



烟台只楚药业有限公司

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FAGRON IBÉRICA, S.A.U

Corresponde al lote de Fagron:

16829-601

Director Técnico

CERTIFICATE OF ANALYSIS

Product Name	Gentamicin Sulfate Sterile EP7.5		
Batch No.	15121722	Manufacturing Date	DEC.,2015
Report No.	1510722	Expiry Date	NOV., 2019
Package Size	5 BOU/Tin, 2 Tin/Cartron	Quantity	10 BOU
Analysis Results			
Items	Specifications		Results
Characters	White or almost white, Hygroscopic powder.		White, Hygroscopic powder.
Solubility	Freely soluble in water,Practically insoluble in ethanol(96 per cent).		Complies
Identification	B) The chromatogram obtained with the test solution shows 5 principal peaks having the same retention times as the 5 principal peaks in the chromatogram obtained with reference solution		Complies
	C) It gives reaction of sulphates		Complies
Appearance of solution	Clear and not more intensely coloured than intensely 6 of the range of reference solutions of the most appropriate colour.		Complies
pH	3.5 to 5.5		5.2
Specific optical rotation (anhydrous substance)	+107°to +121°		+120°
Methanol	Max 1.0%		Not Detected
Composition	C ₁ : 25.0%-45.0%		26.2%
	C _{1a} : 10.0%-30.0 %		24.4%
	C ₂ +C _{2a} + C _{2b} : 35.0%-55.0%		49.4%
Related substance	Impurities A	Max 3.0%	1.3%
	Impurities B	Max 3.0%	0.4%
	Any other impurity	Max 3.0%	0.9%
	Total	Max 10.0%	4.2%
Water	Max 15.0%		8.3%
Sulphated ash	Max 1.0%		0.1%
Sulphate (anhydrous substance)	32.0%-35.0%		34.1%
Sterility	Complies with the test for sterility		Complies
Bacterial endotoxins	Less than 0.71 IU/mg		<0.71 I.U/mg
Assay	Minimum 590 IU/mg(anhydrous substance)		686 IU/mg
	(hydrous substance)		629 IU/mg
Conclusion: This batch product complies with European Pharmacopoeia 7.5 specifications.			

Approver: 李卫河

Reviewer: 陈振峰

Reporter: 刘玉国