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FUJIAN FUKANG PHARMACEUTICAL CO., LTD.

GENTAMICIN SULFATE
CERTIFICATE OF ANALYSIS

BATCH NO. FG 1107337 MANUFACTURE DATE 12 JUL 2011
REPORT DATE 21 JUL 2011 EXPIRY DATE 12 JUL 2015
TOTAL 102 KG BASE SPECIFICATIONS Ph.Eur.7.3
PACKING AND QUANTITY 5 KG BASE/TIN x 20 TINS, 2 KG 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 C	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 D	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)	4.4
SPECIFIC OPTICAL ROTATION	+107° to +121° (anhydrous substance)	+ 119°
COMPOSITION:		
GENTAMICIN C1	25.0% to 45.0%	30.5 %
GENTAMICIN C1a	10.0% to 30.0%	24.6 %
GENTAMICIN C2+C2a+C2b	35.0% to 55.0%	44.9 %
RELATED SUBSTANCES:		
IMPURITY A (SISOMICIN)	Not more than 3.0%	0.9 %
IMPURITY B (GARAMINE)	Not more than 3.0%	0.7 %
ANY OTHER IMPURITY	Not more than 3.0%	1.6 %
TOTAL	Not more than 10.0%	7.3 %
METHANOL*	Not more than 1.0%	Not tested
SULFATE	32.0 % to 35.0% (anhydrous substance)	34.0 %
WATER	Not more than 15.0%	8.5 %
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)	673 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. 7.3.

REPORTED BY [Signature] CHECKED BY [Signature]

APPROVED BY [Signature]

04. Okt. 2011

2011.7.21

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福建省福抗药业股份有限公司
FUJIAN FUKANG PHARMACEUTICAL CO., LTD.

检验报告单
Certificate of Analysis

品名 硫酸庆大霉素
Product Name Gentamicin Sulfate
批号 FG1107337
Batch No. FG1107337
数量 102Kg Base
Quantity 102Kg Base
生产日期 12 JUL 2011
Manufacture Date 12 JUL 2011
报告日期 22 AUG 2011
Report Date 22 AUG 2011

检验方法由客户提供: 4%W/V 水溶液(以庆大霉素计)经 0.2 μ m 滤膜过滤后, 用 1cm 比色皿, 波长为 405nm, 以水作空白, 测定其透光率。

Test method supplied by customer: Filter 4% W/V water solution (calculated on Gentamicin) through a 0.2 μ m membrane and measure the transmittance in 1cm cell at 405nm, against water.

检验结果
Test Result

透光率:
Transmittance: 95.1%

报告人:
Reported by 陈旭明

复核人:
Checked by 王

批准人:
Approved by 王

2011.8.22

2011.8.22

2011.8.22