

METOXSALENO (USP)			
PRODUCT CODE: 1293	CAS Nº: 298-81-	7 ANALYSIS Nº: 368/25	
MANUFACTURER BATCH:	HCFMPC250016	CERTIFICATE ID: 49.197	
SUPPLIER BATCH:		MANUFACTURING DATE: 17/10/2025	
МЕТАРН ВАТСН:	0221125	EXPIRY DATE: 16/10/2030	

ATTRIBUTES SHOULD BE		IS	
Appearance	White crystalline powder	White crystalline powder	
Identification A	Complies	Complies	
Identification B	Complies	Complies	
Assay	98.0 - 102.0 %	99.3 %	
Residue on ignition	=< 0.1 %	0.02 %	
Organic impurities			
Related compound A	=< 0.15 %	Not Detected	
Retaled compound B	=< 0.15 %	Not Detected	
Unspecified impurities	=< 0.10 %	0.04 % (RT = 21.89 min)	
Total impurities	=< 0.5 %	0.04 %	
Water	=< 0.5 %	0.2 %	
COMPLIES WITH			

USP 2025

## **REMARKS**

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

Methoxsalen is subjected to the requirements of the ICH Q3D "Elemental Impurities" quideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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 tightly closed containers, in a dry and well-ventilated place.

Relase date: 26/11/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

(A unit of Kumaon Exports Pvt. Ltd.) Village-Nayagaon, Chandansingh, Block-Kotabagh, Distt. Nainital

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