



CITISINA (IN HOUSE)

PRODUCT CODE: 886	CAS Nº: 485-35-8	ANALYSIS Nº: 046/23
MANUFACTURER BATCH: CTS20221203	CERTIFICATE ID: 37.526	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 25/12/2022	
METAPH BATCH: 0210223	EXPIRY DATE: 25/12/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or light yellow crystalline powder, odorless	White crystalline powder
Solubility	Soluble in ethanol, methanol, acetonitrile, acetone, chloroform; slightly soluble in petroleum ether	Complies (*)
Melting point	154.0 - 157.0 °C	155 °C
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Specific optical rotation	-118.0 / -125.0	-122.8
Loss on drying	=< 1.0 %	0.21 %
Residue on ignition	=< 0.5 %	< 0.01 %
Heavy metals	=< 20 ppm	< 20 ppm (*)
Lead	=< 2 ppm	< 2.0 ppm (*)
Arsenic	=< 2 ppm	< 2.0 ppm (*)
Related substances		
N-Methylcytisine	=< 0.50 %	0.08 %
N-Formylcytisine	=< 0.50 %	Not Detected
Unspecified impurities	=< 0.30 %	0.16 % (RT = 13.812 min)
Total impurities	=< 1.50 %	0.24 %
Assay	=> 98.0 %	99.1 %
Particle size		(*)
80 mesh	100 %	Complies
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
E. Coli	Absence/1g	Absence/1g
S. Aureus	Absence/1g	Absence/1g
P. Aeruginosa	Absence/1g	Absence/1g
C. Albicans	Absence/1g	Absence/1g
Salmonella	Absence/10g	Absence/10g
Residual solvents [In-house]		(**)
Acetone	=< 5000 ppm	1069 ppm
Methanol	=< 3000 ppm	< 50 ppm
Chloroform	=< 60 ppm	< 50 ppm

COMPLIES WITH

Manufacturer Specifications

REMARKS

Botanical name: **Leguminosae plant Sophora alopecuroides.**

Part used: **Seed.**

Cytisine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Analysis date: 23/03/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000349

H. G. (WAICOME PHARMA)

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XinMin Town

408302 Chongqing



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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.

(*) Data adapted from the manufacturer's certificate of analysis.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

STORAGE

Keep the containers tightly closed in a cool and dry place, and protected from the light.

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