

## Certificate of Analysis

Name	Glycyrrhizae uralensis radix
Pin Yin	Gan Cao
Number of Product	1072
Charge	59107203
Lab.-No	LN-4230
Expiration date	3 January 2025
Galenic Form	Granules
Amount	200 g
No. of Certificate	154049_E.01
Issue Date	12 February 2020
Client	Medichin NV Groeningenweg 15 B-3590 Diepenbeek
Sample Receipt	24 January 2020

### Identity

	Result
TLC-Identitiy	conforms <sup>1</sup>

<sup>1</sup> 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 <sup>1</sup>	0.18 mg/kg <sup>2</sup>
Cadmium	0.010 mg/kg	≤ 1.0 mg/kg <sup>1</sup>	0.010 mg/kg <sup>2</sup>
Mercury	0.010 mg/kg	≤ 0.1 mg/kg <sup>1</sup>	<0.010 mg/kg <sup>2</sup>
Arsenic	0.040 mg/kg	≤ 2.0 mg/kg <sup>1</sup>	0.20 mg/kg <sup>2</sup>

<sup>1</sup> According to the current edition of the European Pharmacopoeia.

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

Sample conforms to the current edition of the European Pharmacopoeia 9.7.

### Mycotoxine

	Limit of quantification	Specification	Result
Aflatoxin B1	0.05 µg/kg	≤ 2 µg/kg <sup>1</sup>	0.11 µg/kg <sup>2</sup>
Total Aflatoxin	-	≤ 4 µg/kg <sup>1</sup>	<0.309 µg/kg <sup>2</sup>

<sup>1</sup> According to the current edition of the European Pharmacopoeia.

<sup>2</sup> 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 9.7.

### Pesticide residues

	Specification	Result
Pesticide residues	see footer <sup>1</sup>	positive <sup>2</sup>
Hexachlorocyclohexane (sum)	≤ 0.3 mg/kg <sup>1</sup>	0.001 mg/kg <sup>2</sup>

DDT (sum of o,p' -DDE, p,p'-DDE,  
o,p'-DDT, p,p'-DDT, o,p'-TDE  
and p,p'-TDE)  $\leq 1 \text{ mg/kg}^1$  0.011 mg/kg<sup>2</sup>

<sup>1</sup> 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.

<sup>2</sup> 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 9.7 and the limits of Regulation (EC) No. 396/2005.

## Microbial contamination

	Specification	Result
TAMC	$\leq 5 \cdot 10^5 \text{ KBE/g}^1$	$1.2 \cdot 10^2 \text{ KBE/g}^2$
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 <sup>1</sup>	absent (g) <sup>2</sup>
Salmonella	Absence <sup>1</sup>	absent (25g) <sup>2</sup>

<sup>1</sup> According to the current edition of the European Pharmacopoeia, 5.1.8; Category C.

<sup>2</sup> Determination according to the current edition of the European Pharmacopoeia, 2.6.12 and 2.6.31.

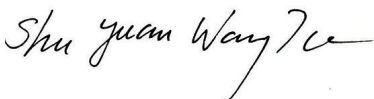
Sample conforms to the current edition of the European Pharmacopoeia 9.7.

---

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, 12 February 2020



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

## Attachement

### TLC Fingerprint

Attachment of Certificate of Analysis

No. of Certificate	154049_E.01
Name	Glycyrrhizae uralensis radix
Pin Yin	Gan Cao
Number of Product	1072
Charge	59107203
Lab.-No	LN-4230

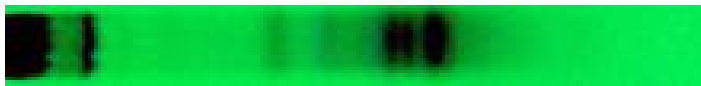
---

#### Chromatographic conditions

Stationary Phase	Silicagel 60 F254
Mobile Phase	27
Spray Reagent	2
Test Date	29.01.20

---

#### UV 254 nm



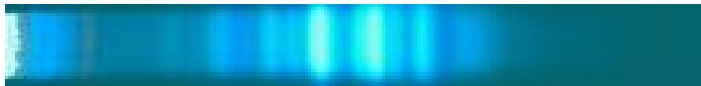
Sample 1072.59107203



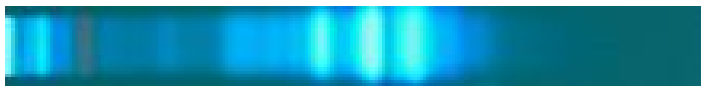
Reference 8126/7

---

#### UV 366 nm



Sample 1072.59107203



Reference 8126/7

---

#### Visual Light / Spray Reagent



Sample 1072.59107203



Reference 8126/7

---

#### UV 366 nm / Spray Reagent



Sample 1072.59107203



Reference 8126/7