



TECHNICAL DATA SHEET

886-TDS-ENG-2025

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	Almost white crystalline powder			
Odour	Characteristic			
Identification A	Complies			
Identification B	Complies			
Identification C	Complies			
Specific optical rotation	-118º / -125º			
Melting point	154 - 157 °C			
Bulk tapped density	40-60 g/100 ml			
Particle size	80 mesh			
Loss on drying	=< 2.0 %			
Residue on ignition	=< 0.1 %			
Assay	=> 98.0 %			
Heavy metals	=< 10 ppm			
Arsenic	=< 2 ppm			
Lead	=< 2 ppm			
Related substances				
N-Methylcytisine	=< 0.5 %			
N-Formylcytisine	=< 0.5 %			
Unspecified impurities	=< 0.3 %			
Total impurities	=< 1.5 %			
Residual solvents				
Methanol	=< 3000 ppm			
Chloroform	=< 60 ppm			
Acetone	=< 5000 ppm			
Microbiological control				
ТАМС	=< 1000 CFU/g			
ТҮМС	=< 100 CFU/g			
Salmonella	Absence/1g			
E. Coli	Absence/1g			
Staphylococcus aureus	Absence/1g			
C. Albicans	Absence/1g			
P. Aeruginosa	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.