



## TECHNICAL DATA SHEET

46433107-TDS-ENG-2025

INDOCIANINA VERDE PHARMA (USP)		
DESCRIPTION DCI: INDOCYANINE GREEN		DESCRIPTION DOE: VERDE INDOCIANINA
CAS Nº: 3599-32-4	EC Nº: 222-751-5	AEMPS CODE: 5074A
MOL. WEIGHT: 776,98	MOL. FORMULA: C43H49N2NaO6S2	ARTICLE CODE: 46433107

ATTRIBUTES	SHOULD BE
Appearance	Dark green or deep green henna powder
Identification A	Complies
Identification B	Complies
Assay	89.0 - 100.0 %
Sodium Iodide	=< 5.0 %
Arsenic	=< 8 ppm
Lead	=< 10 ppm
Loss on drying	=< 6.0 %
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
E. Coli	Absence/1g
S. Aureus	Absence/1g
P. Aeruginosa	Absence/1g
C. Albicans	Absence/1g
Salmonella	Absence/1g

### COMPLIES WITH

USP 2025

### STORAGE

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

### REMARKS

Indocyanine Green 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.