

INDOL-3-CARBINOL

PRODUCT CODE: 32405	CAS Nº: 700-06-1	ANALYSIS Nº: 180/25
MANUFACTURER BATCH: HB-YDJC20250505	CERTIFICATE ID: 46.903	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 05/05/2025	
METAPH BATCH: 0150625	EXPIRY DATE: 04/05/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Off white to white or yellowish, crystalline powder	Yellowish crystalline powder (*)
Particle size	98 % through 80 mesh	Complies
Identification IR	Complies	Complies (*)
Melting point	92 - 99 °C	95 °C (*)
Loss on drying	=< 1.0 %	0.04 % (*)
Assay	=> 98.0 %	99.5 %
Heavy metals	=< 10 ppm	Complies
Arsenic	=< 2 ppm	Complies
Lead	=< 2 ppm	Complies
Cadmium	=< 0.5 ppm	Complies
Mercury	=< 0.5 ppm	Complies
Residual solvents [In-house]	No toluene or benzene	Complies
Microbial contamination		(*)
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g
Staphylococcus aureus	Absent/1g	Absence/1g

COMPLIES WITH

Manufacturer Specifications

REMARKS

Indole-3-Carbinol complies the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

(*) Data controlled by Metapharmaceutical Industrial SL.

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 dark place away from light.

Analysis date: 08/07/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies

Manufacturer: 40001477

