



## TECHNICAL DATA SHEET

46433088-TDS-ENG-2024

GLUTATION-L REDUCIDO (USP)		
DESCRIPTION DCI: REDUCED GLUTATHIONE		DESCRIPTION DOE: GLUTATION REDUCIDO
CAS Nº: 70-18-8	EC Nº: 200-725-4	AEMPS CODE: 1673RD
MOL. WEIGHT: 307,32	MOL. FORMULA: C10H17N3O6S	ARTICLE CODE: 46433088

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

### COMPLIES WITH

USP 2024

### STORAGE

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

### 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".

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.