Certificate of Analysis

Product name: Rifampicinum
Batch number / Weight: 23H22-B16-002623 / 10 g
Analyzed according to: Ph. Eur.11.5
Number of Analysis / Certificate no.: 23H22-B16 / QO0005760
Reference code / No.: V02064 / 20230721

	Requirement	Result	Unit	Standard remark
Appearance	Reddish-brown or brownish-red, crystalline powder	Conform	°C	
Identification A	A374 / A475 about 1,75	1,748		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	4,5 - 6,5	4,81		
Related substances	Conform	Conform		
Impurity A	<=1,5	0,32	%	
Any other impurity	<=1,0	0,65	%	
Sum other impurities	<=3,5	2,09	%	
Loss on drying	<=1,0	0,42	%	
Sulfated ash	<=0,1	0,00	%	
Assay	97,0 - 102,0	99,75	% m/m	
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

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 Fagron PL lab

Release:

15-10-2024
Dominika Sołtysik
Qualified Person

Expiration: 18-7-2027
Conclusion: APPROVED

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

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