

CERTIFICATE OF ANALYSIS

检 验 报 告

Product Name 名称	Ansamitocin P-3 安丝菌素 P-3	Batch number 批号	72190601
Production Date 生产日期	2019.06.08	Retest Date 复验日期	To be determined
Batch Size 批量	944g	Quantity 发货量	

Items 项目	Specifications 标准	Results 结果	Conclusion 结论
Appearance 外观	White or off-white powder 白色或类白色粉末	White powder 白色粉末	Conforms 符合规定
Identification (HPLC) 鉴别	The retention time of major peak of test solution should correspond to that of standard spectrum. 供试品主峰保留时间与对照品主峰的保留时间一致	Conforms 符合规定	Conforms 符合规定
Related Substances 有关物质	Ansamitocin P-3≥90.0% 安丝菌素 P-3≥90.0%	93.9%	Conforms 符合规定
	AP-0+AP-1+AP-2+AP-3+AP-3'+AP-4+AP-4' ≥97.0%	99.6%	Conforms 符合规定
	Other individual impurity NMT 0.5% 其他单个杂质≤0.5%	0.22%	Conforms 符合规定
	Total impurities NMT 3.0% 总杂质≤3.0%	0.41%	Conforms 符合规定
Residual Solvent 残留溶剂	Ethanol NMT 0.5% 乙醇≤0.5%	Not detected 未检出	Conforms 符合规定
	Acetone NMT 0.5% 丙酮≤0.5%	0.01%	Conforms 符合规定
	Ethyl acetate NMT 0.5% 乙酸乙酯≤0.5%	Not detected 未检出	Conforms 符合规定
	Hexane NMT 0.029% 正己烷≤0.029%	Not detected 未检出	Conforms 符合规定
	Methylbenzene NMT 0.089% 甲苯≤0.089%	Not detected 未检出	Conforms 符合规定
Water 水分	NMT 3.0% ≤3.0%	1.72%	Conforms 符合规定

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Residue on ignition 炽灼残渣	NMT 0.1% ≤ 0.1%	0.07%	Conforms 符合规定
Heavy metal 重金属	NMT 20ppm ≤ 20 ppm	< 20 ppm	Conforms 符合规定
Assay (on the anhydrous) 含量(按无水物计)	Ansamitocin P-3 ≥ 90.0% 安丝菌素 P-3 ≥ 90.0%	93.9%	Conforms 符合规定
Conclusion 结论	The results conform to the enterprise standard. 符合企业内控标准		
Storage 储存条件	Store in a well-closed container at a temperature of 2℃~8℃, with excursions between 0℃ and 30℃ 密闭 2~8℃保存, 短途运输可在 0~30℃。		
Manufacturer: CHONGQING DAXIN PHARMACEUTICAL CO., LTD. 生产商: 北大医药重庆大新药业股份有限公司 Address: No. 21, Founder Road, Shuitu Town, Beibei District, Chongqing 400714, P.R. China 地址: 重庆市北碚区水土镇方正大道 21 号 邮编 400714			
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