

Certificate of Analysis

Productname: Dapsonum
Number of analysis/Inspection Code: 1 / KEUR-184148B
Batchnumber: 20F19-F09-371627
Reference code / No.: 3479 / 19/021
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification A	175 - 181	177	°C	Melting point
Identification B	700 - 760	707		Specific absorbance 260 nm
	1150 - 1250	1214		Specific absorbance 295 nm
Identification C	Conform	Conform		TLC
Related substances	Conform	Conform		TLC
Any other impurity	<=1,0	<1,0	%	
Not more than 2 spots	Max. 2 > 0,2%	<0,2	%	
Loss on drying	<=1,5	0,0	%	105 °C
Sulphated ash	<=0,1	<0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Dapsone	99,0 - 101,0	100,8	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

07/10/20

Expiration: 07-2024

Conclusion: APPROVED

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