



浙江国邦药业有限公司

ZHEJIANG GUOBANG PHARMACEUTICAL CO., LTD.

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质量检验报告书 CERTIFICATE OF ANALYSIS

报告单编号 (COA NO.) TS-QCSA00109001-Report04-02

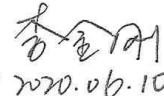
检字号 (Serial No.) E1282005041

检品名称 Product	克拉霉素 Clarithromycin	批号 Batch No.	128-200527-1
包装 Packaging Size	25kg/桶 (drum)	批量 Batch Size	693.00Kg
生产日期 MFG Date	31/05/2020 (d/m/y)	报告日期 Reporting Date	09/06/2020 (d/m/y)
执行标准 According to	EP10/USP43/IP2018	复测日期 Retest Date	30/05/2024 (d/m/y)
发货数量 Shipped quantity			

检验项目 (Tests)		标准规定 (Acceptance Criteria)	结果 (Results)
性状 Characters	外观 Appearance	白色或类白色结晶性粉末 White or almost white, crystalline powder.	白色结晶性粉末 White crystalline powder.
	溶解性 Solubility	溶于丙酮、二氯甲烷, 微溶于无水乙醇、甲醇、乙腈和磷酸盐缓冲液 (pH =2~5) 中, 在水中几乎不溶, Soluble in acetone, methylene chloride; slightly soluble in anhydrous ethanol, in methanol, and in acetonitrile, and in phosphate buffer at pH values of 2 to 5; practically insoluble in water.	/
鉴别 Identification	IR: 红外光吸收图谱应与对照品的图谱一致 IR: Conforms to the spectrum of Clarithromycin RS.		符合 Conforms
	HPLC: 供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 The retention time of the major peak of the Sample solution corresponds to that of Standard solution, as obtained in the Assay.		符合 Conforms
溶液外观 Appearance of solution	应澄清或不深于 II 号浊度标准液和不深于黄色 7 号比色液。 (0.500g/50.0ml methylene chloride.) Clear or not more opalescent than reference suspension II and not more intensely coloured than reference solution Y ₇ .		符合 Conforms
比旋度 Specific optical rotation	-94° ~ -102° (Anhydrous substance, 10mg/ml methylene chloride)		-97.8°
水分 Water	≤2.0%		0.21%
炽灼残渣 Residue on Ignition	≤0.2%		0.01%
结晶性 Crystallinity	应符合规定 Meets the requirements		符合 Conforms
碱度 pH	8.0 ~ 10.0		8.7
有关物质 (HPLC) Related substances	杂质 A Impurity A	≤1.0%	0.27%
	杂质 B Impurity B	≤1.0%	<0.10%
	杂质 C Impurity C	≤1.0%	<0.10%

报告人: 
Reported by:

审核人: 
Reviewed by:

批准人: 
Approved by:



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发货数量 Shipped quantity			

检验项目 (Tests)	标准规定 (Acceptance Criteria)		结果 (Results)
有关物质 (HPLC) Related substances	杂质 D Impurity D	≤1.0%	0.25%
	杂质 E Impurity E	≤1.0%	0.49%
	杂质 F Impurity F	≤1.0%	0.22%
	杂质 G Impurity G	≤1.0%	<0.10%
	杂质 H Impurity H	≤1.0%	<0.10%
	杂质 I Impurity I	≤1.0%	未检出 Not detected
	杂质 J Impurity J	≤1.0%	未检出 Not detected
	杂质 K Impurity K	≤1.0%	未检出 Not detected
	杂质 L Impurity L	≤1.0%	<0.10%
	杂质 M Impurity M	≤1.0%	未检出 Not detected
	杂质 N Impurity N	≤1.0%	未检出 Not detected
	杂质 O Impurity O	≤1.0%	未检出 Not detected
	杂质 P Impurity P	≤1.0%	未检出 Not detected
	大于 0.4% 的杂质个数 Any impurity greater than 0.4%	不得超过 4 个 Not more than 4	1
	其他未知单质 Any unspecified impurity	≤0.10%	<0.10%
总杂质 Total impurities	≤3.5%	1.2%	
含量 (HPLC) Assay	按无水物计算, 含 C ₃₈ H ₆₉ NO ₁₃ 应为 96.0%~102.0% (Anhydrous substance)		99.0%
*残留溶剂 Residual solvents (GC)	乙醇 Ethanol ≤5000ppm		未检出 Not detected

结论: 本品按 EP10/USP43/IP2018 版标准检验, 结果符合规定

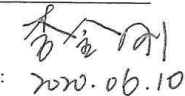
Conclusion: Conforms to EP10/USP43/IP2018 specification for Clarithromycin.

备注(note): 松密度(Bulk density)0.48g/ml 紧密度 (Tapped density) 0.65g/ml

After risk evaluation, elemental impurities meet the requirements.

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