

天方药业有限公司

METAPHARMACEUTICAL TOPFOND PHARMACEUTICAL CO.,LTD

N DE LOTE:

0140723

25/07/2023

检验报告单

Certificate of Analysis

品名/Name: 盐酸林可霉素 Lincomycin Hydrochloride

批号/Batch NO.: 230637037

生产日期/Date of Manufacturing: 2023-06-10

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

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

检品编号/Analysis NO.: 2023700611

批量/Batch Size: 880.00 十亿

报告日期/Date of Report: 2023-06-16

有效日期/EXP Date: 2026-06-09

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% Impurity A(alpha-Amide epimer) ≤ 0.5%; Impurity B(Propylidene analogues) ≤ 0.5%; Impurity C(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% Impurity A(alpha-Amide epimer): 0.3%; Impurity B(Propylidene analogues): 0.3%; Impurity C(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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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
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

Checked by:李贵文

