

偏差报告 Deviation Report

PR#: 4596

Deviation No.:D-2020-0236

Record Status: Closed-Done

基本信息 General Information

厂区 Division: Innovent Biologics (Su Zhou) Co., Ltd

发起人 Originator: 刘, 晶晶(PID-000080)

发起日期 Date Opened: 2020.08.17

简短描述 Short Description:

M1b DS1 DS2007001AC3层析柱保存过程中系统断电 DS2007001AC3 column Stroage process system power off

到期日期 Date Due: 2020.08.18

关闭日期 Date Closed: 2020.08.18

偏差信息 Deviation Information

发现人 Discovery By: 刘晶晶20000454

发现日期 Discovery On: 2020.08.15

汇报人 Report By: 刘晶晶20000454

汇报日期 Report On: 2020.08.15

发生部门 Occurred Department: M1b DS1

汇报部门 Report Department: M1b DS1

偏差描述 Deviation Description:

2020.08.15 17:59, 纯化人员 (20000454) 在一线除病毒前纯化间 (26C15) 按照BPR10032《信迪利单抗注射液M1b3000L原液批生产记录》(批次: DS2007001) 进行1.3.24亲和层析收集液转移步骤前, 需先对混合器进行断电, 然后准备进行亲和层析收集液的转移。纯化人员 (20000454) 在拔出混合器电源插头过程中, 误碰层析系统 (MFG-M1b2-004) 电源插头, 导致层析系统断电, 同时导致层析系统正在运行的IBI308 AC Post Use Treatment DS2007001 001程序在进行平衡液冲洗至1.81CV时程序结束, 因程序IBI308 AC Post Use Treatment DS2007001 001在运行过程中被中断, 未完整执行程序, 故产生偏差

备注: 偏差发生时是2020.08.15 周六, 当时已上报区域QA。故在2020.08.17第一个工作日开启偏差流程

描述的附件 Description attachment:

是否及时上报? Reporting in Time?: Yes

未及时上报的理由 Reason for not in Time:

已采取的即时措施 Immediately Action Taken:

08/17/2020 05:02 PM (GMT+8:00) added by 晶晶 刘 (PID-000080):

- 1、手动运行IBI308 AC Post Use Treatment DS2007001 001剩余步骤: 1) 平衡液冲洗 $\geq 1.19CV$; 2) 保存液冲洗 $\geq 3CV$; , 手动运行图谱命名为: IBI308 AC Post Use Treatment DS2007001 002, 并保存结果图谱。(见附件1) MFG/2020.08.15
- 2、对M1b一线人员进行培训, 在拔出此处混合器插头时, 注意层析系统的插头。(见附件2) MFG/2020.08.17
- 3、生产人员排查车间内未安装倒钩设计的设备, 并提交工单 (40004822) (见附件3), 通知工程部对电源插头未安装倒钩设计的设备, 安装带倒钩设计的电源插头MFG/2020.08.17

08/17/2020 03:43 PM (GMT+8:00) added by 晶晶 刘 (PID-000080):

- 1、手动运行IBI308 AC Post Use Treatment DS2007001 001剩余步骤: 1) 平衡液冲洗 $\geq 1.19CV$; 2) 保存液冲洗 $\geq 3CV$; , 手动运行图谱命名为: IBI308 AC Post Use Treatment DS2007001 002, 并保存结果图谱。(见附件1) MFG/2020.08.15
- 2、对M1b一线人员进行培训, 在拔出此处混合器插头时, 注意层析系统的插头。(见附件2) MFG/2020.08.17
- 3、生产人员排查车间内未安装倒钩设计的设备, 并提交工单 (40004822), 通知工程部对电源插头未安装倒钩设计的设备, 安装带倒钩设计的电源插头MFG/2020.08.17

即时措施附件 Immediately Action Attachment:

附件1 手动运行程序图谱.pdf

附件2 人员培训.pdf

附件3 报修工单.JPG

厂房设施名称 Facility Name:

产品所属阶段 Product Phase:

M1b

Commercial

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初步影响/风险评估 Initial Impact/Risk Assessment

产品影响评估 Product Impact Assessment:

程序IBI308 AC Post Use Treatment是亲和层析柱在线清洗完成后，对亲和层析填料进行保存的程序，故对信迪利单抗注射液M1b3000L原液 DS2007001批次亲和层析收集液无影响。

生产/检测的影响评估 Production/Testing Impact Assessment:

异常发生后，经QA、MST及现场人员讨论后，纯化人员（20000286）手动运行IBI308 AC Post Use Treatment DS2007001 001剩余步骤：1、平衡液冲洗 $\geq 1.19CV$ ，2、保存液冲洗 $\geq 3CV$ ；，手动运行图谱命名为：IBI308 AC Post Use Treatment DS2007001 002（见附件1），保存位置：M1bL1 Downstream\ Result\IBI308\年份\批号\ AC，手动运行平衡液冲洗 $1.50CV$ （ $192.51L$ ）（平衡液实际冲洗体积： $192.51L+231.43L=423.94L$ ），保存液冲洗 $3.20CV$ （ $601.96L-192.51L=409.45L$ ），符合《信迪利单抗注射液M1b3000L原液批生产记录》（BPR100322-10）中要求：平衡液冲洗 $\geq 3CV$ （ $128.177L \times 3=384.531L$ ），保存液冲洗 $\geq 3CV$ （ $128.177L \times 3=384.531L$ ）。故对IBI308亲和层析填料保存效果无影响，对下一批次亲和层析产品无影响。

其他影响评估描述 Other Impact Assessment Description:

纯化人员（20000454）在发现亲和层析系统（MFG- M1b-004）电源断电后，重新连通层析系统的电源，层析系统在2020.08.15 18:00重新启动，查询程序IBI308 AC Post Use Treatment DS2007001 001产生的数据正常保存无异常（见附件4）。本次异常是由于层析系统被人员误触导致断电，层析系统在接电后，系统重新启动，设备运行正常，对后续生产无影响

初步影响评估附件 Initial Impact Assessment Attachment:

附件4 IBI308 AC Post Use Treatment DS2007001 001.pdf

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:

本偏差对IBI308亲和层析填料保存效果无影响，对下一批次亲和层析产品无影响。

偏差发生率 Reoccurrence Probability of Deviation:

过去12个月未发生类似偏差。（关键词：AC，层析柱，断电）

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:

08/17/2020 09:42 PM (GMT+8:00) added by 晓军 吴 (PID-000095):

根据初步影响评估，本偏差对IBI308亲和层析填料保存效果无影响，对下一批次亲和层析产品无影响。因此定义为次要偏差。

是否需要调查？ Investigation Required?: No

主调查人 Lead investigator:

不需要调查的理由 Reason for not Investigation:

本偏差原因明确，对产品质量和后续生产无影响，因此无需进行进一步调查。

调查总结&根本原因分析 Investigation & RCA

调查总结 Investigation Summary:

调查附件 Investigation Attachments:

根本原因分析 Root Cause Analysis:

本次异常是由于层析系统被人员误触导致断电

根本原因分析附件 Root Cause Analysis Attachment:

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原因描述 Cause Description: 本次异常是由于层析系统被人员误触导致断电		
原因分类 Cause Category Human	原因子分类 Cause Sub-Category Personal	原因归属部门 Cause Department M1b DS1

缺陷描述 Defect Description: AC层析柱保存过程中系统断电。	
缺陷类型分类 Defect Category Production/Process	缺陷类型子分类 Defect Sub-Category Others

是否是重复偏差 Repeat Deviation? : No

判定重复偏差的原因 Justification for Repeat Deviation:
过去12个月未发生类似偏差，因此本偏差不是重复偏差。

重复偏差的原因描述 Reason of Repeat Deviation Description:

相关的重复偏差 Repeat Deviation Records

PR#	deviation#	简短描述 Short Description	Record Status
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最终影响/风险评估 Final Impact/Risk Assessment

对产品质量的影响 Impact on Product Quality:

对其他批次的影响 Impact on Other Batches:

对系统/设备的影响 Impact on System/Equipment:

对验证状态的影响 Impact on Validation State:

对产品注册的影响 Impact on Product Registration:

对法规符合性的影响 Impact on Regulation Compliance:

对稳定性的影响 Impact on Stability:

对其他方面的影响 Impact on Other Aspects:

受影响的部门 Impact Departments:

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影响/风险评估附件 Impact/Risk Assessment Attachment:

受影响的产品信息 Impacted Product Information

产品最终处置建议 Product Disposition Proposal:

产品名称 Product Name:	信迪利单抗注射液M1b 3000L原液		
产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
DS30-308	DS2007001	3000L	Release

受影响的物料信息 Impacted Material Information

物料名称 Material Name:

物料代码 Product Code	批号 Batch No.:	数量 Quantity
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受影响的溶液信息 Impacted Media/Buffer Information

溶液名称 Media/Buffer Name:

溶液代码 Media/Buffer Code:	批号 Batch No.:	数量 Quantity:
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受影响的设备信息 Impacted Equipment Information

设备名称 Equipment Name:	层析系统	设备代码 Equipment Code	MFG-M1b2-004
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偏差处理措施 Deviation Action Items

PR#:	
责任人 Assigned To:	部门 Department:
截止日期 Date Due:	完成日期 Completed Date:
确认人 Verified By:	确认日期 Verified On:
行动项详细描述 Action Description:	

纠正信息 Correction Information

PR#:

偏差报告

Deviation Report

PR#:4596Deviation No.:D-2020-0236

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责任人 Assigned To:	部门 Department:
截止日期 Date Due:	完成日期 Completed Date:
确认人 Verified By:	确认日期 Verified On:
行动项详细描述 Action Description:	

纠正与预防措施 CAPA

PR#:	
责任人 Assigned To:	部门 Department:
截止日期 Date Due:	
行动项详细描述 Action Description:	

附件 File Attachments

关联记录 Reference Records

PR#	Record Type	简短描述 Short Description	Record Status
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相关子记录 Related children

PR#	Record Type	简短描述 Short Description	Record Status
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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	赵, 琰	Area QA Initial Reviewed On:	2020.08.17 16:04
Classify Completed By:	吴, 晓军	Classify Completed On:	2020.08.17 21:49

Department Initial Review

Department Leader 1 Reviewed By:	康, 云	Department Leader 1 Reviewed On:	2020.08.18 07:59
Department Leader 2 Reviewed By:	葛, 伟峰	Department Leader 2 Reviewed On:	2020.08.18 12:50
Department Leader 3 Reviewed By:		Department Leader 3 Reviewed On:	
Department Leader 4 Reviewed By:		Department Leader 4 Reviewed On:	
Department Leader 5 Reviewed By:		Department Leader 5 Reviewed On:	
Area QA Leader Reviewed By:	代, 圆圆	Area QA Leader Reviewed On:	2020.08.18 09:01

Quality Initial Approval

Quality Approver 1 Approved By:	周, 峥	Quality Approver 1 Approved On:	2020.08.18 13:06
Quality Approver 2 Approved By:		Quality Approver 2 Approved On:	
Quality Approver 3 Approved By:		Quality Approver 3 Approved On:	

Final Approval

QA Final Review

QA Final Reviewed By:	QA Final Reviewed On:
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Investigator Final Review

QA Representative Reviewed By:	QA Representative Reviewed On:
Investigator 1 Reviewed By:	Investigator 1 Reviewed On:
Investigator 2 Reviewed By:	Investigator 2 Reviewed On:
Investigator 3 Reviewed By:	Investigator 3 Reviewed On:
Investigator 4 Reviewed By:	Investigator 4 Reviewed On:
Investigator 5 Reviewed By:	Investigator 5 Reviewed On:
Investigator 6 Reviewed By:	Investigator 6 Reviewed On:
Investigator 7 Reviewed By:	Investigator 7 Reviewed On:
Investigator 8 Reviewed By:	Investigator 8 Reviewed On:

Department Final Approval

Department Leader 1 Final Approved By:	Department Leader 1 Final Approved On:
Department Leader 2 Final Approved By:	Department Leader 2 Final Approved On:
Department Leader 3 Final Approved By:	Department Leader 3 Final Approved On:
Department Leader 4 Final Approved By:	Department Leader 4 Final Approved On:
Department Leader 5 Final Approved By:	Department Leader 5 Final Approved On:

Quality Final Approval

Quality Approver 1 Final Approved By:	Quality Approver 1 Final Approved On:
Quality Approver 2 Final Approved By:	Quality Approver 2 Final Approved On:

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Record Status: Closed-Done

Quality Approver 3 Final Approved By:

Quality Approver 3 Final Approved On:

Product Final Disposition

Disposition Proposed By:

Disposition Proposed On:

Proposal Reviewed By:

Proposal Reviewed On:

Product Disposition Approved By:

Product Disposition Approved On: