

A080.02.ENG

TECHNICAL DATA SHEET

46433088-TDS-ENG-2025

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 ACompliesIdentification BComplies

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 2025

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.