

河北国龙制药有限公司

检验报告书

Hebei Guolong Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Address: No.9 Xingye street, Shijiazhuang Economic and Technological Development Zone, Hebei province

BG-GL/ZB/04.010-02

Rev04/2024 P1/3

产品名称 Product Name	Azithromycin	生产批号 Batch No.	260307015
包装规格 Packing	25 kg / drum	生产日期 Manufacturing Date	March.19th.2026
重量 Batch Quantity	878.30kg	有效期至 Expiry Date	March.18th.2029
分析号 Analysis No.	C260323001	检测日期 Testing Date	March.23rd.2026
执行标准 Quality Standard	IP2022/USP2024/EP11		
检测项目 TEST ITEMS	标准规定 SPECIFICATION		检测结果 RESULT
性状 Characteristics (IP/ EP)	It is white or almost white powder 本品为白色或类白色粉末		White Powder
溶解度 Solubility (EP/IP/USP)	practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride 本品在水中几乎不溶, 易溶于无水乙醇和二氯甲烷。		Conforms
比旋度 Specific Rotation IP/USP/EP	- 45° ~ - 49°		48°
鉴别 Identification	红外光谱 IR IP/USP/EP	IR spectrum should meet the requirement. 红外光谱应满足要求。	Conforms
	液相色谱 HPLC IP/USP	LC chromatogram should meet the requirement. 液相色谱图应符合要求	Conforms
碱度 Alkalinity IP/USP/EP	9.0~11.0		9.8
溶液澄清度与颜色 Solution clarity and color IP/EP	Should be clear and colorless 溶液应澄清无色		Conforms
结晶性 Crystallinity (USP)	Birefringence and extinction positions 双折射和消光位置		Conforms
水分 Water IP/USP/EP	4.0% ~5.0%		4.6%
炽灼残渣 Residue on Ignition IP/USP	≤0.2%		0.05%
重金属 Heavy metal (IP)	≤10ppm		Conforms
有关物质 Related Substances	Azaerythromycin A (azaerythromycin A)USP/EP	≤0.5%	0.01%
	3-Deoxyazithromycin (azithromycin B) IP/USP/EP	≤1.0%	0.38%
	3'' -O-demethylazithromycin USP azithromycin C EP	≤0.5%	Not detected
	3' -(N,N-Didemethyl) Azithromycin (aminoazithromycin) USP azithromycin E EP	≤0.5%	Not detected
	N-Demethylazithromycin USP azithromycin I EP	≤0.5%	0.01%

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Rev04/2024 P2/3

产品名称 Product Name	Azithromycin	生产批号 Batch No.	260307015
		生产日期 Manufacturing Date	March.19th.2026
包装规格 Packing	25 kg / drum	有效期至 Expiry Date	March.18th.2029
重量 Batch Quantity	878.30kg	检测日期 Testing Date	March.23rd.2026
分析号 Analysis No.	C260323001	报告日期 Report date	March.27th.2026
执行标准 Quality Standard	IP2022/USP2024/EP11		
检测项目 TESTITEMS		标准规定 SPECIFICATION	检测结果 RESULT
有关物质 Related Substances	2-Desethyl-2-Propylazithromycin USP azithromycin O EP	$\leq 0.5\%$	0.17%
	Azithromycin impurity P USP azithromycin P EP	$\leq 0.2\%$	0.04%
	Azithromycin related compound F USP azithromycin F EP	$\leq 0.5\%$	Not detected
	3'-N-[[4-(Acetylamino)phenyl]sulfonyl]-3'- -demethylazithromycin USP azithromycin H EP	$\leq 0.5\%$	Not detected
	Azithromycin N-oxide USP azithromycin L EP	$\leq 0.5\%$	Not detected
	3'-(N,N-Didemethyl)-3'-N-Formylazithromycin USP azithromycin M EP	$\leq 0.5\%$	Not detected
	3'-De(dimethylamino)-3'-Oxoazithromycin USP azithromycin N EP	$\leq 0.5\%$	0.03%
	Desosaminylazithromycin USP azithromycin D/J EP	$\leq 0.3\%$	0.01%
	3'-N-Demethyl-3'-N-[(4- methylphenyl)sulfonyl]azithromycin USP azithromycin G EP	$\leq 0.2\%$	Not detected
	Erythromycin A iminoether USP	$\leq 0.5\%$	Not detected
	Erythromycin A oxime USP	$\leq 0.5\%$	0.02%
	3'-N-[[4-(Acetylamino)phenyl]sulfonyl]- 3',3'-didemethylazithromycin USP	$\leq 0.15\%$	Not detected
	Any other single impurity USP/EP	$\leq 0.2\%$	0.07%
	Total Impurities IP/USP/EP	$\leq 3.0\%$	0.83%
残留溶剂 Residual Solvents	甲醇 Methanol	$\leq 0.3\%$	Not detected
	乙醇 Ethanol	$\leq 0.5\%$	0.001%
	丙酮 Acetone	$\leq 0.5\%$	0.05%
	二氯甲烷 Dichloromethane	$\leq 0.06\%$	0.001%

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BG-GL/ZB/04.010-02 Rev04/2024 P3/3

产品名称 Product Name	Azithromycin	生产批号 Batch No.	260307015
		生产日期 Manufacturing Date	March.19th.2026
包装规格 Packing	25 kg / drum	有效期至 Expiry Date	March.18th.2029
重量 Batch Quantity	878.30kg	检测日期 Testing Date	March.23rd.2026
分析号 Analysis No.	C260323001	报告日期 Report date	March.27th.2026
执行标准 Quality Standard	IP2022/USP2024/EP11		
检测项目 TESTITEMS		标准规定 SPECIFICATION	检测结果 RESULT
残留溶剂 Residual Solvents	苯 Benzene	$\leq 0.0002\%$	Not detected
	甲苯 Methylbenzene	$\leq 0.089\%$	Not detected
	三乙胺 Triethylamine	$\leq 0.032\%$	Not detected
含量 (HPLC) Assay USP		以无水物计算, 含 $C_{38}H_{72}N_2O_{12}$ 应为 945-1030 $\mu\text{g}/\text{mg}$	996 $\mu\text{g}/\text{mg}$
含量 (HPLC) Assay EP/IP		以无水物计算, 含 $C_{38}H_{72}N_2O_{12}$ 应为 96.0%-102.0%	99.3%

结论: 本品按 IP2022、USP2024、EP11 标准检验, 结果符合规定

Conclusion: conforms to IP2022、USP2024、EP11 specification for Azithromycin

备注 (note): 松密度 (Bulk density) 0.53g/ml 紧密度 (Tapped density) 0.79g/ml

Reporter: 吴文静 2026.03.27

Checker: 许淑新 2026.03.27

Director: 李树云 2026.03.27