



ARTEMISININA (ARTEMISIA ANNUA)

PRODUCT CODE: 0319	CAS Nº: 63968-64-9	ANALYSIS Nº: 307/24
MANUFACTURER BATCH: ATS202408001	CERTIFICATE ID: 44.309	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 11/08/2024	
METAPH BATCH: 0321124	EXPIRY DATE: 10/08/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colorless needle crystals	Colorless needle crystals
Identification (1)	Complies	Complies
Identification (2)	Complies	Complies
Identification (3)	Complies	Complies
Identification (4)	Complies	Complies
Melting point	150 - 153 °C	152.6 °C
Optical rotation	+75 / +78	+76.5
Related substances		
Total impurities	=< 0.25 %	< 0.25 %
Loss on drying	=< 0.5 %	0.4 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	98.0 - 102.0 %	100.7 %
Residual solvents [In-house]		
Ethanol	=< 5000 ppm	1397 ppm
Methanol	=< 3000 ppm	< 50 ppm
Dimethyl Sulfoxide	=< 600 ppm	< 50 ppm
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g
Candida Albicans	Absence/1g	Absence/1g
Pseudomonas aeruginosa	Absence/1g	Absence/1g
Staphylococcus aureus	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

COMPLIES WITH

Manufacturer specifications

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Artemisinin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Analysis date: 19/12/2024

Signature: Albert Sanchez Lopez (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000629

CHONGQING WAYCOME PHARMACEUTICAL CO LTD

YUWU ROAD, XINMIN TOWN, 138
408302 DIANJIANG

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STORAGE

Store in a tightly closed container. Store in cool, dry and well-ventilated area.

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Signature: Albert Sanchez Lopez (QP)
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