偏差报告
Deviation Report

PR#: 15336 Deviation No.:D-2021-0272

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: 陈, 永涛(PID-000279) 发起日期 Date Opened: 2021.06.08

简短描述 Short Description:
M1b DS1 IBI308 2nd原液2-8℃暂存验证时间与方案不一致 M1b DS1 IBI308 2nd DS 2-8℃ storage validation time is inconsistent with protocol

到期日期 Date Due: 2021.07.13 关闭日期 Date Closed:

偏差信息 Deviation Information

发现人 Discovery By: 陈永涛20003164 发现日期 Discovery On: 2021.06.07

汇报人Report By: 陈永涛20003164 汇报日期 Report On: 2021.06.07

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

偏差描述 Deviation Description:
2021.06.07 13:30左右，MST员工（20003164）在跟仓库人员（20001623）沟通时，发现信迪利单抗注射液原液（二代细胞株）（批号：DS2103013）第14袋原液应根据《信迪利单抗注射液（二代细胞株）M1b 3000L纯化工艺验证支持性方案》（VALP00282/01）表8原液暂存验证计划“存放2-8℃，≥1个月从2-8℃冰箱取出，取样送检微生物限度和内毒素”，由于产品入库验收记录表（SMP00183-R3/04）中备注 “第14袋储存条件为2~8℃，≤30天”，所以仓库人员在6月3日将第14袋原液从2-8℃冷库（15U03）转移至-40℃冷冻库，上述情况与方案VALP00282产生偏离，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:
N/A

已采取的即时措施 Immediately Action Taken:
06/08/2021 01:38 PM (GMT+8:00) added by 永涛 陈 (PID-000279):
N/A

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 Clinical

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

产品影响评估 Product Impact Assessment:
本次偏差仅涉及原液2-8℃暂存验证的第14袋，该批次其他原液无影响，根据验证方案VALP00282的要求“用于原液暂存验证的原液不能用于生产，送至PD/AS作为实验性研究样品或进行报废”，故对产品质量无影响。

生产/检测的影响评估 Production/Testing Impact Assessment:
该偏差发生在生产结束后的原液暂存验证过程，对生产无影响。

其他影响评估描述 Other Impact Assessment Description:
根据《信迪利单抗注射液（二代细胞株）M1b 3000L纯化工艺验证支持性方案》（VALP00282）中明确要求本次原液2-8℃暂存验证至少执行3个批次，而本次工艺验证只生产3批，故验证方案VALP00282缺少1批验证数据，只能输出阶段性报告，对原液2~8℃暂存验证产生影响。

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:
对产品SISPQ的影响：
本次偏差仅涉及原液2-8℃暂存验证的第14袋，该批次其他原液无影响，根据验证方案VALP00282的要求“用于原液暂存验证的原液不能用于生产，送至PD/AS作为实验性研究样品或进行报废”，故对产品质量无影响。

偏差发生率 Reoccurrence Probability of Deviation:
过去12个月同类型缺陷回顾（关键词搜索：M1b DS1、IBI308 、2nd原液、2-8℃暂存验证时间、与方案不一致）
未发现同类型缺陷。

偏差分级 Deviation Classification: Major

分级的理由 Reason for Classification:
06/09/2021 01:02 PM (GMT+8:00) added by 育芳 刘 (PID-000093):
该偏差还需进一步分析根本原因，根据根本原因考虑建立CAPA措施。
综上，该偏差定义为主要偏差。

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06/09/2021 10:21 AM (GMT+8:00) added by 育芳 刘 (PID-000093):
该偏差还需进一步分析根本原因，分析对于工艺验证的影响。
综上，该偏差定义为主要偏差。

是否需要调查？ Investigation Required? : Yes

主调查人 Lead investigator: 陈, 永涛

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

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缺陷描述 Defect Description:
2021.06.07 13:30左右，MST员工（20003164）在跟仓库人员（20001623）沟通时，发现信迪利单抗注射液原液（二代细胞株）（批号：DS2103013）第14袋原液应根据《信迪利单抗注射液（二代细胞株）M1b 3000L纯化工艺验证支持性方案》（VALP00282/01）表8原液暂存验证计划“存放2-8℃，≥1个月从2-8℃冰箱取出，取样送检微生物限度和内毒素”，由于产品入库验收记录表（SMP00183-R3/04）中备注 “第14袋储存条件为2~8℃，≤30天”，所以仓库人员在6

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

是否是重复偏差 Repeat Deviation? :

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

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:

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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（二代细胞株）

产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
DS01-308B-2	DS2103013		

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: 设备代码 Equipment Code

偏差处理措施 Deviation Action Items

PR#: 15421

责任人 Assigned To:	刘, 浩(PID-000045)	部门 Department:	M1b DS1
截止日期 Date Due:	2021.06.16	完成日期 Completed Date:	2021.06.14
确认人 Verified By:	邓, 陈琪(PID-000209)	确认日期 Verified On:	2021.06.15

行动项详细描述 Action Description:
对信迪利单抗注射液（二代细胞株）三批工艺验证原液（DS2103013，DS2103014，DS2103015）产品入库验收记录表（SMP00183-R3/04）备注信息进行修改，修改为“根据VALP00282方案，第XX袋储存条件为2-8℃”。

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:

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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
15421	Deviation Action Items	修改产品入库验收记录表Modify the product warehousing check record	Closed-Done

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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	邓, 陈琪	Area QA Initial Reviewed On:	2021.06.08 15:36
Classify Completed By:	刘, 育芳	Classify Completed On:	2021.06.09 13:05

Department Initial Review

Department Leader 1 Reviewed By:	康, 云	Department Leader 1 Reviewed On:	2021.06.09 18:30
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:	2021.06.09 16:25

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.06.09 21:11
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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Record Status: Deviation Investigation in Progress

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: