

Tel: +86-591-83815753  
Fax: +86-591-83811455

E-mail: fukang@fz-antibiotic.com  
Add: No.6, Gaogang Avenue, Jiangyin Industrial Estate, Fuqing, Fuzhou, Fujian, China.



FUJIAN FUKANG PHARMACEUTICAL CO., LTD.

GENTAMICIN SULFATE

CERTIFICATE OF ANALYSIS

ACOFARMA:

233512

BATCH NO. FG2301004  
REPORT DATE 19 JAN 2023  
TOTAL 116.44KG BASE  
PACKING AND QUANTITY 5KG BASE/TIN x23TINS, 1KG BASE/TIN x1TIN, 0.44KG BASE

MANUFACTURE DATE 03 JAN 2023

EXPIRY DATE 03 JAN 2027

SPECIFICATIONS Ph. Eur. 11.0

CEP No.R1 - CEP 1998 - 155 - Rev 10

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	White or almost white, hygroscopic powder. Freely soluble in water, practically insoluble in ethanol.	White hygroscopic powder Passes test
IDENTIFICATION B	The chromatogram obtained with test solution (b) shows 5 principal peaks having the same retention times as the 5 principal peaks in the chromatogram obtained with reference solution (a).	Passes test
IDENTIFICATION C	It gives reaction (a) of sulfates.	Passes test
APPEARANCE OF SOLUTION	Solution S is clear and not more intensely coloured than intensity 6 of the reference solution.	Passes test
pH	3.5 to 5.5 (40mg/ml solution)	4.6
SPECIFIC OPTICAL ROTATION	+107° to +121° (anhydrous substance)	+120°
COMPOSITION:		
GENTAMICIN C1	25.0% to 45.0%	33.2%
GENTAMICIN C1a	10.0% to 30.0%	20.0%
GENTAMICIN C2+C2a+C2b	35.0% to 55.0%	46.8%
RELATED SUBSTANCES:		
IMPURITY A (SISOMICIN)	Not more than 3.0%	Less than disregard limit
IMPURITY B (GARAMINE)	Not more than 3.0%	0.6%
ANY OTHER IMPURITY	Not more than 3.0%	1.0%
TOTAL	Not more than 10.0%	2.7%
METHANOL*	Not more than 1.0%	Not tested
SULFATE	32.0% to 35.0% (anhydrous substance)	34.0%
WATER	Not more than 15.0%	9.0%
SULFATED ASH	Not more than 1.0%	0.1%
BACTERIAL ENDOTOXINS	Less than 0.71 IU/mg	0.06 IU/mg
ASSAY	Not less than 590 IU/mg (anhydrous substance)	683 IU/mg
MICROBIAL ENUMERATION:		
TOTAL AEROBIC MICROBIAL COUNT	Not more than 100 CFU/g	0 CFU/g
TOTAL YEAST AND MOLD COUNT	Not more than 10 CFU/g	0 CFU/g
HISTAMINE	Not more than 8 ppm	1ppm

Remark: \* No methanol is used during the production.

CONCLUSION: THE SUBJECT BATCH COMPLIES WITH Ph. Eur. 11.0.

REPORTED BY 林诗源  
2023.01.19

CHECKED BY 吴厚英  
2023.01.19

APPROVED BY 王...  
2023.01.19