

Certificate of Analysis

Product name: **Nifuroxazidum**

Batch number / Weight: **20H28-F01-217206 / 50 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Intense yellow, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Specific absorbance	940 - 1000	996		
Impurity A	$\leq 0,05$	Conform	%	
Related substances	Conform	Conform		
Impurity E	$\leq 0,3$	0,1	%	
Impurity B	$\leq 0,3$	$< 0,05$	%	
Impurity C	$\leq 0,3$	0,0	%	
Impurity D	$\leq 0,3$	0,1	%	
≤ 1 such peak $\geq 0,1\%$	≤ 1	1	%	
≤ 1 such peak $\geq 0,1\%$	≤ 1	Conform	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Sum of impurities other than E	$\leq 0,5$	0,1	%	
Loss on drying	$\leq 0,5$	0,0	%	
Sulphated ash	$\leq 0,1$	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Nifuroxazide	98,5 - 101,5	99,3	%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

18-01-2022

Expiration: 30-04-2025

Conclusion: APPROVED

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