

Certificate of Analysis

Product name: Gentamicini sulfas
Batch number: 20B20-B01-196557
Base unit: 10g
Expiration date: 30.04.2023
Quality: Ph.Eur.
Manufacturing date: 29.04.2020
Inspection report no.: INS-20-00770
Manufacturer: Fuan Pharmaceutical Group Yantai Justaware Pharmaceutical Co.,Ltd
Manufacturer's batch number: 190510001

Description	Claim	Result	Unit	Laboratory
Appearance	white or almost white, hygroscopic powder	conform		
Identification B	acc. to Ph. Eur.	conform		Biocentrum
Identification C	acc. to Ph. Eur.	conform		
Appearance of solution	acc. to Ph. Eur.	conform		
pH	3,5 - 5,5	4,50		
Specific optical rotation	+107 to +121	+116,2		
Composition:				
Gentamicin C1	25,0 - 45,0	30,42	%	Biocentrum
Gentamicin C1a	10,0 -30,0	18,84	%	Biocentrum
Sum of gentamicins C2, C2a and C2b	35,0 - 55,0	50,74	%	Biocentrum
Related substances	Impurity A: max. 3,0% Impurity B: max. 3,0% Any other impurity: max. 3,0% Total: max. 10,0%	1,4 0,2 1,3 2,7	%	Biocentrum
Methanol	max. 1,0%	<0,01	%	El. spol
Sulfate	32,0 - 35,0	33,21	%	
Water	max. 15,0%	6,74	%	El. spol
Sulfated ash	max. 1,0%	0,02	%	
Assay	min. 590 IU/mg	667	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, Biocentrum, El spol.

Release:
 Dorota Sutkowska
 Qualified Person



Fagron sp. z o.o.
 Dorota Sutkowska
 osoba wykwalifikowana
 qualified person

Date of releasing: 11.05.2020

Conclusion: Approved