

TECHNICAL DATA SHEET

M010202-TDS-ENG-2026

GLUTATION-L REDUCIDO (EUR. PH.)		
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: M010202

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Complies
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
Specific optical rotation	-17.5 / -15.5
Related substances	
Impurity C	=< 1.5 %
Impurity D	=< 1.0 %
Impurity A	=< 0.5 %
Impurity B	=< 0.5 %
Impurity E	=< 0.5 %
Any other impurity	=< 0.2 %
Total impurities	=< 2.5 %
Chlorides	=< 200 ppm
Sulfates	=< 300 ppm
Ammonium	=< 200 ppm
Iron	=< 10 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 12.2

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

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manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.