METAPHARMACEUTICAL

TECHNICAL DATA SHEET

886-TDS-ENG-2026

CITISINA (IN HOUSE)		
DESCRIPTION DCI: CYTISINE	DESCRIPTION DOE: CITISINA	
CAS Nº: 485-35-8	EC Nº: 207-616-0	AEMPS CODE: 9280B
MOL. WEIGHT: 190,24	MOL. FORMULA: C11H14N2O	ARTICLE CODE: 886

ATTRIBUTES	SHOULD BE
Appearance	White or light yellow crystalline powder
Solubility	Freely soluble in water and ethanol 96 %, soluble in chloroform and acetonitrile
Melting point	154.0 - 157.0 ºC
Identification A	Complies
Identification B	Complies
Identification C	Complies
Appearance of solution	
Clarity	Not more intensely opalescent than reference suspension II
Colour	Not more intensely coloured than reference solution Y1
Specific optical rotation	-120º / -125º
Chlorides	=< 0.02 %
Sulfates	=< 0.03 %
Loss on drying	=< 0.5 %
Residue on ignition	=< 0.10 %
Related substances	
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Assay	99.0 - 101.0 %
Residual solvents [In-house]	
Acetone	=< 5000 ppm
Ethanol	=< 5000 ppm
Ethyl acetate	=< 5000 ppm
Chloroform	=< 60 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
E. Coli	Absence/1g
P. Aeruginosa	Absence/1g
Salmonella	Absence/1g
S. Aureus	Absence/1g

COMPLIES WITH

Manufacturer Specifications

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STORAGE

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

REMARKS

Botanical name: **Leguminosae plant Sophora alopecuroides**.
Part used: **Seed**.

Cytisine 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".

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.

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