

Certificate of Analysis

Productname: Dapsonum
Number of analysis/Inspection Code: 1 / KEUR-181439B
Batchnumber: 20B05-F02-368689
Reference code / No.: 3479 / 19/006
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification A	175 - 181	176	°C	Melting point
Identification B	700 - 760	736		Specific absorbance 260 nm
	1150 - 1250	1206		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	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Dapsone	99,0 - 101,0	99,5	%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:
Wai Lung Chung
Pharmacist - Qualified Person

03/25/20

Expiration: 02-2024

Conclusion: APPROVED

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