偏差报告
Deviation Report

PR#: 4346 Deviation No.:D-2020-0230

Record Status: Closed-Done

基本信息 General Information

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

发起人 Originator: 方, 银川(PID-000082) 发起日期 Date Opened: 2020.08.02

简短描述 Short Description:
M1b DS1 DS2006009批次AC1上样管道未及时排气泡 The sample pipe did not discharge bubbles in time during AC1 of DS2006009

到期日期 Date Due: 2020.08.04 关闭日期 Date Closed: 2020.08.04

偏差信息 Deviation Information

发现人 Discovery By: 方银川05030032 发现日期 Discovery On: 2020.08.01

汇报人Report By: 方银川05030032 汇报日期 Report On: 2020.08.01

发生部门 Occurred Department: M1b DS1 汇报部门 Report Department: M1b DS1

偏差描述 Deviation Description:
2020.08.01 15:42在除病毒前纯化间（26C15）进行批次DS2006009信迪利单抗注射液M1b 3000L原液纯化 AC1上样时，现场人员（05030032）发现未执行批记录中“1.3.11 产品管道排空冲洗”步骤，与《信迪利单抗注射液M1b 3000L原液纯化批生产记录》（BPR100322）中规定亲和层析上样前上样管道应排空冲洗不符，故发起偏差。

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:
08/02/2020 09:35 PM (GMT+8:00) added by 银川 方 (PID-000082):
1.重新执行信迪利单抗注射液M1b 3000L原液（DS2006009）纯化批生产记录中“1.3.11 产品管道排空冲洗”步骤。 生产部 2020.08.01

即时措施附件 Immediately Action Attachment:

附件1.重新执行1.3.11 产品管道排空冲洗步骤.jpg

厂房设施名称 Facility Name: 产品所属阶段 Product Phase:

M1b Commercial

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

产品影响评估 Product Impact Assessment:
偏差调查：
本次偏差发生时间是2020.08.01 15:42，在信迪利单抗注射液M1b 3000L原液（DS2006009）亲和层析Cycle1上样时，现场人员（05030032）发现未执行《信迪利单抗注射液M1b 3000L原液纯化批生产记录》（BPR100322）中“1.3.11 产品管道排空冲洗”步骤，就已经开启IBI308 AC Process程序，为防止因未排空上样管路导致气泡进入层析系统，立即Pause亲和层析程序。在T0112-CH0301管路打开后，通过观察纯化区域上样管路中的视镜，未发现DS2006009 CF收获液，说明此时产品尚未进入亲和层析系统。立即上报MST、QA和生产，经讨论决定，手动关闭T0112罐底阀门XV-T0112-14，重新执行“1.3.11 产品管道排空冲洗”步骤，管路排气泡完成后，继续开始上样。
经调查，未执行的“1.3.11 产品管道排空冲洗”步骤在《信迪利单抗注射液M1b 3000L原液纯化批生产记录》（BPR100322）第21页上，操作人员（05030045和05030032）在执行“1.3.10 亲和层析Cycle1的500L配液袋安装”时，将批记录第20页、21页拿至一次性混合器旁进行确认操作，未及时归还至亲和层析系统处的整份批记录中，也未与后续操作人员（20002046和20000387）进行沟通，因此操作人员（20002046和20000387）在执行批记录第22页“1.3.12 亲和层析Cycle1”步骤时由于批记录第21页未在亲和层析系统现场，导致未执行“1.3.11 产品管道排空冲洗”步骤。
影响评估：

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通过观察纯化区域上样管路中的视镜，可知信迪利单抗注射液M1b 3000L原液DS2006009 CF收获液未进入层析系统和层析柱。后重新执行“1.3.11 产品管道排空冲洗”，按照批记录中的规定打开了相应的阀门流路，进行管道排空，排空体积104.99L，符合批记录中“≥70L”的要求，管道排空冲洗之后开始上样，上样过程正常，未发生气泡陷阱报警，对亲和层析Cycle1工艺无影响。
在重新执行“1.3.11产品管道排空冲洗”步骤前，已关闭罐底阀门XV-T0112-14，因此管道排空过程对信迪利单抗注射液M1b 3000L原液DS2006009 CF收获液无影响。
综上，本偏差对DS2006009批次信迪利单抗注射液M1b 3000L原液质量未造成影响。

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

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

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

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:
CF收获液未进入层析系统和层析柱，重新执行管道排空，排空体积为104.99L，符合批记录要求，管道排空冲洗之后开始上样，上样过程正常，未发生气泡陷阱报警，对亲和层析Cycle1工艺无影响。重新执行管道排空前已关闭罐底阀门，因此管道排空过程对CF收获液无影响。本偏差对DS2006009批次信迪利单抗注射液M1b 3000L原液质量未造成影响。

偏差发生率 Reoccurrence Probability of Deviation:
过去12个月内没有类似缺陷发生（搜索关键词：亲和层析、上样管道、排空），故不对偏差等级进行升级。

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:
08/03/2020 07:17 PM (GMT+8:00) added by 祯 吴 (PID-000094):
本偏差对DS2006009批次信迪利单抗注射液M1b 3000L原液质量未造成影响，且过去12个月内没有类似缺陷发生，故定义为次要偏差。

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，且未对产品质量造成影响，故无需进一步调查。

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:

未执行的“1.3.11 产品管道排空冲洗”步骤在《信迪利单抗注射液M1b 3000L原液纯化批生产记录》（BPR100322）第21页上，操作人员（05030045和05030032）在执行“1.3.10 亲和层析Cycle1的500L配液袋安装”时，将批记录第20页、21页拿至一次性混合器旁进行确认操作，未及时归还至亲和层析系统处的整份批记录中，也未与后续操作人员（20002046和20000387）进行沟通，因此操作人员（20002046和20000387）在执行批记录第22页“1.3.12 亲和层析Cycle1”步骤时由于批记录第21页未在亲和层析系统现场，导致未执行“1.3.11 产品管道排空冲洗”步骤。

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

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原因描述 Cause Description:
操作人员未及时归还拆分的批记录，并且未与后续操作人员进行沟通。

原因分类 Cause Category	原因子分类 Cause Sub-Category	原因归属部门 Cause Department
Human	Communication	M1b DS1

缺陷描述 Defect Description:
2020.08.01 15:42在除病毒前纯化间（26C15）进行批次DS2006009信迪利单抗注射液M1b 3000L原液纯化 AC1上样时，现场人员（05030032）发现未执行批记录中“1.3.11 产品管道排空冲洗”步骤，与《信迪利单抗注射液M1b 3000L原液纯化批生产记录》（BPR100322）中规定亲和层析上样前上样管道应排空冲洗不符，故发起偏差。

缺陷类型分类 Defect Category	缺陷类型子分类 Defect Sub-Category
Others	Human execution error

缺陷描述 Defect Description:
2020.08.01 15:42在除病毒前纯化间（26C15）进行批次DS2006009信迪利单抗注射液M1b 3000L原液纯化 AC1上样时，现场人员（05030032）发现未执行批记录中“1.3.11 产品管道排空冲洗”步骤，与《信迪利单抗注射液M1b 3000L原液纯化批生产记录》（BPR100322）中规定亲和层析上样前上样管道应排空冲洗不符，故发起偏差。

缺陷类型分类 Defect Category	缺陷类型子分类 Defect Sub-Category
Production/Process	Operation

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个月内没有类似缺陷发生（搜索关键词：亲和层析、上样管道、排空），故不是重复偏差。

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

相关的重复偏差 Repeat Deviation Records

PR#	deviation#	简短描述 Short Description	Record Status

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:

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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:

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	DS2006009	3000L	

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

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:

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

偏差处理措施 Deviation Action Items

PR#: 4364

责任人 Assigned To:	方, 银川(PID-000082)	部门 Department:	M1b DS1
截止日期 Date Due:	2020.08.04	完成日期 Completed Date:	2020.08.04
确认人 Verified By:	吴, 祯(PID-000094)	确认日期 Verified On:	2020.08.04

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行动项详细描述 Action Description:
对M1b纯化一线人员进行培训，强调在执行批生产记录中的工艺操作时，应当确认页码是连续的。当操作需要将完整的一个工序批记录拆分时，应当和该工序其他人员做好沟通，并及时归还拆分的记录。

纠正信息 Correction Information

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

相关子记录 Related children

PR#	Record Type	简短描述 Short Description	Record Status
4364	Deviation Action Items	对M1b纯化一线人员进行培训 Train the personnel of M1b purification line 1	Closed-Done

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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	赵, 琰	Area QA Initial Reviewed On:	2020.08.03 16:27
Classify Completed By:	吴, 祯	Classify Completed On:	2020.08.03 19:31

Department Initial Review

Department Leader 1 Reviewed By:	康, 云	Department Leader 1 Reviewed On:	2020.08.03 22:15
Department Leader 2 Reviewed By:		Department Leader 2 Reviewed On:	
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:	2020.08.03 20:07

Quality Initial Approval

Quality Approver 1 Approved By:	周, 峥	Quality Approver 1 Approved On:	2020.08.04 08:31
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:	

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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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: