

Certificate of Analysis

Product name: Gentamicini sulfas
Batch number: 22C17-B10-223360
Base unit: 10g
Expiration date: 31.08.2025
Quality: Ph. Eur.
Manufacturing date: 25.05.2022
Inspection report no.: INS-22-3945
Manufacturer: Fuan Pharmaceutical Group Yantai Justaware Pharmaceutical Co.,Ltd
Manufacturer's batch number: 210920013

Description	Claim	Result	Unit	Laboratory
Appearance	white or almost white, hygroscopic powder	conform		Fagron Poland
Identification B	acc. to Ph. Eur.	conform		Fagron Poland
Identification C	acc. to Ph. Eur.	conform		Fagron Poland
Appearance of solution	acc. to Ph. Eur.	conform		Fagron Poland
pH	3,5 - 5,5	4,75		Fagron Poland
Specific optical rotation	+107 to +121	+118		Fagron Poland
Composition:				
Gentamicin C1	25,0 - 45,0	29,0	%	Fagron Poland
Gentamicin C1a	10,0 - 30,0	19,3	%	Fagron Poland
Sum of gentamicins C2, C2a and C2b	35,0 - 55,0	51,7	%	Fagron Poland
Related substances	Impurity A: max. 3,0% Impurity B: max. 3,0% Any other impurity: max. 3,0% Total: max. 10,0%	0,6 <0,1 <0,3 0,6	%	Fagron Poland
Methanol	max. 1,0%	<0,3	%	El. spol
Sulfate	32,0 - 35,0	34,8	%	Fagron Poland
Water	max. 15,0%	9,69	%	El. spol
Sulfated ash	max. 1,0%	0,12	%	Fagron Poland
Assay	min. 590 IU/mg (anhydrous substance)	725	IU/mg	El. spol
Bacterial endotoxins	less than 0,71 IU/mg	<0,71	IU/mg	El. spol
Metallic residues	CHMP/ICH/353369/2013	conform		data producer
Residual solvents	CPMP/ICH/82 260/06	conform		data producer
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	conform		data producer

Analysis performed by the laboratory: Fagron Poland, El spol.

Release:
 Ewelina Gadzinowska
 Qualified Person

Date of releasing: 09.09.2022

Conclusion: Approved