Certificate of Analysis

Product name: **Nifuroxazidum**

Batch number / Weight: **21J07-B08-221871 / 50 G**

Analysed according to: **Ph.Eur.10.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Intense yellow, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Specific absorbance	940 - 1000	948		
Impurity A	<=0,05	Conform	%	
Related substances	Conform	Conform		
Impurity E	<=0,3	0,14	%	
Impurity B	<=0,3	<0,05	%	
Impurity C	<=0,3	0,00	%	
Impurity D	<=0,3	<0,05	%	
<=1 such peak >=0,1%	<=1	<0,05	%	
<=1 such peak >=0,1%	<=1	Conform	%	
Unspecified impurities	<=0,10	<0,05	%	
Sum of impurities other than E	<=0,5	0,00	%	
Loss on drying	<=0,5	0,00	%	
Sulphated ash	<=0,1	0,04	%	
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	100,28	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

14-07-2022

Expiration: 13-12-2025

Conclusion: APPROVED

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