Certificate of Analysis

Product name: **Doxycyclini hyclas**

Batch number / Weight: **23L01-B01-235317 / 50 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23L01-B01 / INS-23-9587**

Reference Code / No.: **V01412 / H202206007**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow, hygroscopic, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Yellow	Conform		
Identification C	White	Conform		
pH	2,0 - 3,0	2,42		
Lightabsorbing impurities	<=0,07	<0,07		
Related substances	Conform	Conform		
Impurity A	<=2,0	0,99	%	
Impurity F	<=1,2	0,97	%	
Impurity B	<=0,5	0,09	%	
Impurity C	<=0,2	<0,05	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=3,0	2,05	%	
Ethanol	4,3 - 6,0	4,72	%	
Water (Karl Fischer)	1,4 - 2,8	1,99	%	
Sulphated ash	<=0,4	0,00	%	
Endotoxins	<1,14	<1,14	IU/mg	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	95,0 - 102,0	98,32	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA	<=10^3	<10	CFU/g	
Total yeasts and moulds (TYMC)	<=10^2	<1	CFU/g	

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@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,CBMiA

Release:
Agnieszka Pszczółka
Qualified Person

25-01-2024

Expiration: 05-06-2026

Conclusion: APPROVED

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

fagron.pl

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