



CISTINA-L (EUR. PH.) FARMACEUTICA

PRODUCT CODE: 0402	CAS Nº: 56-89-3	ANALYSIS Nº: 268/24
MANUFACTURER BATCH: CD4.29.65	CERTIFICATE ID: 43.951	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 25/07/2024	
METAPH BATCH: 0221024	EXPIRY DATE: 25/07/2028	

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	-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 %	0.04 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	98.5 - 101.0 %	99.1 %

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 adapted from the manufacturer's certificate of analysis.

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.

Analysis date: 13/12/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

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