

DIFENCIPRONA (DIFENILCICLOPROPENONA)

PRODUCT CODE: 46433142	CAS Nº: 886-38-4	ANALYSIS Nº: 277/25
MANUFACTURER BATCH: DCP20250502	CERTIFICATE ID: 48.079	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 17/05/2025	
METAPH BATCH: 0070925	EXPIRY DATE: 16/05/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Dark orange-yellow or brown powder	Polvo marronoso
Identification IR	Complies	Complies
Residue on ignition	=< 0.05 %	0.02 %
Water	=< 0.5 %	0.3 %
Assay	=> 98.0 %	98.6 %
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
S. Aureus	Absence/1g	Absence/1g
E. Coli	Absence/1g	Absence/1g
C. Albicans	Absence/1g	Absence/1g
P. Aeruginosa	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

COMPLIES WITH

Manufacturer's Specifications

REMARKS

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

Diphenciprone 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".

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

Analysis date: 06/10/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

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