

Certificate of Analysis

Name	Angelicae pubescentis Radix
Pin Yin	Du Huo
Number of Product	1241
Charge	46124101
Lab.-No	LN-1531
Expiration date	13 September 2021
Galenic Form	Granules
Amount	200 g
No. of Certificate	150983_E.01
Issue Date	21 December 2016
Client	Medichin NV Groeningenweg 15 B-3590 Diepenbeek
Sample Receipt	25 November 2016

Identity

	Result
TLC-Identitiy	conforms ¹

¹Determination 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	0.16 mg/kg ²
Cadmium	0.010 mg/kg	≤ 1.0 mg/kg ¹	0.094 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	0.16 mg/kg ²

¹According to the current edition of the European Pharmacopoeia.

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

Sample conforms to the footnoted specification(s).

Mycotoxins

	Limit of quantification	Specification	Result
Aflatoxin B1	0.10 µg/kg	≤ 2 µg/kg ¹	<0.10 µg/kg ²
Total Aflatoxin	-	≤ 4 µg/kg ¹	<0.40 µg/kg ²

¹According to the current edition of the European Pharmacopoeia.

²Determination 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
Anthrachinone	$\leq 0.02 \text{ mg/kg}^1$	0.02 mg/kg^2

¹According 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.

²Determination 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).

Microbiology

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

¹According to the current edition of the European Pharmacopoeia, 5.1.8; Category C.

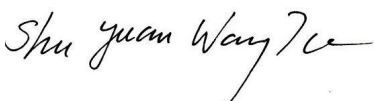
²Determination according to the current edition of the European Pharmacopoeia, 2.6.12 and 2.6.31.

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, 21 December 2016



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

Attachement

TLC Fingerprint

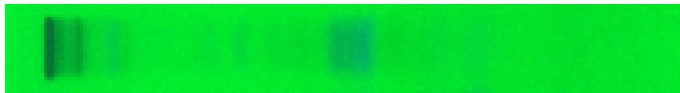
Attachment of Certificate of Analysis

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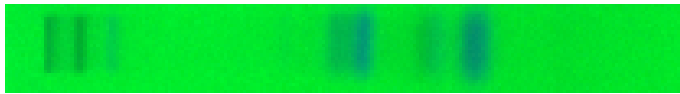
Chromatographic conditions

Stationary Phase	Silicagel 60 F254
Mobile Phase	27
Spray Reagent	2
Test Date	30.11.16

UV 254 nm

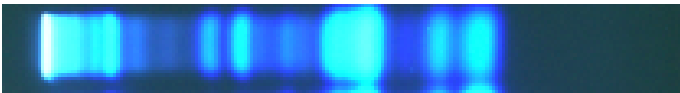


Sample 1241.46124101

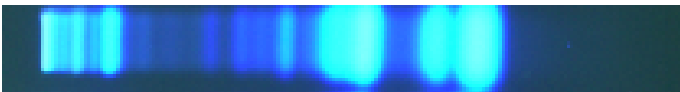


Reference 6896/2

UV 366 nm



Sample 1241.46124101

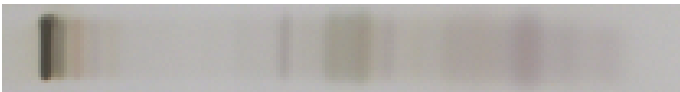


Reference 6896/2

Visual Light / Spray Reagent

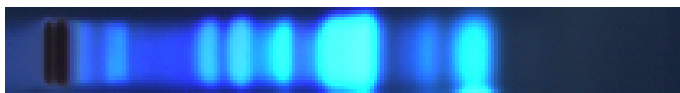


Sample 1241.46124101

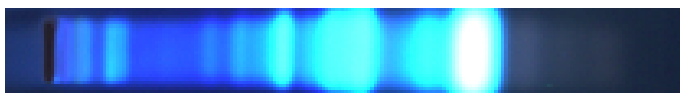


Reference 6896/2

UV 366 nm / Spray Reagent



Sample 1241.46124101



Reference 6896/2