

Certificate of Analysis

Product name: Rifampicinum
Batch number / Weight: 19L23-F01-219943 / 50 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	crystalline powder Reddish-brown or brownish-red,	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	4,5 - 6,5	5,9		
Related substances	Conform	Conform		
Impurity A	<=1,5	0,8	%	
Any other impurity	<=1,0	<0,5	%	
Sum other impurities	<=3,5	0,8	%	
Loss on drying	<=1,0	0,2	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Rifampicin	97,0 - 102,0	100,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

27-04-2022

Expiration: 30-06-2023

Conclusion: APPROVED

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