

偏差报告 Deviation Report

PR#: 14097

Deviation No.:D-2021-0225

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: 刘, 晶晶(PID-000080)

发起日期 Date Opened: 2021.05.09

简短描述 Short Description:

M1b DS1 IBI308 2ndAC层析柱清洁验证TOC样品破损 Damage of TOC sample for IBI308 2nd AC chromatographic column cleaning validation

到期日期 Date Due: 2021.07.15

关闭日期 Date Closed:

偏差信息 Deviation Information

发现人 Discovery By: 范传扬20003467

发现日期 Discovery On: 2021.05.09

汇报人 Report By: 刘晶晶20000454

汇报日期 Report On: 2021.05.09

发生部门 Occurred Department: M1b DS1

汇报部门 Report Department: M1b DS1

偏差描述 Deviation Description:

2021.05.09 10:06纯化人员 (20003467) 在对《M1b 1线层析系统和层析柱(IBI308二代细胞株)清洁验证方案》(VALP00302) 验证样品进行送样途中, 用于检测TOC项目的样品 (TOC瓶) 不慎掉落, 导致样品损坏, 无法用于样品检测。故发起偏差调查。

样品名称: "IBI308(二代细胞株)-层析柱 (带AC填料) -DS2103014-CV2", 见附件1

描述的附件 Description attachment:

附件1 破损样品.docx

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:

05/09/2021 02:22 PM (GMT+8:00) added by 晶晶 刘 (PID-000080):

IBI308(二代细胞株)-层析柱 (带AC填料) -DS2103014-CV2" 验证的其他样品继续送样 MFG 2021.05.09

即时措施附件 Immediately Action Attachment:

附件2 送样单.pdf

厂房设施名称 Facility Name:

产品所属阶段 Product Phase:

M1b

Others

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

产品影响评估 Product Impact Assessment:

该偏差发生时IBI308 2nd PPQ2亲和层析工序产品收集已结束, 且该样品为IBI308 2nd亲和层析柱使用后CIP清洁验证检测TOC项目样品, 故该偏差对IBI308 2nd PPQ2批次产品质量无影响。

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

该样品为IBI308 2nd PPQ2期间, 《M1b 1线层析系统和层析柱(IBI308二代细胞株)清洁验证方案》(VALP00302) 中的亲和层析柱清洁验证检测TOC项目样品。样品破损发生后, 已及时发起偏差行动项 (见PR14098): 对微生物检测剩余样品进行分装40ml, 用于TOC项目检测, TOC检测结果为2.39ppm, 超出方案中可接受范围≤2ppm。故无法证明IBI308 2nd PPQ3生产前层析柱被清洗彻底, 故需后续评估。

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

该样品为IBI308 2nd PPQ2期间, 《M1b 1线层析系统和层析柱(IBI308二代细胞株)清洁验证方案》(VALP00302) 中亲和层析柱清洁验证样品, 此样品破损导致IBI308 2nd PPQ2 亲和层析柱CIP验证TOC项目缺少数据。

虽然已发起偏差行动项 (见PR14098): 对微生物检测剩余样品进行分装40ml, 用于TOC项目检测, 且TOC检测结果为2.39ppm, 但是此时样品已经过二次分装, 样品分装前是储存在无菌取样袋中, 非TOC样品专属容器 (TOC瓶), 无菌取样袋可能会引入TOC, 对于样

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品TOC超标的情况仍需后续调查再确定对清洁验证的影响。

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:

1、该偏差发生时IBI308 2nd PPQ2亲和层析工序产品收集已结束，且该样品为IBI308 2nd亲和层析柱使用后CIP清洁验证检测TOC项目样品，故该偏差对IBI308 2nd PPQ2批次产品质量无影响。

2、该样品为IBI308 2nd PPQ2期间，《M1b 1线层析系统和层析柱(IBI308二代细胞株)清洁验证方案》(VALP00302)中的亲和层析柱清洁验证检测TOC项目样品。样品破损发生后，已及时发起偏差行动项(见PR14098)：对微生物检测剩余样品进行分装40ml，用于TOC项目检测，TOC检测结果为2.39ppm，超出方案中可接受范围 ≤ 2 ppm。故无法证明IBI308 2nd PPQ3生产前层析柱被清洗彻底，故需后续评估。

3、该样品为IBI308 2nd PPQ2期间，《M1b 1线层析系统和层析柱(IBI308二代细胞株)清洁验证方案》(VALP00302)中亲和层析柱清洁验证样品，此样品破损导致IBI308 2nd PPQ2 亲和层析柱CIP验证TOC项目缺少数据。

虽然已发起偏差行动项(见PR14098)：对微生物检测剩余样品进行分装40ml，用于TOC项目检测，且TOC检测结果为2.39ppm，但是此时样品已经过二次分装，样品分装前是储存在无菌取样袋中，非TOC样品专属容器(TOC瓶)，无菌取样袋可能会引入TOC，对于样品TOC超标的情况仍需后续调查再确定对清洁验证的影响。

偏差发生率 Reoccurrence Probability of Deviation:

过去12个月类似缺陷回顾(关键词：M1b DS1、IBI308、清洁验证、TOC)，未发生类似缺陷。

偏差分级 Deviation Classification: Major

分级的理由 Reason for Classification:

06/10/2021 04:36 PM (GMT+8:00) added by 四弟 李 (PID-000227):

故该偏差对IBI308 2nd PPQ2批次产品质量无影响, 对清洁验证的影响需进一步调查评估，故考虑定义为主要偏差。

05/10/2021 07:03 PM (GMT+8:00) added by 四弟 李 (PID-000227):

该偏差对产品质量无影响，过去12个月未发生类似缺陷，定义为次要偏差。

是否需要调查？ Investigation Required?: Yes

主调查人 Lead investigator: 邱 明

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:

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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:
纯化人员（20003467）在对《M1b 1线层析系统和层析柱(1B1308二代细胞株)清洁验证方案》（VALP00302）验证样品进行送样途中，用于检测TOC项目的样品（TOC瓶）不慎掉落，导致样品损坏，无法用于样品检测。故发起偏差调查。

缺陷类型分类 Defect Category
Production/Process

缺陷类型子分类 Defect Sub-Category
Operation

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:

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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:

产品代码 Product Code	产品批号 Batch No.:	数量 Quantity	处理决定 Disposition
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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:	设备代码 Equipment Code
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偏差处理措施 Deviation Action Items

PR#: 14098

责任人 Assigned To: 田, 楠(PID-000199)	部门 Department:	QC1
截止日期 Date Due: 2021.05.10	完成日期 Completed Date:	2021.05.10
确认人 Verified By: 吴, 烜(PID-000235)	确认日期 Verified On:	2021.05.10

行动项详细描述 Action Description:

在微生物限度样品处理完成后, 从检测微生物限度项目的剩余样品中, 分装40ml/支*1支样品, 用于TOC项目检测, 并提供检测结果。分装样品编号: IBI308 (二代细胞株)-层析柱(带AC填料)-DS2103014-CV2-RT01。

PR#: 14326

责任人 Assigned To: 刘, 晶晶(PID-000080)	部门 Department:	QC1
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截止日期 Date Due: 2021.05.18 完成日期 Completed Date: 2021.05.19
 确认人 Verified By: 吴, 烜(PID-000235) 确认日期 Verified On: 2021.05.19
 行动项详细描述 Action Description:
 取样方式: 在IBI3082nd 亲和层析柱使用前CIP, 0.5MNaOH冲洗2.95后hold程序, 待0.5MNaOH≥3.0CV后暂停程序, 手动将进口溶液切换成WFI, 并将层析柱手动bypass, 点击Hold待层析系统前后电导保持一致后, 暂停程序, 手动将层析柱in line状态, Hold的程序待WFI冲洗2.8CV后, 手动降低流速取TOC样品。
 取样点: 按照《M1b 1线层析系统和层析柱(IBI308二代细胞株)清洁验证方案》(VALP00302) 8.3.4.3中要求执行。

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# 14098	Record Type Deviation Action Items	简短描述 Short Description 样品分装 Sample packaging	Record Status Closed-Done
14326	Deviation Action Items	IBI308 2nd PPQ3 AC层析柱使用前取CIP淋洗水样The pre CIP rinse water sample of IBI308 2nd PPQ3 AC chromatography column	Closed-Done
15485	Interim Investigation Report	D-2021-0225第一次阶段性报告 D-2021-0225 1st interim investigation report	Closed-Done

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Initial Approval

QA Initial Review

Area QA Initial Reviewed By:	吴, 烜	Area QA Initial Reviewed On:	2021.05.09 13:22
Classify Completed By:	李, 四弟	Classify Completed On:	2021.05.10 19:14

Department Initial Review

Department Leader 1 Reviewed By:	邓, 献存	Department Leader 1 Reviewed On:	2021.05.10 19:21
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:	2021.05.10 19:43

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.05.10 21:16
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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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: