



Article	5245	Gentamicinsulfat, API (Urspr.: Fisch u. mikrob. Herk.)	
Synonym		Gentamicini sulfas	
Synonym		Gentamicin sulfate, API(origin: fish and microbial)	
Batch	23001024		
Specification	Ph.Eur.10.1		
Production date	09.2022	Retest date	09.2026

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
HPLC	According to specification	Complies
C	According to specification	Complies
Thin-layer chromatography	According to specification	Complies
Tests	According to specification	Complies
Appearance of solution	According to specification	Complies
pH-Value	3,5 ... 5,5	4,6
Specific optical rotation	107 ... 121	116
Related substances	According to specification	Complies
Impurity A	Max. 3,0 %	< 0,5 %
Impurity B	Max. 3,0 %	0,8 %
Any other impurity	Max. 3,0 %	< 3,0 %
Total of all impurities	Max. 10 %	5 %
Methanol	Max. 1,0 %	< 1,0 %
Sulphates	32,0 ... 35,0 %	33,5 %
Water	Max. 15,0 %	7,9 %
Sulphated ash	Max. 1,0 %	0,2 %
Composition	According to specification	Complies
Gentamicin C1	25,0 ... 45,0 %	31,3 %
Gentamicin C1a	10,0 ... 30,0 %	21,4 %
Sum of gentamicins C2, C2a and C2b	35,0 ... 55,0 %	47,2 %
Content	Min. 590 I.E./mg	629 I.E./mg
Correction factor weighing (f, NRF)	1,000	1,036

Certificate of analysis



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Test	Specification	Result
Complies specification		Yes

Release date	14.06.2023	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Fujian Fukang Pharmaceutical Co., Ltd.		
Manufacturer batch	FG2209235		
Manufacturer street	No. 6, Gaogang Avenue		
Manufacturer city	Fuqing 350 309, Fuzhou, Fujian		
Manufacturer country	Volksrepublik China **		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 23001024 complies specification.

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