



INDOCIANINA VERDE PHARMA (USP)

PRODUCT CODE: 46433107	CAS Nº: 3599-32-4	ANALYSIS Nº: 265/24
MANUFACTURER BATCH: IDG20240502	CERTIFICATE ID: 43.919	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 27/05/2024	
METAPH BATCH: 0191024	EXPIRY DATE: 26/05/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	Dark green or deep green henna powder	Deep green henna powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Assay	89.0 - 100.0 %	99.6 %
Sodium Iodide	=< 5.0 %	3.2 %
Arsenic	=< 8 ppm	< 8 ppm
Lead	=< 10 ppm	< 10 ppm
Loss on drying	=< 6.0 %	3.3 %
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
E. Coli	Absence/1g	Absence/1g
S. Aureus	Absence/1g	Absence/1g
P. Aeruginosa	Absence/1g	Absence/1g
C. Albicans	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

COMPLIES WITH

USP 2024

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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.

STORAGE

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

Analysis date: 07/11/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349