Client	Medichin NV Groeningenweg 15 B-3590 Diepenbeek
Sample Receipt	19 July 2018

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	0.064 mg/kg ²
Cadmium	0.010 mg/kg	≤ 1.0 mg/kg ¹	0.012 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	0.33 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 footnoted specification(s).

Mykotoxine

	Limit of quantification	Specification	Result
Aflatoxin B1	0.05 µg/kg	≤ 2 µg/kg ¹	0.14 µg/kg ²
Total Aflatoxin	-	≤ 4 µg/kg ¹	<0.290 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 footnoted specification(s).

Pesticide residues

	Specification	Result
Pesticide residues	see footer ¹	positive ²
Pyraclostrobin	≤ 0.1 mg/kg ¹	0.006 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, 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 LC-MS/MS and GC-MS.

Sample conforms to the footnoted specification(s).

Microbial contamination

	Specification	Result
TAMC	≤ 5 · 10 ⁵ KBE/g ¹	2 · 10 ² KBE/g ²
TYMC	≤ 5 · 10 ⁴ KBE/g ¹	3 · 10 ¹ KBE/g ²
Bile-tolerant, gram(-) bacteria	≤ 1 · 10 ⁴ KBE/g ¹	<1 · 10 ² 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.

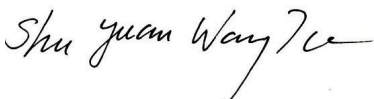
² Determination according to the current edition of the European Pharmacopoeia, 2.6.12 and 2.6.31.

Sample conforms to the footnoted specification(s).

This Certificate of Analysis is based on the German Legislation Act (Apothekenbetriebsordnung (ApBetrO) §§ 6 + 11) according to the Mutual Recognition Agreement (MRA, chapter 15) between the EU and Switzerland.

Phytax GmbH is accredited by Swissmedic as an analytical laboratory and is GMP certified. We hereby certify that the above information is accurate. The respective sample determination by Phytax GmbH refers exclusively to the specified sample received by Phytax GmbH and to the specific study commissioned for that sample. Further analyses were not carried out.

Schlieren, 29 August 2018



Phytax GmbH
Dr. Shu-Yuan Wang-Tschen
Qualified person

Attachement

TLC Fingerprint

Attachment of Certificate of Analysis

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Chromatographic conditions

Stationary Phase	Silicagel 60 F254
Mobile Phase	27
Spray Reagent	2
Test Date	27.07.18

UV 254 nm



Sample 1056.18051056



Reference 7416/11

UV 366 nm



Sample 1056.18051056

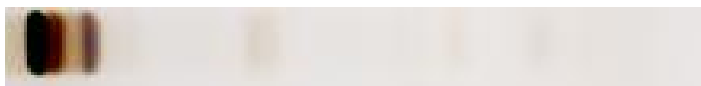


Reference 7416/11

Visuelles Licht / Sprühreagenz



Sample 1056.18051056



Reference 7416/11

UV 366 nm / Sprühreagenz



Sample 1056.18051056



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