

GLUTATION-L REDUCIDO (USP)

PRODUCT CODE: 46433088	CAS Nº: 70-18-8	ANALYSIS Nº: 097/25
MANUFACTURER BATCH: GTR20250202	CERTIFICATE ID: 46.051	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 12/02/2025	
METAPH BATCH: 0140425	EXPIRY DATE: 11/02/2030	

ATTRIBUTES	SHOULD BE	IS
Appearance	White crystals or crystalline powder	White crystalline powder (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Assay	98.0 - 101.0 %	98.5 % (*)
Ammonium	<= 200 ppm	Complies
Arsenic	<= 2 ppm	Complies
Chlorides	<= 200 ppm	Complies
Sulfates	<= 300 ppm	Complies
Iron	<= 10 ppm	Complies
Residue on ignition	<= 0.1 %	0.06 % (*)
Related Compounds		
Individual impurities	<= 1.5 %	0.23 %
Total impurities	<= 2.0 %	0.56 %
Clarity and colour of solution	Clear and colorless	Clear and colourless (*)
Loss on drying	<= 0.5 %	0.1 % (*)

COMPLIES WITH

USP 2025

REMARKS

Reduced L-Glutathione is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

(*) 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

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

Analysis date: 30/04/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Manufacturer: 40000349

