

Certificate of Analysis

Name	Rehmanniae praep., Radix
Pin Yin	Shu Di Huang
Number of Product	1078
Charge	18051078
Lab.-No	LN-2867
Expiration date	30 July 2023
Galenic Form	Granules
Amount	200 g
No. of Certificate	152498_E.01
Issue Date	29 August 2018
Client	Medichin NV Groeningenweg 15 B-3590 Diepenbeek
Sample Receipt	19 July 2018

Identity

TLC-Identitiy	Result 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	0.63 mg/kg ²
Cadmium	0.010 mg/kg	≤ 1.0 mg/kg ¹	0.038 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	0.72 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	<0.050 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 footnoted specification(s).

Pesticide residues

	Specification	Result
Pesticide residues	see footer ¹	positive ²
Dimethomorph (sum of isomers)	$\leq 0.05 \text{ mg/kg}^1$	0.007 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	$\leq 5 \cdot 10^5 \text{ KBE/g}^1$	$2.8 \cdot 10^2 \text{ KBE/g}^2$
TYMC	$\leq 5 \cdot 10^4 \text{ KBE/g}^1$	$<1 \cdot 10^1 \text{ KBE/g}^2$
Bile-tolerant, gram(-) bacteria	$\leq 1 \cdot 10^4 \text{ KBE/g}^1$	$<1 \cdot 10^1 \text{ KBE/g}^2$
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.

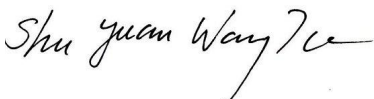
² Determination according to the current edition of the European Pharmacopoeia, 2.6.12 and 2.6.31.

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

No. of Certificate	152498_E.01
Name	Rehmanniae praep., Radix
Pin Yin	Shu Di Huang
Number of Product	1078
Charge	18051078
Lab.-No	LN-2867

Chromatographic conditions

Stationary Phase	Silicagel 60 F254
Mobile Phase	93
Spray Reagent	2
Test Date	31.07.18

UV 254 nm



Sample 1078.18051078



Reference 7424/2

UV 366 nm



Sample 1078.18051078



Reference 7424/2

Visuelles Licht / Sprühreagenz



Sample 1078.18051078



Reference 7424/2

UV 366 nm / Sprühreagenz



Sample 1078.18051078



Reference 7424/2