

Certificate of Analysis

Product name: Nifuroxazidum

Batch number / Weight: 22J20-B02-233806 / 50 G

Analysed according to: Ph.Eur.11.2

Number of analysis / Inspection Code 22J20-B02 / INS-22-9329

Reference Code / No.: V01646 / 1555-1

Tests	Requirement	Result	Unit	Standard remark
Appearance	Intense yellow, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Specific absorbance	940 - 1000	964,5		
Impurity A	<=0,05	<0,05	%	
Related substances	Conform	Conform		
Impurity E	<=0,3	0,15	%	
Impurity B	<=0,3	<0,05	%	
Impurity C	<=0,3	0,00	%	
Impurity D	<=0,3	0,05	%	
<=1 such peak >=0,1%	<=1	Conform	%	
Unspecified impurities	<=0,10	<0,05	%	
Sum of impurities other than E	<=0,5	0,05	%	
Loss on drying	<=0,5	0,08	%	
Sulphated ash	<=0,1	0,00	%	
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	101,02	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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:

Ewelina Gadzinowska

Qualified Person

06-12-2023

Expiration: 15-06-2027

Conclusion: APPROVED

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