

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

检验号/Analysis NO.:2021700160

批号/Batch NO.:210537049

批量/Batch Size:1040.00十亿

生产日期/Date of Manufacturing:2021-05-20

报告日期/Date of Report:2021-06-02

检验标准/Test Standards:欧洲药典10.0版及企业内控标准/Ph. Eur. 10.0&In-house

有效日期/EXP Date:2024-05-19

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 ctystalline powder	类白色结晶性粉末 Almost white ctystalline powder	符合规定 Conform
溶解度 Solubility	本品易溶于水，微溶于乙醇（96%），不溶于丙酮 Very soluble in water, Slightly soluble in ethanol(96%), insoluble in acetone.	本品易溶于水，微溶于乙醇（96%），不溶于丙酮 Very soluble in water, Slightly soluble in ethanol (96%), insoluble in acetone.	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 Appearance of Solution	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 Y6	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 Y6	符合规定 Conform
pH	3.6~5.4	4.2	符合规定 Conform
比旋度(+) Specific optical rotation	136°~149°	144°	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(Propylene analoques)≤0.5%; ImpurityC(N-Demethyl lincomycin)≤0.2%; Unspecified impurity≤0.10%; Total impurities≤2.0%	杂质A: 0.2%; 杂质B峰面积的总和: 0.2%; 杂质C: 未检出; 非特定杂质: 未检出; 总杂质: 0.4% ImpurityA(alpha-Amide epimer): 0.2%; ImpurityB(Propylene analoques): 0.2%; ImpurityC(N-Demethyl lincomycin): undetected; Unspecified impurity: undetected; Total impurities: 0.4%	符合规定 Conform
水分 Water	3.1%~4.5% 天方药业有限公司 质量检验专用章	3.9%	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	符合规定 conform	符合规定 Conform
残留溶剂 Residual solvents	正丁醇:≤500ppm 辛醇:≤100ppm n-Butanol:Not more than 500ppm octanol:Not more than 100ppm	正丁醇:285ppm 辛醇:10ppm n-Butanol:285ppm octanol:10ppm	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: 101.4%; 盐酸林可霉素B: 2.5% Sum of the contents of lincomycin hydrochloride and lincomycin B hydrochloride:101.4%; Lincomycin B hydrochloride:2.5%	符合规定 Conform

结论:本品按盐酸林可霉素欧洲药典10.0版及企业内控标准检验,结果符合规定

Conclusion:The above certificate of analysis is in compliance with Ph.Eur.10.0&In-house

负责人/Assessed by: 天方药业有限公司

检验者/Tested by:余艳茹 刘芝 苏艳霞

复核者/Checked by:宋丹丹

