

江苏九阳生物制药有限公司
JOYANG LABORATORIES

环孢素(EP)检验报告单

(Certificate of Analysis For Ciclosporin EP)

15/11/2021

依据《环孢素(EP)质量标准》(QA-SMP-J026)制定此记录

第1页 共2页

Established in accordance with <Specifications of Ciclosporin EP> (QA-SMP-J026)

记录编号(Record No.): QC-R-A134-06

检验报告单号(Analysis Report No.): JYDXIE210007

品名(Product Name): 环孢素(Ciclosporin)

送检目的(Analysis Scope): 全检
(Total Analysis)

批号(Batch No.): 210301DXI

来源(Source): 107 车间

数量(Quantity): 61.89Kg

送检日期(Anal.Date): 2021 年 04 月 11 日

规格(Packaging Specification): 10kg/听

报告日期(Report.Date): 2021 年 10 月 20 日

生产日期(Mfg. Date): 2021 年 03 月 01 日

有效日期(Exp.Date): 2024 年 02 月 28 日

贮藏条件(Storage conditions): 遮光, 密封保存(Preserve in tight, light-resistant containers)

检验项目(Item)	标准规定(Specifications)	检验结果(Results)
外观 (Appearance)	白色或类白色粉末 (White or almost white powder)	白色粉末 (White powder)
鉴别(1) (Identification)(1)	红外法(KBr 压片法): 供试品的 红外光吸收图谱应与对照 的图谱相一致 (IR(KBr Disc): The IR spectrum of the substance is concordant with the reference spectrum)	红外法(KBr 压片法): 供试品 的红外光吸收图谱应与对 照的图谱相一致 (IR(KBr Disc): The IR spectrum of the substance is concordant with the reference spectrum)
鉴别(2) (Identification)(2)	液相色谱: 供试品溶液的主 峰保留时间应与对照品溶液 主峰保留时间一致 (HPLC: the principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution)	液相色谱: 供试品溶液的主 峰保留时间应与对照品溶液 主峰保留时间一致 (HPLC: the principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution)
溶液澄清度与颜色 (Appearance of solution)	澄清, 不得比黄色 5 号或棕 黄色 5 号或红色 7 号标准比 色液更深 (The solution is clear and not more intensely colored than reference solution Y5, BY5 or R7)	澄清, 浅于黄色 5 号标准比 色液 (The solution is clear and not more intensely colored than reference solution Y5)
比旋度(按无水物计) (Specific optical rotation) (dried substance)	-185° ~ -193°	-189°
重金属(Heavy metals)	≤0.0020%	<0.0020%
干燥失重(Loss on drying)	≤2.0%	0.2%
含量(按无水物计) (Assay(dried substance))	98.5% ~ 101.5%	98.9%



江苏九阳生物制药有限公司
JOYANG LABORATORIES
环孢素(EP)检验报告单
(Certificate of Analysis For Ciclosporin EP)

依据《环孢素(EP)质量标准》(QA-SMP-J026)制定此记录

第2页 共2页

Established in accordance with <Specifications of Ciclosporin EP> (QA-SMP-J026)

记录编号(Record No.): QC-R-A134-06

检验报告单号(Analysis Report No.): JYDXIE210007

品名(Product Name): 环孢素(Ciclosporin)

送检目的(Analysis Scope): 全检
(Total Analysis)

批号(Batch No.): 210301DXI

来源(Source): 107 车间

数量(Quantity): 61.89Kg

送检日期(Anal.Date): 2021 年 04 月 11 日

规格(Packaging Specification): 10kg/听

报告日期(Report.Date): 2021 年 10 月 20 日

生产日期(Mfg. Date): 2021 年 03 月 01 日

有效日期(Exp.Date): 2024 年 02 月 28 日

贮藏条件(Storage conditions): 遮光, 密封保存(Preserve in tight, light-resistant containers)

检验项目(Item)		标准规定(Specifications)	检验结果(Results)
有关物质 (Related substance)	杂质 B、E 之和 (Sum of impurities B and E)	≤0.5%	0.2%
	杂质 G (impurity G)	≤0.4%	0.1%
	其他单个已知杂质 (Any other specified impurity)	≤0.3%	0.3%
	单个未知杂质 (Any unspecified impurity)	≤0.1%	未检出 (Not detected)
	总杂质 (Total impurities)	≤1.5%	0.7%
残留溶剂 (Residual solvents)	丙酮残留量 (Acetone)	≤1000ppm	未检出 (Not detected)
	石油醚残留量 (Petroleum ether)	≤100ppm	1ppm
包装外观 (Packaging appearance)		符合《产品包装外观标准》 (Conforms to <Specification for Packaging Appearance of Final Product>)	符合《产品包装外观标准》 (Conforms to <Specification for Packaging Appearance of Final Product>)

结论(Conclusion): 符合 EP10.5 规定 (Comply with EP10.5)

备注(Note): /

报告人: 温婵娟 2021.10.20 复核人: 毛江 2021.10.20
(Drafted by) (Reviewed by)

检测中心主任: 邱江 2021.10.20
(QC manager)

生产地址: 中国江苏盐城射阳经济开发区海都北路 9 号, 224300

Manufacturing Site: No.9 Haidu North Road, Sheyang Economic Development Zone, Yancheng, Jiangsu, 224300 CHINA

电话(Tel): 86-515-88319898

传真(Fax): 86-515-88319595

网址(Web Site): Http://www.joyanglab.com/