

Certificate of Analysis

Productname:	name: Dapsonum	
Number of analysis/Inspection Code:	1 / KEUR-181417B	
Batchnumber:	20B05-F02-368688	
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

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