

Certificate of Analysis

Productname: Methoxsalenum
Number of analysis/Inspection Code: 1 / KEUR-180801B
Batchnumber: 19H05-B02-366096
Reference code / No.: 4124 / HCFMPC190002
Analysed according to: USP/DAC

Tests	Requirement	Result	Unit	Standard remark
USP 43		Conform		
Appearance	White to cream needle-like crystals; fluffy	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		HPLC
Water	<= 0,5	0,1	%	Karl Fischer
Residue on ignition	<= 0,1	0,0		
Chromatographic impurities	Conform	Conform	%	HPLC
Impurity A	<=0,15	n.d.	%	
Impurity B	<=0,15	0,14	%	
Unspecified impurities	<=0,10	n.d.	%	
Total impurities	<=0,5	0,1	%	
Assay Methoxsalen	98,0 - 102,0	99,5	%m/m	Anhydrous
DAC 2019/2		Conform		
Appearance	White to pale yellow powder with different crystal shapes	Conform		
Identification B	Conform	Conform		IR-spectrum
Loss on drying	<=0,5	0,1	%	105°C
Sulphated ash	<=0,1	0,0	%	
Related substances	Conform	Conform		HPLC
Impurity A	<=1,0	0,1	%	
Any other impurity	<=1,0	0,2	%	
Sum of impurities	<=2,0	0,3	%	
Assay Methoxsalen	98,0 - 102,0	98,8	%m/m	Dried
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:

dr. M.J. Vincenten - van Maanen

Pharmacist - Qualified Person

02/28/20

Expiration: 06-2024

Conclusion: APPROVED

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