# Product Review

# Period 14 Nov 2022 – 13 Nov 2023

**Fasenra 30mg**
**AstraZeneca Speke**

**Compiled by**

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**Approved by**

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## 1 Summary and Conclusion

The scope of this Product Review covers the operations carried out at AstraZeneca Speke for the period 14th Nov 2022 through to the 13th Nov 2023.

AstraZeneca Speke is approved for QC testing, QP Certification and release of Fasenra.

This PQR report is a site-specific review for Fasenra 30mg, including Accessorised Pre-filled Syringe (APFS) solution for injection and Auto Injector (AI) dosage forms. The purpose of the PQR is to provide input to and having all applicable information of the product to support the generation of an Integrated Summary Product Review (ISPR) issued by AstraZeneca Global Technical Operations. This ISPR will consider major trends or issues across all sites across the Fasenra Supply Chain.

This PQR for the Speke site provides documented evidence that during this period the process to test and release this product remained under a state of control and that the validation status has been maintained and is compliant with registered specifications. This review identified no recommendations for improvement.

In total, six (06) batches of Final Drug Product (FDP) were approved and released (one [01] APFS and seven [05] Auto Injector) and zero [00] were rejected. The total number of dispositioned batches from the Speke Site remains similar to the previous year (08 batches). During the start of this reporting period AZ Speke have remained on the Centralised Marketing Authorisation, with US testing of Fasenra for certification and release. As of 01 Jan 2021, all existing Centrally Authorised Marketing Authorisations were automatically converted into UK Marketing Authorisations effective in Great Britain (only) and issued with a UK MA number on 01 January 2021. US testing for certification and release has remained for the duration of the reporting period.

Section 4 (Review of latest Summaries from Product Reviews from bulk formulated products or drug product (for Finished Product Packaging site) and Section 5 (Starting and Packaging Materials [ROW requirement]) are not applicable to the Speke Site PQR due to the licensed scope of activity performed for Fasenra at this facility. Subsequently the subsections in Section 7 (7.2, 7.3, 7.4, 7.5, 7.6 and 7.7) are also not relevant for the site-specific scope of this PQR. An Integrated Summary Product Review (ISPR) will be issued for this product and reporting period. This ISPR will consider major trends or issues across all sites and thus the supply chain as well regulatory change/ commitment.

There were no batches with results outside of registered specification (OOS) during the review period.

A total number of four (04) changes were raised; related to equipment remediation and retirement, QC testing, sample receipt and product release. All changes were risk assessed and managed by the site during the period of this review. These changes were managed in accordance with global and site change control procedures. The management of each change to the product and facility was assessed through evaluation of compliance to GMP and the relevant Marketing Authorisations. The accumulation of minor / incremental changes has also been considered and there is no additional action needed. The number of changes on the

site is assessed during the site Management Review process which assures that the capacity of the site to respond effectively to change is actively managed.

No critical (00) and no (00) major deviations were raised during the period of this review. All deviations were risk assessed and managed by the site during the period of this review. All deviations were determined to have no product or license impact. There were no trends identified among these deviations. These deviations were managed in accordance with site deviation procedures. There is a reduction in Major deviation when compared to the previous review period, this is most probably due to the reduced number of batches tested and released at the Speke site.

The complaints, recalls, stock recoveries or field alerts undertaken on product released, and returned products or salvaged goods sections are not applicable for this site specific PQR in the period of the review as it is the responsibility of the packaging site to collate this data.

All internal contractual agreements are present and effective and the Supply Chain Map for Fasenra to assure agreements and compliance across the supply chain in support of product certification and release (EudraLex Vol 4 Annex 16) is confirmed and approved by Quality Assurance / Qualified Persons at the Speke site.

The conclusion from this review is that the qualification status for equipment with direct impact on product quality has been maintained in a state of control, no further qualification / validation / calibration or maintenance activities are required.

Inspection of Reference and Retain samples has confirmed that all batches delivered continue to meet the registered specification.

This review provides documented evidence that during this period the process to test and release this product remained under a state of control and that the validation status has been maintained and is compliant with registered specifications. This review identified no recommendations for improvement.

## 2 Batches reviewed (approved and rejected)

Table 1: Batches (with batch number) for final dispositions during the period are presented in Appendix 1 of this report.

| **Batches reviewed** | **Number of batches Previous Period** | **Number of batches current reporting period** |
|---|---|---|
| Final dispositions during the period | 8 | 6 |
| APFS Batches approved | 1 | 1 |
| APFS Batches rejected | 0 | 0 |
| AI Batches approved | 7 | 5 |
| AI Batches rejected | 0 | 0 |

Table 2: Batches rejected during the PR-period.

| **Batch No.** | **Reason** |
|---|---|
| **N/A** | **No batches rejected during this reporting period** |

**Conclusion:**

The total number of dispositioned batches from the previous year has decreased in alignment with the supply strategy. The reject rate has remained at 0%. Based on this review of batches reviewed and approved there is no trend to indicate a quality or system issue.

## 3 Reprocessed & reworked batches

**Has there been any reworked/reprocessed batches during the period** ☐ Yes ☑ No

**Total number of reprocessed or reworked batches: 0**

**Total number of batches reviewed: 6**

**Percentage of batches Reworked & Reprocessed: 0%**

Table 3: Reprocessed and reworked batches during the review period.

| Batch No. | Reprocess/ Rework | Reason | New batch identity | Final disposition |
|---|---|---|---|---|
| N/A | N/A | N/A | N/A | N/A |

**Conclusion:** No reprocessing or rework occurred on any batches of Fasenra.

## 4 Product Reviews from previous manufacturing stage

Previous manufacturing steps have not been reviewed. They will be reviewed as part of the ISPR. Section 4 is not applicable as an Integrated Summary Product Review (ISPR) will be issued for this product and reporting period. This ISPR will consider major trends or issues across all sites."

## 5 Starting and Packaging Materials (ROW requirement)

Section 5 is not applicable for this partial PQR review.

## 6 Analytical Data

**(ROW requirement: include critical in-process controls)**

Analytical testing is performed on imported DP batches at Speke; the disposition decision is made by a Qualified Person at the Speke Site. Statistical analysis and trending is not required within the site PQR; this will be included within the Integrated Summary Product Review (ISPR) issued for this product and reporting period. This ISPR will consider major trends or issues across all sites.

Table 4: Summary Table of Speke Analytical Data test results

| Product Stage | Test Method | Specification Reference | No. of batched tested | Status |
|---|---|---|---|---|
| APFS /Autoinjector | Lateral Flow | SPEC-0123449/ SPEC-0123440 | 7* | Satisfactory |

| Product Stage | Test Method | Specification Reference | No. of batched tested | Status |
|---|---|---|---|---|
| APFS | Break Loose/ Glide Force and Deliverable Volume | SPEC-0123449 | 2* | Satisfactory |
| Autoinjector | Auto-Injector Functionality | SPEC-0123440 | 5 | Satisfactory |
| PFS-SA | Osmolality | SPEC-0123448 | 1* | Satisfactory |
| | Visible Particles | | 0 | Satisfactory |
| | Capillary Isoelectric Focusing | | 1* | Satisfactory |
| | Polysorbate 20 | | 1* | Satisfactory |
| | SEC | | 1* | Satisfactory |
| | pH | | 1* | Satisfactory |
| | Sub Visible Particle counting | | 0 | Satisfactory |
| | UV | | 1* | Satisfactory |
| | Colour/Clarity | | 1* | Satisfactory |
| | Gel Electrophoresis | | 0 | Satisfactory |
| | CE-SDS | | 1* | Satisfactory |
| | Bioassay | | 1* | Satisfactory |
| | Sterility | | 0 | Satisfactory |
| | Endotoxin | | 0 | Satisfactory |

*One Confirmatory batches was tested in this period to comply with regulations to supply to Canada. This testing consisted of the standard APFS testing along with a portion of the PFS-SA tests.

**Conclusion:**
All Fasenra batches tested within the reporting period were found to meet the registered specification.

## 7 Changes

### 7.1 Changes – Computerised Systems

Table 5: Changes to computeried systems

| Change Description | ID-number | Type of change | Implementation date |
|---|---|---|---|
| Windows 10 System Update requires the retirement of several PCs | QE-038996 | Low Change | 30 May 2023 |

**Comments**
There is one (1) Low level Change for Computerised Systems at the Speke site.

### 7.2 Changes – Equipment/Instruments

Table 6: Changes to equipment or instruments

| Change Description | ID-number | Type of change | Implementation date |
|---|---|---|---|
| Retirement and Replacement of incubators in the Bioassay Labs (01-61/01-62) | QE-048543 | High Change | 07 Sept 2023 |

**Comments**

There is one (1) high level change for Equipment/instruments at the Speke site.

### 7.3 Changes – Other

Table 7: Changes – Other

| Change Description | ID-number | Type of change | Implementation date |
|---|---|---|---|
| Define process for Canada Confirmatory testing | QE-068914 | Low Change | 15 Oct 2023 |

**Comments**

There is one (1) Low level change for Other type at the Speke Site.

### 7.4 Changes – Quality/ Compliance

Table 9: Changes – Quality Compliance

| Change Description | ID-number | Type of change | Implementation Date |
|---|---|---|---|
| Update to the Speke Fasenra Supply Chain to add Sweden Biologics Centre and allow release to the Great Britain Market | QE-048543 | Low Change | 25 April 2023 |

**Comments**

There is one (1) low level change for Quality / Compliance at the Speke Site.

### 7.5 Marketing Authorization variations (ROW requirement)

This section is Not Applicable it will be covered in the ISPR.

Post-marketing commitments (ROW requirement)

This section is Not Applicable it will be covered in the Integrated Summary Product Review (ISPR) ISPR.

**Section 7 Changes Conclusion:**

A total number of four (04) changes were raised, all of them risk assessed and managed by the site during the period of this review. These changes were managed in accordance with change control procedures, one of the changes was retiring and replacing of equipment, one was changes to computerised systems and retirement, one was to support process changes that are directly associated with testing and the final one was to include additional release sites.

The impacts of these changes to the product were assessed through evaluation of compliance to registered specification, detail within the marketing authorisation and GMP with no adverse effects were observed. The accumulation of minor/incremental changes has also been considered and there is no additional action needed.

**Effectiveness of corrective and preventive actions taken:**

None required.

## 8 Stability data – N/A

This section is not applicable.

## 9 Deviations

### 9.1 OOS results Table 10: OOS results previous and current review

| | Previous Review | Actual Review |
|---|---|---|
| **Total number OOS** | 0 | 0 |

There were zero (0) Out of Specification (OOS) results initiated at Speke related to Fasenra PFS or Fasenra APFS testing during the review period 14Nov2022-13Nov2023.

### 9.2 Deviation reports

Table 11: Total deviation reports previous and current review

| Record ID | Description | Criticality | Review Period |
|---|---|---|---|
| 256018 | CO2 Standard 'As Found' Calibration Out of Tolerance | Major | 14Nov2021-13Nov2022 |
| 257642 | CO2 Standard CI80090 'As Found' Calibration Out of Tolerance | Major | 14Nov2021-13Nov2022 |
| 257643 | Variation to pack process approved prior to change implementation Fasenra | Major | 14Nov2021-13Nov2022 |

Table 12: Total Number of Major or Critical deviation reports previous and current review

| | Previous Review | Current Review |
|---|---|---|
| **Total** | 3 | 0 |
| **Number of critical deviations** | 0 | 0 |
| **Number of repeat critical deviations** | 0 | 0 |
| **Number of major deviations** | 3 | 0 |

**Comment on any trend within the review period and from previous review:**
There were zero (00) critical, zero (00) major associated with Fasenra. For the current review period refer to table 11.

***An assessment of major and critical deviations has been performed for:***

- ***Repeat Deviations***
- ***Total number of deviations***
- ***Total number of deviations by classification***
- ***Event categories and / or root cause categories identified***

No trend has been identified between current and the previous review period.

**Repeat Deviations**

A review of all major deviations confirmed Zero (0) repeat deviations in the current reivew process.

**Impacted batches**:

A review of all Major deviations confirmed zero (0) batches were rejected or partially rejected.

**Effectiveness of corrective and preventive actions taken for critical and Major deviations**

An effectiveness check is used to identify/verify successful root cause identification and corrective action via the use of CAPAs. Procedures provide guidance on when an effectiveness check is required or appropriate.

There were zero (0) E-Checks raised for Critical or Major deviation during this review period.

**Conclusion:**
All Deviations raised between 14 November 2022 to the 13 November 2023 associated with MEDI-563 have been analysed and assessed with regards to Number, Criticality, Event Type and Root Cause Tier 1.

A total of Zero (00) Critical, zero (00) Major deviations were raised, twelve (12) Minors and Zero (00) OOSs were risk assessed and managed by the site during the period of this review. The deviations were managed in accordance with site deviation procedure SOP-0106378. All deviations associated with Medi-563 have been closed. All associated CAPAs and E-Checks for Major and critical deviation have been completed and are effective.

No significant trends have been identified. There has been a reduction in Major deviation when compared to the previous review period, three (03) major deviation in 2021-2022 compared to zero (00) major deviations in 2022-2023.

One possible reason for the reduction of Major deviations is that the number of batch dispositions at UK1 Speke has decreased 25% from eight (08) to six (06).

The number of deviations impacting the site, together with trend analysis, is assessed during the sites monthly Quality Management Review process. This assures the site actively manages the capability to respond to deviations. Therefore, no further action is required by the UK Speke Site at this time.

## 10 Complaints (Product Quality) – N/A

Section 10 is not applicable.

## 11 Recalls, Stock recoveries, Field Alerts

Section 11 is not applicable.

## 12 Returned and salvaged goods (US products only)

Section 12 is not applicable.

## 13 Contractual agreements / arrangements

Standard Internal and Marketing Company Quality Assurance Agreements are set up in accordance with 6-P1-cv-M, Internal Quality Assurance Agreements (QAAs). Marketing Authorisation Holder, sites and functions with separately signed QAAs are illustrated in the supply QAA map and listed in the table below.

Table 13: Marketing Authorisation Holder (MAH), sites and functions with separately signed QAAs

| Name of the Contractor/Partner | Reference Number | Comments |
|---|---|---|
| QAA ES&M and Speke Liverpool Bio Ops | AGR-0002584 | Effective |
| Speke and Luton MAH/MC | AGR-0004057 | Effective |
| Speke and Movianto, Netherlands | MOVNL/001 | Effective |
| Speke and Movianto, UK | Movuk001 | Effective |
| SBC and Speke | AGR-0004095 | Effective |
| MC QAA Canada and MedImmune Speke | AGR-0006220 | Effective |
| QAA Speke and AZ Switzerland MAH_MC | AGR-0006755 | Effective |
| QAA Speke and AZ Thailand Ltd MAH_MC | AGR-0006756 | Effective |

**Conclusion:**

AGR-0002484 has been retired following the divestment of AZ West Chester to a CMO (as detailed in QE-032815) and is now managed under AGR-0002584 (QAA ES&M and Speke Liverpool Bio Ops).
All contractual agreements between the site and customers or suppliers have been reviewed and are current.

## 14 Qualification status of relevant Equipment and Utilities (EU requirement)

Table 14: Validation of QC Equipment (Speke)

| Equipment | Documentation Reference | Title | Date |
|---|---|---|---|
| FR-8901 | PRO-0184985 | Revalidation of FR-8901 | 30 Nov 2022 |
| IN-8940 | PRO-0185159 | Revalidation of IN-8940, VL-500800 | 18 Nov 2022 |
| IN-8941 | PRO-0185160 | Revalidation of IN-8941 | 18 Nov 2022 |
| IN-8944 | PRO-0185161 | Revalidation of IN-8944 | 29 Nov 2022 |
| IN-8945 | PRO-0185162 | Revalidation of IN-8945 | 29 Nov 2022 |
| LE-9927 | PRO-0185625 | Qualification event for the addition of ELSD detector to LE-9927 | 12 Dec 2022 |
| LE-9938 | PRO-0185630 | Qualification event for the addition of an ELSD detector for LE-9938 VL- | 12 Dec 2022 |

| | | | |
|---|---|---|---|
| | | 500949 | |
| LE-9945 | PRO-0186680 | IOQ Addendum MALDI Biotyper, LE-9945 | 23 Nov 2022 |
| RG-9009 | PRO-0184988 | Revalidation of RG-9009 VL-500817-RV2 | 14 Dec 2022 |
| RG-9012 | PRO-0187287 | OQ Addendum for the Refrigerator RG-9012 | 07 Dec 2022 |
| FR-8963 | PRO-0185790 | IOQ PHCbi Low Freezer, FR-8963 | 29 Dec 2022 |
| FR-8964 | PRO-0185965 | IOQ PHCbi Low Freezer, FR-8964 | 29 Nov 2022 |
| FR-8965 | PRO-0185966 | IOQ PHCbi Low Freezer, FR-8965 | 01 Dec 2022 |
| FR-8966 | PRO-0185969 | IOQ PHCbi Low Freezer, FR-8966 | 02 Dec 2022 |
| FR-8967 | PRO-0185970 | IOQ PHCbi Low Freezer, FR-8967 | 05 Dec 2022 |
| RG-9035 | PRO-0185715 | IOQ of the PHCbi Refrigerator, RG-9035, | 29 Nov 2022 |
| BC-8650 | PRO-0187103 | Re-qualification of BC-8650 VL-500117-RV21 | 07 Feb 2023 |
| CR-8700 | PRO-0192235 | Requalification of the Vindon Lab Cold Store 5 °C 2003, CR-8700, EQUIP-011169, VL-500253 | 01 Sep 2023 |
| ER-8745 | PRO-0190611 | Revalidation of Walk-in room ER-8745 | 24 Aug 2023 |
| FR-8729 | PRO-0187259 | Revalidation for the New Brunswick Freezer FR-8729 | 27 Jan 2023 |
| FR-8899 | PRO-0186580 | Revalidation for Panasonic Ultra Low Temperature Freezer FR-8899 VL-500819-RV2 | 16 Mar 2023 |
| FR-8906 | PRO-0192054 | Requalification of Freezer ID No. FR-8906 | 28 Sep 2023 |
| FR-8911 | PRO-0182191 | Requalification of freezer FR-8911 | 09 Oct 2023 |
| FR-8926 | PRO-0189628 | Revalidation of FR-8926 | 30 Mar 2023 |
| FR-8928 | PRO-0192116 | Requalification of Freezer ID No. FR-8928 | 20 Oct 2023 |
| FR-8931 | PRO-0195498 | Periodic Re Qualification of Freezer FR-8931 | 09 Oct 2023 |
| FR-8932 | PRO-0195770 | Periodic Requalification of FR-8932 | 31 Oct 2023 |
| FR-8934 | PRO-0190485 | Revalidation of Freezer ID No. FR-8934 | 26 May 2023 |
| FR-8949 | PRO-0186625 | Revalidation of FR-8949 | 11 Apr 2023 |
| IN-8550 | PRO-0190993 | Re-qualification Incubator IN-8550 | 30 Jun 2023 |
| IN-8735 | PRO-0189023 | Revalidation of IN-8735 VL-500274-RV5 | 17 Mar 2023 |
| IN-8821 | PRO-0188842 | Revalidation of Incubator IN8821 VL-500244-RV5 | 30 Mar 2023 |
| IN-8822 | PRO-0189367 | Revalidation of IN-8822 | 30 Mar 2023 |
| IN-8854 | PRO-0100181 | Revalidation for the Binder Oven, Identification Number IN-8854 | 14 Apr 2023 |
| IN-8829 | PRO-0189683 | OQ Addendum for the Thermo Scientific Heratherm Incubator. Identification Number IN-8829 | 31 Mar 2023 |
| IN-8881 | PRO-0192223 | Requalification of the Thermo Fisher Heracell Incubator IN-8881, EQUIP-011321, VL-500160 | 01 Sep 2023 |

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|---|---|---|---|
| IN-8883 | PRO-0188043 | IN-8883 OQ Addendum, VL-500450-OQ-A1 | 25 Jan 2023 |
| IN-8884 | PRO-0195933 | Periodic Requalification of IN-8884 | 17 Oct 2023 |
| IN-8947 | PRO-0184989 | Revalidation of IN-8947 VL-500807-RV2 | 30 Mar 2023 |
| IN-8948 | PRO-0184987 | Revalidation of IN-8948 VL-500808-RV2 | 30 Mar 2023 |
| IN-8949 | PRO-0185163 | Revalidation of IN-8949 VL-500809-RV1 | 22 Mar 2023 |
| IN-8950 | PRO-0185164 | Revalidation of IN-8950 | 21 Mar 2023 |
| IN-8951 | PRO-0185165 | Revalidation of IN-8951 | 27 Mar 2023 |
| IN-8952 | PRO-0186574 | Revalidation of IN-8952 | 20 Mar 2023 |
| IN-8953 | PRO-0186576 | Revalidation of IN-8953 | 18 Jan 2023 |
| IN-8954 | PRO-0184986 | Revalidation of IN-8954 VL-500831-RV2 | 02 Mar 2023 |
| IN-8955 | PRO-0188844 | Revalidation of IN-8955 VL-500839-RV2 | 10 Mar 2023 |
| IN-8946 | PRO-0184984 | Revalidation of IN-8946 VL-500806-RV2 | 07 Mar 2023 |
| IN-8960 | PRO-0188517 | OQ Addendum for the Oven IN-8960 | 23 Mar 2023 |
| LE-9928 | PRO-0188505 | IOQ Addendum 2 for the Perkin Elmer Envision Plate Reader, Identification number LE-9928 (VL-500906-IOQ-A2) | 21 Jun 2023 |
| LE-9939 | PRO-0188887 | Windows 10 Upgrade of the Beckman Coulter HIAC 9703+, LE9939, EQUIP-011441 | 31 Jul 2023 |
| LE-9952 | PRO-0187896 | IOQ for the Amersham 800 Image Quant for use in QC AMB | 23 Feb 2023 |
| LE-9952 | PRO-0189044 | Performance Qualification Protocol Addendum for the Image Quant 800 LE-9952 (VL-501173-PQP A1) | 04 May 2023 |
| LE-9953 | PRO-0187897 | IOQ for the Amersham 800 Image Quant for use in QC Biosafety | 22 Feb 2023 |
| LE-9953 | PRO-0189048 | Performance Qualification Protocol for the Amersham Image Quant 800 LE-9953 | 12 Apr 2023 |
| RG-9008 | PRO-0185038 | Revalidation for RG-9008 | 13 Mar 2023 |
| RG-9010 | PRO-0195480 | Periodic Re-Qualification Event of refrigerator RG-9010 | 29 Sep 2023 |
| RG-9023 | PRO-0195768 | Periodic Requalification of RG-9023 | 20 Oct 2023 |
| RG-9024 | PRO-0190444 | RG-9024 Re-Qualification | 24 May 2023 |
| RG-9025 | PRO-0190339 | RG-9025 Re-Qualification | 23 May 2023 |
| LE-9961 | PRO-0187569 | IOQ for the MCS NEXGEN MULTI CARTRIDGE READER, LE-9961. | 25 Jan 2023 |
| IN-8974 | PRO-0187773 | IOQ of the Binder Incubator, IN-8974 | 09 Jan 2023 |
| BC-8620 | PRO-0190833 | Qualification of the BioMAT 2, Class 2 BSC (BC8620) within the PCR Laboratory, Room 1-78 | 10 Oct 2023 |
| BC-8622 | PRO-0190828 | Qualification of the BioMAT 2, Class 2 BSC (BC8622) within the PCR Laboratory, Room 1-78 | 04 Oct 2023 |
| IN-8977 | PRO-0191900 | IOPQ of the Binder Incubator, IN- | 01 Sep 2023 |

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|---|---|---|---|
| | | 8977 | |
| IN-8978 | PRO-0192073 | IOPQ of the Binder Incubator, IN-8978 | 01 Sep 2023 |
| IN-8979 | PRO-0191674 | IOQ of the Binder Incubator, IN-8979 | 01 Sep 2023 |
| IN-8980 | PRO-0191687 | IOPQ of the Binder Incubator, IN-8980 | 31 Aug 2023 |
| IN-8981 | PRO-0195718 | IOPQ of the Thermo Fisher Incubator, IN-8981 | 27 Oct 2023 |
| FR-8968 | PRO-0191886 | IOPQ of the PHCbi Freezer, FR-8968 | 23 Aug 2023 |
| FR-8969 | PRO-0191887 | IOPQ of the PHCbi Freezer, FR-8969 | 23 Aug 2023 |
| IN-8982 | PRO-0195846 | IOPQ of the Thermo Fisher Heracell Incubator, IN-8982 | 24 Oct 2023 |
| IN-8983 | PRO-0195850 | IOPQ of the Thermo Fisher Heracell Incubator, IN-8983 | 24 Oct 2023 |

**Conclusion:**

Qualification and validation activities performed at Speke have been reviewed and demonstrate that the systems are operating in a state of control.

## 15 Other

Table 15: Summary of any unacceptable retain/reserve inspections:

| Batch Number | Date of Manufacture | Reason/comment | Reference No. |
|---|---|---|---|
| Not Applicable | Not Applicable | Not Applicable | Not Applicable |

**Effectiveness of corrective and preventive actions taken:**

None required.

**Conclusion:**

Inspection of Reserve and Retain samples has confirmed that all batches delivered continue meet the registered specification.

## 16 Enclosures, Appendices

### Appendix 1: List of Batches Released in review Period

**PQR Fasenra 14 Nov 2022 – 13 Nov 2023**

| Number | Material | Material Description | Market | Presentation | Batch | Date of Disposition | Status |
|---|---|---|---|---|---|---|---|
| 1 | 100011765 | FASENRA INJ 30MG PFS 1X1ML GB | Great Britain | APFS | PL0124 | 17Nov22 | Approved |
| 2 | 100012382 | FASENRA PEN INJ 30MG AI 1X1ML GB | Great Britain | AI | PN0122 | 01Feb23 | Approved |
| 3 | 100012382 | FASENRA PEN INJ 30MG AI 1X1ML GB | Great Britain | AI | TA0163 | 25Apr23 | Approved |
| 4 | 100012382 | FASENRA PEN INJ 30MG AI 1X1ML GB | Great Britain | AI | TB0107 | 28Jun23 | Approved |
| 5 | 100012382 | FASENRA PEN INJ 30MG AI 1X1ML GB | Great Britain | AI | TJ0178 | 02Oct23 | Approved |
| 6 | 100012382 | FASENRA PEN INJ 30MG AI 1X1ML GB | Great Britain | AI | TJ0043 | 09Oct23 | Approved |

Document Approvals

| | |
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