

Certificate of Analysis

Product name: Dapsonum
Batch number / Weight: 25E07-B05-021599 / 25 g
Producer / Producer Batch Number: Atul Ltd. - PI Division / 25/001
Analyzed according to: Ph.Eur. 12.2
Number of Analysis / Certificate no.: 25E07-B05 / QO0031242

	Requirement	Result	Unit	Standard remark
Appearance	white or slightly yellowish-white, crystalline powder	Conform		
Identification	Conform	Conform		
Related substances	Conform	Conform		
Impurity B	<=0,4	0,26	%	
Impurity A	<=0,3	0,21	%	
Impurity C	<=0,3	0,10	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,57	%	
Loss on drying	<=1,5	0,08	%	
Sulfated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
Assay	99,0 - 101,0	99,80	% m/m	

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE LAB

Release:

9-4-2026
 Agnieszka Pszczółka
 Qualified Person

Expiration: 31-1-2030

Conclusion: APPROVED

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