

PR#: 15324

Deviation No.:D-2021-0269

Record Status: Closed-Done

基本信息 General Information

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

发起人 Originator: 赵 阳(PID-000328)

发起日期 Date Opened: 2021.06.08

简短描述 Short Description:

M1b DS1 谷氨酰胺浓缩液储物袋取样口脱落 samling tubing of Glutamine solution storage bag was broken

到期日期 Date Due: 2021.06.09

关闭日期 Date Closed: 2021.06.09

偏差信息 Deviation Information

发现人 Discovery By: 葛杰20003818

发现日期 Discovery On: 2021.06.07

汇报人 Report By: 赵阳05020026

汇报日期 Report On: 2021.06.07

发生部门 Occurred Department: M1b DS1

汇报部门 Report Department: M1b DS1

偏差描述 Deviation Description:

2021.06.07 14:30 生产人员(工号: 20003818, 20001319, 20000795)在将IBI308谷氨酰胺浓缩液(批号: DS2105003-S016-01)储液袋由M1b车间三楼培养基配制间搬运至二楼培养基暂存间后,在将该储液袋放置于冰箱的过程中,储液袋同冰箱内壁发生刮蹭,导致储液袋取样头掉落(见附件1 取样头掉落),且导致储液袋表面出现未破损的凹槽(见附件2 未破损凹槽)。与正常储液袋状态不一致,故发起偏差调查。

描述的附件 Description attachment:

附件2 未破损凹槽.jpg

附件1 取样头掉落.jpg

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:

06/09/2021 04:12 PM (GMT+8:00) added by 阳 赵 (PID-000328):

将该批次IBI308谷氨酰胺浓缩液(批号: DS2105003-S016-01)排放处理(见附件3 排放处理)。

MFG 2021.06.07

06/08/2021 10:50 AM (GMT+8:00) added by 阳 赵 (PID-000328):

将该批次IBI308谷氨酰胺浓缩液(批号: DS2105003-S016-01)排放处理。

MFG 2021.06.07

即时措施附件 Immediately Action Attachment:

附件3 排放处理.jpg

厂房设施名称 Facility Name:

M1b

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:

由于本批次还未进入到3000L流加谷氨酰胺培养阶段,在发现该偏差后,及时上报,制定了即使措施:生产人员对IBI308谷氨酰胺浓缩液(批号: DS2105003-S016-01)进行排放处理。综上,该批次谷氨酰胺浓缩液未用于生产,未对产品造成影响。

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

本偏差发生后,已申请重新配制IBI308谷氨酰胺浓缩液(见附件4 生产流程订单申请修改表,附件5 空白记录补领申请单),并已于2021.06.07完成。可按时配制本批次3000L流加培养用谷氨酰胺浓缩液。该批次IBI308谷氨酰胺浓缩液重新配制完成后,将不经转运放置培养基暂存间的冰箱内,而直接放置于生产车间使用。

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

该偏差的根本原因是现使用的冰箱容量较小，不易储存IBI308谷氨酰胺浓缩液（配制量50KG），导致在将该溶液放入冰箱的过程中容易发生刮蹭。已采购更大容量的冰箱（澳柯玛YC-1006，见附件6 采购需求申请），以用于暂存谷氨酰胺浓缩液。采购预计完成日期为2021.06.23（见附件7 采购订单）。在冰箱到货前，谷氨酰胺浓缩液配制完成后，会暂存于培养基配制间。使用谷氨酰胺浓缩液当日，再将其运至生产车间直接使用，不再存放于培养基暂存间的冰箱内。无需开启第二部分调查。

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

- 附件5 空白记录补领申请单.jpg
- 附件6 采购需求申请.jpg
- 附件4 生产流程订单申请修改表.jpg
- 附件7 采购订单.jpg

偏差分级 Deviation Classification

偏差严重性 Deviation Severity:

对产品SISPQ的影响：

由于本批次还未进入到3000L流加谷氨酰胺培养阶段，在发现该偏差后，及时上报，制定了即使措施：生产人员对IBI308谷氨酰胺浓缩液（批号：DS2105003-S016-01）进行排放处理。综上，该批次谷氨酰胺浓缩液未用于生产，未对产品造成影响。

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：谷氨酰胺浓缩液、储物袋取样口脱落、挤压、刮蹭）未发现同类型缺陷。

偏差分级 Deviation Classification: Minor

分级的理由 Reason for Classification:

06/09/2021 04:37 PM (GMT+8:00) added by 育芳 刘 (PID-000093):

该偏差原因及影响明确，无需进行进一步调查。

综上，该偏差定义为次要偏差。

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:

该偏差原因及影响明确，无需进行进一步调查。

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:

该偏差的原因是现使用的冰箱容量较小，不易储存IBI308谷氨酰胺浓缩液（配制量50KG），导致在将该溶液放入冰箱的过程中容易发生刮蹭。

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

原因描述 Cause Description:

该偏差的原因是现使用的冰箱容量较小，不易储存IBI308谷氨酰胺浓缩液（配制量50KG），导致在将该溶液放入冰箱的过程中容易发生刮蹭。

原因分类 Cause Category

Machine

原因子分类 Cause Sub-Category

Facility/Utility/Equipment/Instrument Others

原因归属部门 Cause Department

M1b DS1

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缺陷描述 Defect Description:

2021.06.07 14:30生产人员(工号:20003818,20001319,20000795)在将IBI308谷氨酰胺浓缩液(批号:DS2105003-S016-01)储液袋由M1b车间三楼培养基配制间搬运至二楼培养基暂存间后,在将该储液袋放置于冰箱的过程中,储液袋同冰箱内壁发生刮蹭,导致储液袋取样头掉落,且导致储液袋表面出现未破损的凹槽,与正常储液袋状态不一致,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?: N/A

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

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
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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:

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: Other

溶液代码 Media/Buffer Code:	批号 Batch No.:	数量 Quantity:
Other	DS2105003-S016-01	50KG

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#:

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:

PR#:15324

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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
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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:	王, 杨晨	Area QA Initial Reviewed On:	2021.06.08 11:09
Classify Completed By:	刘, 育芳	Classify Completed On:	2021.06.09 16:41

Department Initial Review

Department Leader 1 Reviewed By:	邓, 献存	Department Leader 1 Reviewed On:	2021.06.09 21:41
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:	2021.06.09 16:49

Quality Initial Approval

Quality Approver 1 Approved By:	管, 国兴	Quality Approver 1 Approved On:	2021.06.09 22:03
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: