

Certificate of Analysis

Product name: Dapsonum
Batch number / Weight: 24J17-B01-007638 / 25 g
Producer / Producer Batch Number: Atul Ltd. - PI Division / 24/007
Analyzed according to: Ph. Eur.11.6
Number of Analysis / Certificate no.: 24J17-B01 / QO0012414

	Requirement	Result	Unit	Standard remark
Appearance	white or slightly yellowish-white, crystalline powder	Conform		
Identification	A	Conform		
Related substances	Acc. to Ph. Eur.	Conform		
Impurity B	<=0,4	0,25	%	
Impurity A	<=0,3	0,19	%	
Impurity C	<=0,3	0,09	%	
Any other impurity	<=0,10	0,057	%	
Total impurities	<=1,0	0,59	%	
Loss on drying	<=1,5	0,21	%	
Sulfated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP
Assay	99,0 - 101,0	100,23	% 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:

12-3-2025
 Agnieszka Pszczółka
 Qualified Person

Expiration: 31-7-2029

Conclusion: APPROVED

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