

Certificate of Analysis

Product name: Dapsonum

Batch number / Weight: 21L01-B02-213248 / 10 G

Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification A	175 - 181	179,5	°C	
Identification B	700 - 760	732,4		
	1150 - 1250	1205,1		
Identification C	Conform	Conform		
Related substances	Conform	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Dapsone	99,0 - 101,0	100,34	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Dominika Sołtysik Qualified Person

28-04-2022

Expiration: 31-01-2026

Conclusion: APPROVED

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