

Certificate of Analysis

Product name: **Gentamicini sulfas**

Batch number / Weight: **22I14-B01-228153 / 10 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22I14-B01 / INS-22-9358**

Reference Code / No.: **V00598 / 210920013**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, hygroscopic powder	Conform		
Identification B	acc. to Ph. Eur.	Conform		
Identification C	acc. to Ph. Eur.	Conform		
Appearance of solution	acc. to Ph. Eur.	Conform		
pH	3,5 - 5,5	4,75		
Specific optical rotation	+107 - +121	+119,5		
Composition	acc. to Ph. Eur.	Conform		
Gentamicin C1	25,0 - 45,0	29,0	%	
Gentamicin C1a	10,0 - 30,0	19,3	%	
Sum of gentamicins C2, C2a and	35,0 - 55,0	51,7	%	
Related substances	acc. to Ph. Eur.	Conform		
Impurity A	<=3,0	0,6	%	
Impurity B	<=3,0	<0,1	%	
Any other impurity:	<=3,0	<0,3	%	
Total	<=10,0	0,6	%	
Methanol	<= 1,0	<0,3	%	
Sulfate	32,0 - 35,0	34,8	%	
Water	<= 15,0	9,69	%	
Sulfated ash	<=1,0	0,12	%	
Assay	>= 590 (anhydrous substance)	725	IU/mg	
Bacterial endotoxins	< 0,71	<0,71	IU/mg	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

fagron.pl Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
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 FAPL,ELspol,Selvita,Mikrografi

Release:
Ewelina Gadzinowska
Qualified Person

26-01-2023

Expiration: 31-08-2025

Conclusion: APPROVED

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

fagron.pl

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