



## GLUTATION-L REDUCIDO (USP)

PRODUCT CODE: 46433088	CAS Nº: 70-18-8	ANALYSIS Nº: 167/24
MANUFACTURER BATCH: GTR20240301	CERTIFICATE ID: 42.599	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 06/03/2024	
METAPH BATCH: 0130624	EXPIRY DATE: 05/03/2029	

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 %	99.5 %
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 %	< 0.1 %
Related Compounds		(*)
Individual impurities	<= 1.5 %	0.24 %
Total impurities	<= 2.0 %	0.54 %
Clarity and colour of solution	Clear and colorless	Clara e incolora
Loss on drying	<= 0.5 %	0.3 %

### COMPLIES WITH

USP 2024

### 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 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

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

Analysis date: 02/07/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies

Manufacturer: 40000349