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FUJIAN FUKANG PHARMACEUTICAL CO., LTD.

GENTAMICIN SULFATE
CERTIFICATE OF ANALYSIS

BATCH NO.	FG 1406168	MANUFACTURE DATE	14 JUN 2014
REPORT DATE	30 JUN 2014	EXPIRY DATE	14 JUN 2018
TOTAL	106 KG BASE	SPECIFICATIONS	Ph.Eur.8.0
PACKING AND QUANTITY	5 KG BASE/TIN x 21 TINS, 1KG BASE/TIN x 1 TIN		

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	White or almost white, hygroscopic powder, freely soluble in water, practically insoluble in ethanol.	White
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)	4.5
SPECIFIC OPTICAL ROTATION	+107° to +121° (anhydrous substance)	+ 119°
COMPOSITION:		
GENTAMICIN C1	25.0% to 45.0%	28.9 %
GENTAMICIN C1a	10.0% to 30.0%	21.8 %
GENTAMICIN C2+C2a+C2b	35.0% to 55.0%	49.3 %
RELATED SUBSTANCES:		
IMPURITY A (SISOMICIN)	Not more than 3.0%	Less than disregard limit
IMPURITY B (GARAMINE)	Not more than 3.0%	0.9 %
ANY OTHER IMPURITY	Not more than 3.0%	1.0 %
TOTAL	Not more than 10.0%	5.7 %
METHANOL*	Not more than 1.0%	Not tested
SULFATE	32.0 % to 35.0% (anhydrous substance)	34.0 %
WATER	Not more than 15.0%	7.5 %
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)	671 IU/mg
MICROBIAL LIMIT:		
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

Remark: *No methanol is used during the production.

CONCLUSION: THE SUBJECT BATCH COMPLIES WITH Ph.Eur. 8. 0.

REPORTED BY *[Signature]* CHECKED BY *[Signature]* APPROVED BY *[Signature]*

07. Okt. 2014 *[Signature]*

2014. 6. 30

2014. 6. 30

2014. 6. 20