

FUJIAN FUKANG PHARMA CEUTICAL CO., LTD. GENTAMICIN SULFATOTE ACOFARMA

福抗药业

CERTIFICATE OF ANALYSIS 7

BATCH NO.

FG2301004

URE DATE

03 JAN 2023

REPORT DATE

19 JAN 2023

EXPIRY DATE

03 JAN 2027

TOTAL

116.44KG BASE

SPECIFICATIONS

Ph Eur 110

PACKING AND QUANTITY

5KG BASE/TIN ×23TINS, 1KG BASE/TIN ×1TIN, 0.44KG BASE

CEP No.R1 - CEP 1998 - 155 - Rev 10

Freely soluble in water, practically insoluble in ethanol. 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). IDENTIFICATION C It gives reaction (a) of sulfates. APPEARANCE OF SOLUTION Solution S is clear and not more intensely coloured than intensity 6 of the reference solution. PH 3.5 to 5.5 (40mg/ml solution) 4.6 SPECIFIC OPTICAL ROTATION +107° to +121° (anhydrous substance) +120° COMPOSITION: GENTAMICIN C1 25.0% to 45.0% 33.2% GENTAMICIN C1a 10.0% to 30.0% 20.0% GENTAMICIN C2+C2a+C2b 35.0% to 55.0% 46.8% RELATED SUBSTANCES: IMPURITY A (SISOMICIN) Not more than 3.0% Less than disregard limit IMPURITY B (GARAMINE) Not more than 3.0% 0.6% ANY OTHER IMPURITY Not more than 1.0% Not more than 1.0% METHANOL* Not more than 1.0% WATER Not more than 1.0% 1.0% SULFATE SULFATE ASH Not more than 1.0% 0.1% BACTERIAL ENDOTOXINS Less than 0.71 IU/mg 0.0.06 IU/mg (anhydrous substance) MICROBIAL ENUMERATION: TOTAL AEROBIC MICROBIAL COUNT Not more than 10 CFU/g 0 CFU/g	TESTS	SPECIFICATIONS	RESULTS
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IMPURITY B (GARAMINE) ANY OTHER IMPURITY Not more than 3.0% 1.0% TOTAL Not more than 10.0% METHANOL* Not more than 1.0% Not more than 1.0% Not more than 1.0% Not more than 1.0% WATER Not more than 15.0% SULFATED ASH Not more than 1.0% Not more than 1.0% SULFATED ASH Not more than 1.0% Not more than 1.0% Not more than 1.0% O.1% BACTERIAL ENDOTOXINS Less than 0.71 IU/mg Not less than 590 IU/mg (anhydrous substance) MICROBIAL ENUMERATION: TOTAL AEROBIC MICROBIAL COUNT Not more than 100 CFU/g O CFU/g			
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TOTAL Not more than 10.0% 2.7% METHANOL* Not more than 1.0% Not tested SULFATE 32.0% to 35.0% (anhydrous substance) 34.0% WATER Not more than 15.0% 9.0% SULFATED ASH Not more than 1.0% 0.1% BACTERIAL ENDOTOXINS Less than 0.71 IU/mg 0.0.06 IU/mg ASSAY Not less than 590 IU/mg 0.0.06 IU/mg (anhydrous substance) MICROBIAL ENUMERATION: TOTAL AEROBIC MICROBIAL COUNT Not more than 100 CFU/g 0 CFU/g		Not more than 3.0%	0.6%
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SULFATE 32.0% to 35.0% (anhydrous substance) 34.0% WATER Not more than 15.0% 9.0% SULFATED ASH Not more than 1.0% 0.1% BACTERIAL ENDOTOXINS Less than 0.71 IU/mg 0.0.06 IU/mg ASSAY Not less than 590 IU/mg 683 IU/mg MICROBIAL ENUMERATION: TOTAL AEROBIC MICROBIAL COUNT Not more than 100 CFU/g 0 CFU/g	TOTAL	Not more than 10.0%	2.7%
WATER Not more than 15.0% 9.0% SULFATED ASH Not more than 1.0% 0.1% BACTERIAL ENDOTOXINS Less than 0.71 IU/mg 0.0.06 IU/mg ASSAY Not less than 590 IU/mg (anhydrous substance) MICROBIAL ENUMERATION: TOTAL AEROBIC MICROBIAL COUNT Not more than 100 CFU/g 0 CFU/g	METHANOL*	Not more than 1.0%	Not tested
SULFATED ASH Not more than 1.0% 0.1% BACTERIAL ENDOTOXINS Less than 0.71 IU/mg ASSAY Not less than 590 IU/mg (anhydrous substance) MICROBIAL ENUMERATION: TOTAL AEROBIC MICROBIAL COUNT Not more than 100 CFU/g 0 CFU/g	SULFATE	32.0% to 35.0% (anhydrous substance)	34.0%
SULFATED ASH BACTERIAL ENDOTOXINS Less than 0.71 IU/mg Not less than 590 IU/mg (anhydrous substance) MICROBIAL ENUMERATION: TOTAL AEROBIC MICROBIAL COUNT Not more than 100 CFU/g 0.1% 0.006 IU/mg 683 IU/mg 0 CFU/g	WATER	Not more than 15.0%	9.0%
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ASSAY Not less than 590 IU/mg (anhydrous substance) MICROBIAL ENUMERATION: TOTAL AEROBIC MICROBIAL COUNT Not more than 100 CFU/g 0 CFU/g		Less than 0.71 IU/mg	
TOTAL AEROBIC MICROBIAL COUNT Not more than 100 CFU/g 0 CFU/g			
V Cro/g	MICROBIAL ENUMERATION:		
	TOTAL AEROBIC MICROBIAL COUNT	Not more than 100 CFU/g	0 CFU/ø
V CI O/E	TOTAL YEAST AND MOLD COUNT	Not more than 10 CFU/g	_
	HISTAMINE		•

Remark: * No methanol is used during the production.

CONCLUSION: THE SUBJECT BATCH COMPLIES WITH Ph. Eur. 11.0.

REPORTED BY 环钙调

CHECKED BY

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APPROVED BY TO 1 VATUI

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