

## Certificate of Analysis

**Product name:** Nitrofurantoin 200 MG & Syrspend SF PH4 NEO Convenience Pack (100 ML)

**Batch number:** 22E17-H07-72093

**Analysed according to:** IHS

### Analytical records Nitrofurantoin 21H02-H08-00481

Tests	Requirement	Result	Unit	Standard remark
Appearance	A yellow, crystalline powder or yellow crystals	Conform		
Identification A	Conform	Conform		UV-spectrum
Identification B	Conform	Conform		
Related substances	<= 1,0	Conform	%	TLC
Loss on drying	<= 1,0	0,0	%	105°C oven
Sulfated ash	<= 0,1	0,0	%	
Assay	98,0 - 102,0	99,2	%m/m	Dried
Particle size	90 - 100% > 75µm	97	%	Alpine AJS system, house
Particle size	50 - 100% > 180µm	67	%	
Particle size	< 10% > 425µm	2	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		DP

Analysis performed by the authorized internal lab and by the authorized lab of Fagron sp.zo.o

Meets the requirements of the PH.EUR 10.3

### Analytical records Syrspend® SF PH4 NEO 22C29-H08-00941

Tests	Requirement	Result	Unit	Standard remark
Appearance	White powder	Conform		
Identification	Conform	Conform		Starch
Identification	Conform	Conform		Potassium
pH	4,0 – 5,0	4,0		
Solubility in water	Dispersible	Conform		
Rheology 9,3/sec	25 – 275	105	cP	
Rheology 0,93/sec	75 - 450	150	cP	
Assay Sorbic acid	2,4 – 3,0	Conform	%	
Total aerobic Microbial Count (TAMC)	<= 10 <sup>2</sup>	Conform	CFU/g	
Total Yeasts and Moulds Count (TYMC)	<= 10 <sup>1</sup>	Conform	CFU/g	
Escherichia Coli	Absent	Conform	/g	

Analysis performed by the authorized internal lab

Meets the requirements of the IHS

Release:

Konstantina Tziolia

Pharmacist - QA Manager / QP

17/05/2022

Expiration: 29-03-2024

Conclusion: APPROVED

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