

Certificate of Analysis

Name	Citri reticulatae, Pericarpium
Pin Yin	Chen Pi
Number of Product	1185
Charge	23031185
Lab.-No	LN-7151
Expiration date	30 June 2028
Galenic Form	Granules
Amount	200 g
No. of Certificate	157432_E.01
Issue Date	13 July 2023
Client	Medichin NV Groeningenweg 15 B-3590 Diepenbeek
Sample Receipt	16 June 2023

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	0.037 mg/kg ²
Cadmium	0.010 mg/kg	≤ 1.0 mg/kg ¹	<0.010 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	0.079 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.^{EXT}

Sample conforms to the current edition of the European Pharmacopoeia.

Mycotoxine

	Limit of quantification	Specification	Result
Aflatoxin B1	0.05 µg/kg	≤ 2 µg/kg ¹	0.065 µg/kg ²
Total Aflatoxin	-	≤ 4 µg/kg ¹	<0.215 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.^{EXT}

Sample conforms to the current edition of the European Pharmacopoeia.

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.^{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	$1.8 \cdot 10^2$ KBE/g ²
TYMC	$\leq 5 \cdot 10^4$ KBE/g ¹	$1.6 \cdot 10^2$ 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 (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.^{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 (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, 13 July 2023



Dr. med. Severin Buehlmann
Deputy Responsible 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	04.07.23

UV 254 nm



Sample 1185.23031185



Reference 9597/3

UV 366 nm



Sample 1185.23031185



Reference 9597/3

Visuelles Licht / Sprühreagenz



Sample 1185.23031185



Reference 9597/3

UV 366 nm / Sprühreagenz



Sample 1185.23031185



Reference 9597/3