

Certificate of analysis



Article	5245	Gentamicinsulfat, API (Urspr.: Fisch u. mikrob. Herk.)	
Synonym		Gentamicini sulfas	
Synonym		Gentamicin sulfate, API(origin: fish and microbial)	
Batch	22000754		
Specification	Ph.Eur.10.1		
Production date	08.2021	Retest date	08.2025

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	4,8	
Specific optical rotation	107 ... 121	117	
Related substances	According to specification	Complies	
Impurity A	Max. 3,0 %	< 0,5 %	
Impurity B	Max. 3,0 %	1,0 %	
Any other impurity	Max. 3,0 %	< 1,1 %	
Total of all impurities	Max. 10 %	7 %	
Methanol	Max. 1,0 %	< 1,0 %	
Sulphates	32,0 ... 35,0 %	34,0 %	#
Water	Max. 15,0 %	8,5 %	
Sulphated ash	Max. 1,0 %	0,1 %	#
Composition	According to specification	Complies	
Gentamicin C1	25,0 ... 45,0 %	29,8 %	
Gentamicin C1a	10,0 ... 30,0 %	25,1 %	
Sum of gentamicins C2, C2a and C2b	35,0 ... 55,0 %	45,1 %	
Content	Min. 590 I.E./mg	633 I.E./mg	
Correction factor weighing (f, NRF)	1,000	1,036	

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Complies specification		Yes

Release date	15.06.2022	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Fujian Fukang Pharmaceutical Co., Ltd.		
Manufacturer batch	FG2108205		
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 22000754 complies specification.

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