

Hangzhou Huarong Pharm Co., Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

FAX: 0086-571-81131109

CERTIFICATE OF ANALYSIS

GENTAMICIN SULFATE

BATCH NO.	FG2312258	MANUFACTURE DATE	09 DEC 2023
REPORT DATE	26 DEC 2023	EXPIRY DATE	09 DEC 2027
TOTAL	109.27KG BASE	SPECIFICATIONS	USP-NF
PACKING AND QUANTITY	12.5KG BASE/DRUM×8DRUMS, 9KG BASE/DRUM×1DRUM, 0.27KG BASE		

TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	White to buff powder. Freely soluble in water, insoluble in alcohol, in acetone, in chloroform, in ether, and in benzene.	White powder Complies
IDENTIFICATION	A: IR: Meets the requirement. B: Test for sulfate: Meets the requirement.	Passes test Passes test
SPECIFIC ROTATION	Between +107° and +121°	+117°
pH	Between 3.5 and 5.5	4.7
LOSS ON DRYING	Not more than 18.0%	7.3%
RESIDUE ON IGNITION	Not more than 1.0%	0.1%
LIMIT OF METHANOL	Not more than 1.0%	Not tested*
CONTENT OF GENTAMICINS		
C1a	Between 10% and 35%	20%
C2+C2a	Between 25% and 53%	49%
C2b+ C1	Between 25% and 50%	32%
BACTERIAL ENDOTOXINS	Not more than 0.5 EU/mg	<0.06 EU/mg
ASSAY (ON DRIED BASIS)	Not less than 590 µg/mg	673µg/mg
RELATED SUBSTANCES:		
IMPURITY A (SISOMICIN)	Not more than 3.0%	Less than disregard limit
IMPURITY B (GARAMINE)	Not more than 3.0%	0.8%
ANY OTHER IMPURITY	Not more than 3.0%	1.0%
TOTAL	Not more than 10.0%	3.0%
MICROBIAL ENUMERATION	Not more than 100 CFU/g	0 CFU/g
TOTAL AEROBIC MICROBIAL COUNT		
+ TOTAL YEAST AND MOLD COUNT		
PARTICLE SIZE	<10 µm: More than 60% <20 µm: More than 75%	80% 91%
HISTAMINE	Not more than 8ppm	<1ppm

*Remark: No methanol is used during the production

CONCLUSION: THE SUBJECT BATCH COMPLIES WITH CURRENT VERSION OF USP-NF.

