

TECHNICAL DATA SHEET

002677-TDS-ENG-2026

LITIO OROTATO MONOHIDRATO		
DESCRIPTION DCI: LITHIUM OROTATE		DESCRIPTION DOE: LITIO OROTATO
CAS Nº: 5266-20-6	EC Nº: 226-081-4	AEMPS CODE: ---
MOL. WEIGHT: 162,03	MOL. FORMULA: C ₅ H ₃ LiN ₂ O ₄	ARTICLE CODE: 002677

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Slightly soluble in water
Identification	Complies
Specific absorbance at 285 nm	290.0 - 340.0 nm
Appearance of solution	Clear and not more intensely colored than reference solution B7
Acidic reacting substances	Complies
Alkaline reacting substances	Complies
Chlorides	=< 100 ppm
Heavy metals	=< 20 ppm
Water	9.7 - 11.3 %
Loss on drying	=< 0.5 %
Aminoácidos	Absence
Related substances	
Impurity A	=< 0.2 %
Any impurity	=< 0.10 %
Sum of impurities	=< 0.3 %
Assay	98.5 - 100.5 %

COMPLIES WITH

Manufacturer Specifications

STORAGE

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

REMARKS

Lithium Orotate 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.