

<b>CISTINA-L (EUR. PH.) FARMACEUTICA</b>			
PRODUCT CODE: 0402		CAS Nº: 56-89-3	ANALYSIS Nº: 377/25
MANUFACTURER BATCH:	CD4.47.05	CERTIFICATE ID:	49.352
SUPPLIER BATCH:	----	MANUFACTURING DATE:	23/11/2024
METAPH BATCH:	0311125	EXPIRY DATE:	23/11/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7	Complies
Specific optical rotation	-224 / -218	-222.7 (*)
Ninhydrin-positive substances		
Any ninhydrin-positive substance	=< 0.2 %	< 0.05 %
Total	=< 0.5 %	< 0.05 %
Chlorides	=< 200 ppm	< 200 ppm
Sulfates	=< 300 ppm	< 100 ppm
Ammonium	=< 0.02 %	< 0.004 %
Iron	=< 10 ppm	< 10 ppm
Loss on drying	=< 0.5 %	0.08 % (*)
Sulfated ash	=< 0.1 %	0.07 % (*)
Assay	98.5 - 101.0 %	100.9 % (*)

#### COMPLIES WITH

European Pharmacopoeia 11.0

#### REMARKS

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

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

(\*) 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.

#### STORAGE

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

Release date: 15/12/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies



Manufacturer: 40000360  
BCF LIFE SCIENCES (Bretagne Chimie Fine Life Sciences)  
Boisel  
56140 Pleucadeuc  
(FRANCE)

Original certificate available upon request

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