

天方药业有限公司
TOPFOND PHARMACEUTICAL CO.,LTD
检验报告单
Certificate of Analysis

品名/Name:盐酸林可霉素Lincomycin Hydrochloride

检品编号/Analysis NO.:2023700611

批号/Batch NO.:230637037

批量/Batch Size:880.00十亿

生产日期/Date of Manufacturing:2023-06-10

报告日期/Date of Report:2023-06-16

检验标准/Test Standards:欧洲药典11.0版及企业内控标准和R1-CEP2008-225-Rev02/Ph. E

有效日期/EXP Date:2026-06-09

ur. 11.0&In-house and R1-CEP2008-225-Rev02

Items/检验项目	Standards/标准	Results/检验结果	Conclusions 结论
性状 Characters	本品为白色或类白色结晶性粉末 White or almost white crystalline powder	类白色结晶性粉末 Almost white crystalline powder	符合规定 Conform
鉴别 Identification	A.本品红外光吸收图谱应与盐酸林可霉素对照品的图谱一致。 B.本品的水溶液显氯化物的鉴别反应(a) A.IR:consistent with that obtained with Lincomycin Hydrochloride reference standard. B.The solution gives reaction(a) of chlorides	A.本品红外光吸收图谱与盐酸林可霉素对照品的图谱一致。 B.本品的水溶液显氯化物的鉴别反应(a) A.IR:consistent with that obtained with Lincomycin Hydrochloride reference standard. B.The solution gives reaction(a) of chlorides	符合规定 Conform
溶液外观 Solution Appearance	溶液应澄清,且颜色不深于黄色6号标准比色液 Clear and not more intensely coloured than reference solution Y ₆	溶液澄清,且颜色不深于黄色6号标准比色液 Clear and not more intensely coloured than reference solution Y ₆	符合规定 Conform
pH	3.6~5.4	4.4	符合规定 Conform
比旋度(+) Specific optical rotation	136°~149°	143°	符合规定 Conform
有关物质 Related substances	杂质A≤0.5%; 杂质B峰面积的总和≤0.5%; 杂质C≤0.2%; 非特定杂质≤0.10%; 总杂质≤2.0% ImpurityA(alpha-Amide epimer)≤0.5%; ImpurityB(Propylidene analogues)≤0.5%; ImpurityC(N-Demethyl lincomycin)≤0.2%; Unspecified impurities≤0.10%; Total impurities≤2.0%	杂质A:0.3%; 杂质B峰面积的总和:0.3%; 杂质C:未检出; 非特定杂质:0.06%; 总杂质:0.7% ImpurityA(alpha-Amide epimer):0.3%; ImpurityB(Propylidene analogues):0.3%; ImpurityC(N-Demethyl lincomycin):undetected; Unspecified impurities:0.06%; Total impurities:0.7%	符合规定 Conform
水分 Water	3.1% ~ 4.5%	3.8%	符合规定 Conform



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硫酸灰分 Sulphated ash	≤0.4%	0.1%	符合规定 Conform
细菌内毒素 Bacterial endotoxin	<0.50IU/mg Less than 0.50IU/mg	<0.50IU/mg Less than 0.50IU/mg	符合规定 Conform
残留溶剂 Residual solvents	正丁醇≤500ppm n-Butanol:Not more than 500ppm	正丁醇:360ppm n-Butanol:360ppm	符合规定 Conform
含量(以无水物计) Assay(on anhydrous basis)	盐酸林可霉素及盐酸林可霉素B含量的总和: 96.0%~102.0%; 盐酸林可霉素B≤5.0% Sum of the contents of lincomycin hydrochloride and lincomycin B hydrochloride:96.0~102.0%; Lincomycin B hydrochloride:Not more than 5.0%	盐酸林可霉素及盐酸林可霉素B含量的总和:100.5% ; 盐酸林可霉素B:2.9% Sum of the contents of lincomycin hydrochloride and lincomycin B hydrochloride:100.5%; Lincomycin B hydrochloride:2.9%	符合规定 Conform

结论:本品按盐酸林可霉素欧洲药典11.0版及企业内控标准和R1-CEP2008-225-Rev02检验,结果符合规定

Conclusion:The above certificate of analysis is in compliance with Ph.Eur.11.0&In-house and R1-CEP2008-225-Rev02

负责人/Assessed by:

检验者/Tested by:王淑云 陈爱玲 付富生

复核者/Checked by:李贵文

