Certificate of Analysis

Product name: Rifampicinum
Batch number / Weight: 26A27-B13-019781 / 10 g
Analyzed according to: Ph. Eur. 12.1
Number of Analysis / Certificate no.: 26A27-B13 / QO0028200
Reference code / No.: V02064 / 25A22-B09-007506

	Requirement	Result	Unit	Standard remark
Appearance	Reddish-brown or brownish-red, crystalline powder	Conform		
Identification	A, B, C	Conform		
pH	4,5 - 6,5	4,80		
Related substances	Acc. to Ph. Eur.	Conform		
Impurity A	<=1,5	0,08	%	
Any other impurity	<=1,0	0,46	%	
Sum of impurities other than A	<=3,5	1,50	%	
Loss on drying	<=1,0	0,14	%	
Sulfated ash	<=0,1	0,06	%	
Assay	97,0 - 102,0	101,22	% m/m	
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

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

Release:

19-2-2026
Ewelina Gadzinowska
Qualified Person

Expiration: 27-2-2028
Conclusion: APPROVED

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

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