

Certificate of Analysis

Product name: **Methoxsalenum**
Batch number / Weight: **22D19-B01-226328 / 5 G**
Analysed according to: **USP**
Number of analysis / Inspection Code **22D19-B01 / INS-22-5682**
Reference Code / No.: **V01876 / HCFMPC220004**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to cream needle-like crystals, fluffy	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Water	<= 0,5	0,031	%	
Residue on ignition	<= 0,1	0,06	%	
Related substances	Conform	Conform		
Methoxalen Related Compound	<= 0,15	0,000	%	
Methoxalen Related Compound	<= 0,15	0,061	%	
Unspecified impurities	<= 0,10	0,001	%	
Total impurities	<= 0,5	0,06	%	
Assay Methoxsalen	98,0 - 102,0	101,0	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol	<= 3000 ppm	<3000	ppm	
Toluene	<= 890 ppm	<890	ppm	
	<= 290 ppm	<290	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Own lab

Release:

Agnieszka Pszczółka

Qualified Person

20-12-2022

Expiration: 24-02-2027

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.