

CISTINA-L (EUR. PH.) FARMACEUTICA

PRODUCT CODE: 0402	CAS Nº: 56-89-3	ANALYSIS Nº: 018/24
MANUFACTURER BATCH: CD3.48.15	CERTIFICATE ID: 41.012	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 08/12/2023	
METAPH BATCH: 0050224	EXPIRY DATE: 08/12/2027	

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 %	0.1 % (*)
Sulfated ash	=< 0.1 %	0.06 % (*)
Assay	98.5 - 101.0 %	100.2 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

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.

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: 04/03/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

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

