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FUJIAN FUKANG PHARMACEUTICAL CO.,LTD.

GENTAMICIN SULFATE CERTIFICATE OF ANALYSIS

NEW CHEMIC (U.S.) INC
50 CHESTNUT RIDGE ROAD
SUITE 117
MONTVALE, NJ 07645

BATCH NO.	FG 1810283	MANUFACTURE DATE	✓ 17 OCT 2018
REPORT DATE	31 OCT 2018	EXPIRY DATE	✓ 17 OCT 2022
TOTAL	114.04 KG BASE	SPECIFICATIONS	USP41
PACKING AND QUANTITY	12.5 KG BASE/DRUM × 9 DRUMS, 1 KG BASE/DRUM × 1 DRUM, 0.54KG 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	4.5
✓ LOSS ON DRYING	Not more than 18.0%	7.2 %
✓ RESIDUE ON IGNITION	Not more than 1.0%	0.2 %
✓ LIMIT OF METHANOL	Not more than 1.0%	Not tested*
CONTENT OF GENTAMICINS		
✓ C1a	Between 10% and 35%	22 %
✓ C2+C2a	Between 25% and 53%	45 %
✓ C2b+C1	Between 25% and 50%	33 %
BACTERIAL ENDOTOXINS	Not more than 0.5 EU/mg	<0.06 EU/mg
✓ ASSAY (ON DRIED BASIS)	Not less than 590 μg/mg	674 μg/mg
RELATED SUBSTANCES:		
IMPURITY A (SISOMICIN)	Not more than 3.0%	Less than disregard limit
IMPURITY B (GARAMINE)	Not more than 3.0%	0.7 %
ANY OTHER IMPURITY	Not more than 3.0%	0.8 %
TOTAL	Not more than 10.0%	3.7 %
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%	77 % 85 %

*Remark: No methanol is used during the production.

CONCLUSION: THE SUBJECT BATCH COMPLIES WITH USP41.

REPORTED BY 苏文静 CHECKED BY 李静子 APPROVED BY [Signature]