

TECHNICAL DATA SHEET

M010250-TDS-ENG-2026

FOSFATIDIL COLINA 30% Farma		
DESCRIPTION DCI: PHOSPHATIDYL CHOLINE		DESCRIPTION DOE: FOSFATIDILCOLINA
CAS Nº: 8002-43-5	EC Nº: 232-307-2	AEMPS CODE: 1595A
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: M010250

ATTRIBUTES	SHOULD BE
Appearance	Pale yellow hygroscopic powder
Identification A	Complies
Assay	
Phosphatidylcholine	=> 30.0 %
Phosphatidylethanolamine	=< 15.0 %
Phosphatidylinositol	=< 14.0 %
Phosphatidic acid	=< 8.0 %
Lead	=< 10 ppm
Hexane insoluble matter	=< 0.3 %
Acetone insoluble matter	=> 50.0 %
Water	=< 2.0 %
Peroxide value	=< 10.0 meq/Kg
Acidity index	=< 35.0 KOH/g
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
E. Coli	Absence/g
Salmonella	Absence/10g

COMPLIES WITH

USP 2026

STORAGE

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

REMARKS

Product suitable as a pharmaceutical excipient.

Phosphatidyl Choline 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.