偏差报告
Deviation Report

PR#: 15162 Deviation No.:D-2021-0262

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: 邱, 明(PID-000241) 发起日期 Date Opened: 2021.06.02

简短描述 Short Description:
MFG IBI308二代亲和层析系统清洁验证TOC超限IBI308 second generation affinity chromatography system cleaning validation TOC over limit

到期日期 Date Due: 2021.07.07 关闭日期 Date Closed:

偏差信息 Deviation Information

发现人 Discovery By: 刘晶晶20000454 发现日期 Discovery On: 2021.05.12

汇报人Report By: 邱明20001026 汇报日期 Report On: 2021.06.02

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

偏差描述 Deviation Description:
2021.05.12 生产人员（20003467）接到QC（20002815）通知，2021.05.09依据清洁验证方案《M1b1线层析系统和层析柱（IBI308二代细胞株）清洁验证方案》（VALP00302）取的清洁验证TOC样品“IBI308（二代细胞株）-AC层析系统-DS2103014-CV2-RT”检测结果为2.47ppm，超出清洁验证方案（VALP00302）预设的可接受范围（≤ 1ppm），详见检测报告（附件1），故发起偏差调查。

描述的附件 Description attachment:
\\NAS.xdsw.local\UserFolder\ming.qiu\桌面\附件1 IBI308二代亲和层析系统CV2 TOC检测结果.pdf

是否及时上报？ Reporting in Time? : No

未及时上报的理由 Reason for not in Time:
未及时将检测结果通知到QA，信息反馈比较慢，导致偏差未及时上报。

已采取的即时措施 Immediately Action Taken:

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:
Commercial

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

产品影响评估 Product Impact Assessment:
该偏差发生在IBI308二代PPQ2（DS2103014）批次，亲和层析系统使用后清洁验证过程中，淋洗水TOC超出预设可接受范围，对下一批次产品（即IBI308二代PPQ3（DS2103015）可能产生影响，具体影响在偏差第二阶段进行评估。

生产/检测的影响评估 Production/Testing Impact Assessment:
依据清洁验证方案《M1b1线层析系统和层析柱（IBI308二代细胞株）清洁验证方案》（VALP00302），亲和层析系统执行3次清洁验证，本偏差发生在亲和层析系统执行第2次清洁验证过程中，淋洗水取样TOC检测结果不合格，对清洁验证结果产生影响，具体影响在偏差第二阶段进行评估。

其他影响评估描述 Other Impact Assessment Description:
在IBI308二代PPQ3（DS2103015）批次，亲和层析系统使用后清洁验证结果合格，因此对产品切换无影响。

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

偏差分级 Deviation Classification

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偏差严重性 Deviation Severity:
对产品SISPQ的影响：
该偏差发生在IBI308二代PPQ2（DS2003014）批次，亲和层析系统使用后清洁验证过程中，淋洗水TOC超出预设可接受范围，但是在下一批次使用前（即IBI308二代PPQ3）亲和层析系统和层析柱CIP后淋洗水取样TOC检测结果合格，因此该偏差对IBI308二代PPQ3批次生产和产品质量无影响。
对清洁验证的影响：
依据清洁验证方案《M1b1线层析系统和层析柱（IBI308二代细胞株）清洁验证方案》（VALP00302），亲和层析系统执行3次清洁验证，本偏差发生在亲和层析系统执行第2次清洁验证过程中，淋洗水取样TOC检测结果不合格，对清洁验证产生影响，具体影响在偏差第二阶段进行评估。

偏差发生率 Reoccurrence Probability of Deviation:
过去12个月该区域同类型缺陷回顾（关键词搜索： IBI308、二代、亲和层析系统、清洁验证TOC超限）
未发现同类型缺陷。

偏差分级 Deviation Classification: Major

分级的理由 Reason for Classification:
06/03/2021 08:25 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，确定对清洁验证的影响。
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: 庞, 博峰

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:
2021.05.12 生产人员（20003467）接到QC（20002815）通知，2021.05.09依据清洁验证方案《M1b1线层析系统和层析柱（IBI308二代细胞株）清洁验证方案》（VALP00302）取的清洁验证TOC样品“IBI308（二代细胞株）-AC层析系统-DS2103014-CV2-RT”检测结果为2.47ppm，超出清洁验证方案（VALP00302）预设的可接受范围（≤ 1ppm），详见检测报告，故发起偏差调查。

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

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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:

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: Other

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产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
Other	IBI308二代 M1b 3000L原液（DS2103015）	N/A	

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#:

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#:

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:

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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

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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	吴, 烜	Area QA Initial Reviewed On:	2021.06.02 22:16
Classify Completed By:	刘, 育芳	Classify Completed On:	2021.06.04 13:36

Department Initial Review

Department Leader 1 Reviewed By:	邓, 献存	Department Leader 1 Reviewed On:	2021.06.04 14:06
Department Leader 2 Reviewed By:	康, 云	Department Leader 2 Reviewed On:	2021.06.04 20:50
Department Leader 3 Reviewed By:	张, 红林	Department Leader 3 Reviewed On:	2021.06.04 13:45
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:	2021.06.04 13:44

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.06.04 22:24
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: