

**CISTINA-L (EUR. PH.) FARMACEUTICA**

PRODUCT CODE: 0402	CAS Nº: 56-89-3	ANALYSIS Nº: 160/22
MANUFACTURER BATCH: CD1.32.13	CERTIFICATE ID: 35.447	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 19/08/2021	
METAPH BATCH: 0210122	EXPIRY DATE: 19/08/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder (*)
Solubility	Practically insoluble in water and in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides	Complies
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	-221 (*)
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 %	0.02 % (*)
Sulfated ash	=< 0.1 %	0.01 %
Assay	98.5 - 101.0 %	100.9 % (*)

COMPLIES WITH

European Pharmacopoeia 10.0

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.

(*) Data controlled by Metapharmaceutical Industrial SL.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

STORAGE

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

Analysis date: 11/07/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000360

BCF LIFE SCIENCES (Bretagne Chimie Fine Life Sciences)

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