METAPHARMACEUTICAL

TECHNICAL DATA SHEET

0402-TDS-ENG-2025

CISTINA-L (EUR. PH.) FARMACEUTICA		
DESCRIPTION DCI: cystine	DESCRIPTION DOE: CISTINA	
CAS Nº: 56-89-3	EC Nº: 200-296-3	AEMPS CODE: 1266A
MOL. WEIGHT: 240,3	MOL. FORMULA: C6H12N2O4S2	ARTICLE CODE: 0402

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water and in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7
Specific optical rotation	-224 / -218
Ninhydrin-positive substances	
Any ninhydrin-positive substance	=< 0.2 %
Total	=< 0.5 %
Chlorides	=< 200 ppm
Sulfates	=< 300 ppm
Ammonium	=< 0.02 %
Iron	=< 10 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep closed and store in a dry place at room temperature. Protect the product from light.

REMARKS

L-Cystine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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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