

Certificate of Analysis

Product name: Rifampicinum
Batch number / Weight: 22F28-B03-217932 / 50 G
Analysed according to: Ph. Eur. 10
Number of analysis / Inspection Code 22F28-B03 / INS-22-5980
Reference Code / No.: V02064 / 20220407

Tests	Requirement	Result	Unit	Standard remark
Appearance	Reddish-brown or brownish-red, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	4,5 - 6,5	5,27		
Related substances	Conform	Conform		
Impurity A	<=1,5	0,62	%	
Any other impurity	<=1,0	0,57	%	
Sum other impurities	<=3,5	1,82	%	
Loss on drying	<=1,0	0,60	%	
Sulphated ash	<=0,1	0,02	%	
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	100,24	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Acetone	<=5000	<5000	ppm	
Buthanol	<=5000	<5000	ppm	
n-Butyl acetate	<=5000	<5000	ppm	
Ethylacetate	<=5000	<5000	ppm	

fagron.pl

Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

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:

Agnieszka Pszczółka

Qualified Person

26-09-2022

Expiration: 31-07-2025

Conclusion: APPROVED

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

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl