偏差报告
Deviation Report

PR#: 15006 Deviation No.:D-2021-0257

Record Status: Deviation Investigation in Progress

基本信息 General Information

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

发起人 Originator: 程, 思光(PID-000040) 发起日期 Date Opened: 2021.05.28

简短描述 Short Description:
M1b DS2 IBI305原液C6袋冻融容器漏液 the freeze-thaw container of C6 DS bulk is leaking

到期日期 Date Due: 2021.07.02 关闭日期 Date Closed:

偏差信息 Deviation Information

发现人 Discovery By: 刘潇20003394 发现日期 Discovery On: 2021.05.28

汇报人Report By: 程思光05080032 汇报日期 Report On: 2021.05.28

发生部门 Occurred Department: M1b DS2 汇报部门 Report Department: M1b DS2

偏差描述 Deviation Description:
2021.05.28 原液分装间（25C22）进行DS2104003原液分装，分装完成后，在2021.05.28 14:51纯化人员（20003394）在取样过程中发现取样原液冻融器（C6）漏液，故发起偏差。

描述的附件 Description attachment:
附件1：C6漏液图片.jpg

是否及时上报？ Reporting in Time? : Yes

未及时上报的理由 Reason for not in Time:
NA

已采取的即时措施 Immediately Action Taken:
05/28/2021 06:05 PM (GMT+8:00) added by 思光 程 (PID-000040):
即时措施：隔离C6袋原液，用A7袋进行原液全检样品取样 完成部门：M1bDS2 完成时间2021.05.28

即时措施附件 Immediately Action Attachment:

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:
DS2104003批次共分装10袋（A1、B3、A4、B5、C6、A7、B8、C9、A10、B11），除C6袋漏液外其他袋均正常，故对除C6袋外的其他袋原液无影响。偏差发生后经MST、MFG和QA讨论，已建立偏差行动项（PR#15009）领用新的管道和滤器对C6袋原液重新过滤至C12冻融容器中，用于重新过滤的滤器完整性通过。
过滤前取样检测微生物限度，细菌内毒素，蛋白含量与蛋白纯度（SEC-HPLC）样品，滤后取原液全检样品和稳定性考察样品。通过进一步偏差调查并结合检测结果评估对DS2104003批次第C6袋原液质量影响。

生产/检测的影响评估 Production/Testing Impact Assessment:
C6袋漏液后，采取即时措施，使用A7袋原液作为原液中段样品代替C6袋，与A1袋和B11袋混合后取样进行IBI305 DS2104003原液全检，故本偏差对检测无影响。

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

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

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偏差分级 Deviation Classification

偏差严重性 Deviation Severity:
1、DS2104003批次共分装10袋（A1、B3、A4、B5、C6、A7、B8、C9、A10、B11），除C6袋漏液外其他袋均正常，故对除C6袋外的其他袋原液无影响。偏差发生后经MST、MFG和QA讨论，已建立偏差行动项（PR#15009）领用新的管道和滤器对C6袋原液重新过滤至C12冻融容器中，用于重新过滤的滤器完整性通过。
过滤前取样检测微生物限度，细菌内毒素，蛋白含量与蛋白纯度（SEC-HPLC）样品，滤后取原液全检样品和稳定性考察样品。通过进一步偏差调查并结合检测结果评估对DS2104003批次第C6袋原液质量影响。
2、C6袋漏液后，采取即时措施，使用A7袋原液作为原液中段样品代替C6袋，与A1袋和B11袋混合后取样进行IBI305 DS2104003原液全检，故本偏差对检测无影响。

偏差发生率 Reoccurrence Probability of Deviation:
过去12个月未发生类似缺陷（关键词：M1b DS2、原液袋、漏液）

偏差分级 Deviation Classification: Major

分级的理由 Reason for Classification:
05/31/2021 06:19 PM (GMT+8:00) added by 四弟 李 (PID-000227):
该偏差需进一步调查并结合检测结果评估对原液质量的影响，故定义为主要偏差。

是否需要调查？ Investigation Required? : Yes

主调查人 Lead investigator: 王, 国正

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

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:

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

原因描述 Cause Description:

原因分类 Cause Category	原因子分类 Cause Sub-Category	原因归属部门 Cause Department

缺陷描述 Defect Description:
2021.05.28 原液分装间（25C22）进行DS2104003原液分装，分装完成后，在2021.05.28 14:51纯化人员（20003394）在取样过程中发现取样原液冻融器（C6）漏液，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? :

判定重复偏差的原因 Justification for Repeat Deviation:

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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

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:

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: 贝伐珠单抗注射液M1b 3000L原液

产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition

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DS30-305	DS2104003	3000L	N/A

受影响的物料信息 Impacted Material Information

物料名称 Material Name: 12L celsius FFT冻融器

物料代码 Product Code	批号 Batch No.:	数量 Quantity
W01040032	2004021	1

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: 设备代码 Equipment Code

偏差处理措施 Deviation Action Items

PR#: 15009

责任人 Assigned To:	程, 思光(PID-000040)	部门 Department:	M1b DS2
截止日期 Date Due:	2021.05.28	完成日期 Completed Date:	2021.05.29
确认人 Verified By:	邓, 陈琪(PID-000209)	确认日期 Verified On:	2021.05.31

行动项详细描述 Action Description:
1、对IBI305 DS2104003批次C6袋原液重新过滤，对过滤器进行完整性测试；
2、过滤前取样检测微生物限度与细菌内毒素；
3、参考《贝伐珠单抗注射液原液过滤返工方案同步验证方案》（VALP00032）滤前取蛋白含量与蛋白纯度（SEC-HPLC）样品，滤后取原液全检样品，取样量参考《贝伐珠单抗注射液M1b3000L原液放行质量标准》（SPC100081）；
4、参考《贝伐珠单抗注射液原液过滤返工方案同步验证方案》（VALP00032）滤后取稳定性考察样品，取样量参考《 贝伐珠单抗注射液原液稳定性考察方案》（STP00102）。

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

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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
15009	Deviation Action Items	重新过滤C6袋原液并取样送检 Re-filtrate the C6 DS bulk and take sample to test	Closed-Done

Innovent 信达生物制药

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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	邓, 陈琪	Area QA Initial Reviewed On:	2021.05.28 18:06
Classify Completed By:	李, 四弟	Classify Completed On:	2021.05.31 18:42

Department Initial Review

Department Leader 1 Reviewed By:	邓, 献存	Department Leader 1 Reviewed On:	2021.05.31 20:41
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:	2021.05.31 20:10

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.05.31 21:07
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: