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FUKANG PHARMACEUTICAL

FUJIAN FUKANG PHARMACEUTICAL CO., LTD.

GENTAMICIN SULFATE
CERTIFICATE OF ANALYSIS

BATCH NO.	FG 1609253	MANUFACTURE DATE	13 SEP 2016
REPORT DATE	13 OCT 2016	EXPIRY DATE	13 SEP 2020
TOTAL	112.45 KG BASE	SPECIFICATIONS	Ph.Eur.8.0
PACKING AND QUANTITY	5 KG BASE/TIN x 22 TINS, 2 KG BASE/TIN x 1 TIN, 0.45KG BASE		

CEP No. R1-CEP 1998-155-Rev 07

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)	4.8
SPECIFIC OPTICAL ROTATION	+107° to +121° (anhydrous substance)	+ 118°
COMPOSITION:		
GENTAMICIN C1	25.0% to 45.0%	29.0 %
GENTAMICIN C1a	10.0% to 30.0%	21.3 %
GENTAMICIN C2+C2a+C2b	35.0% to 55.0%	49.7 %
RELATED SUBSTANCES:		
IMPURITY A (SISOMICIN)	Not more than 3.0%	0.6 %
IMPURITY B (GARAMINE)	Not more than 3.0%	0.7 %
ANY OTHER IMPURITY	Not more than 3.0%	0.9 %
TOTAL	Not more than 10.0%	4.1 %
METHANOL*	Not more than 1.0%	Not tested
SULFATE	32.0 % to 35.0% (anhydrous substance)	33.8 %
WATER	Not more than 15.0%	7.8 %
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)	677 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

Remark: *No methanol is used during the production.

CONCLUSION: THE SUBJECT BATCH COMPLIES WITH Ph.Eur. 8.0.

REPORTED BY 苏文静 2016.10.13
CHECKED BY 黄杰 2016.10.12

SELECTCHEMIE AG
Datum/Visum: 13. Dez 2016
APPROVED BY

2016.10.13