

DIINDOLILMETANO						
PRODUCT CODE: 151383	CAS Nº: 1968-05	-4 ANAL	ANALYSIS Nº: 248/25			
MANUFACTURER BATCH:	HB-EYDJW20250701	CERTIFICATE ID:	47.719			
SUPPLIER BATCH:		MANUFACTURING DATE:	05/07/2025			
МЕТАРН ВАТСН:	0460725	EXPIRY DATE:	30/06/2028			

ATTRIBUTES	SHOULD BE	IS	
Appearance	White, almost white or brown yellow, fine or	Almost white crystalline powder	
	crystalline powder	(*)	
Odour	Charasteristic	Charasteristic	
Taste	Charasteristic	Charasteristic	
Assay	=> 99.0 %	99.55 %	
Particle size	98 % through 80 mesh	80 MESH	
Loss on drying	=< 0.5 %	0.34 %	
Melting point	165.0 - 169.0 °C	168.2 °C (*)	
Bulk density	45 - 60 g/100 mL	48 g/100 mL	
Residue of solvent	None	Complies	
Heavy metals	=< 10 ppm	Complies	
Lead	=< 1 ppm	Complies	
Arsenic	=< 2 ppm	Complies	
Cadmium	=< 2 ppm	Complies	
Mercury	=< 1 ppm	Complies	
Benzene	Without benzene	Not Detected	
Residual solvents [In-house]			
Methanol	=< 3000 ppm	Complies	
Microbial contamination			
TAMC	=< 1000 CFU/g	Complies	
TYMC	=< 100 CFU/g	Complies	
Escherichia coli	Absence/1g	Complies	
Salmonella	Absence/1g	Complies	
Staphylococcus aureus	Absent/1g	Complies	
COMPLIES WITH			

Manufacturer Specificactions

REMARKS

According to Regulation (EU) 2015/2283, Diindolylmethane is classified as a NOVEL FOOD and its use as food excipient is NOT permited.

Diindolylmethane 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".

(*) 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 quidelines 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.

Manufacturer: 40001477

Analysis date: 31/07/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

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STORAGE

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

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