Performance Analysis Report

**Product:** Actemra DS\_tocilizumab G5.2 (SC)

**Site:** OCN

**Author:** Yiming Peng

**Email Address:** [pengy12@gene.com](mailto:pengy12@gene.com)

**Date:** 03 October, 2017

**Report ID:** 000596

**Analysis Period:** 01-Jan-2016 To 31-Dec-2016

**Analysis Date Type:** Sampling

##### .

## 1. PURPOSE

This performance analysis report summarizes the statistical analysis and evaluation of historical batch results for selected critical quality attributes (CQAs) for Actemra DS\_tocilizumab G5.2 (SC) at OCN.

The objective of performance analysis is to identify and prioritize potential supply chain interruption risks resulting from production of non-conforming lots in its pharmaceutical manufacturing network. This approach focuses on the proactive identification of opportunities for improvements through statistical analysis and evaluation of products’ historical results for critical quality attributes (CQAs) relative to their corresponding release criteria.

## 2. PERFORMANCE ANALYSIS

The PPMP and the strategy document are the source of CQAs defined for PA for each product.

**Table 1. Selected CQA Release Specifications for Actemra DS\_tocilizumab G5.2 (SC) at OCN**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Product | Attribute Name | LSL | USL | Unit |
| Actemra DS\_tocilizumab G5.2 (SC) | CE-SDS\_Main\_Peak | 95 | NA | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | CE-SDS\_Other | NA | 1 | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | IC\_Arg | 75 | 125 | MMOL\_L |
| Actemra DS\_tocilizumab G5.2 (SC) | IC\_His | 15 | 25 | MMOL\_L |
| Actemra DS\_tocilizumab G5.2 (SC) | IC\_Met | 22 | 38 | MMOL\_L |
| Actemra DS\_tocilizumab G5.2 (SC) | IEC\_1Q-H\_Peak | NA | 15 | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | IEC\_Main\_Peak | 50 | NA | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | IEC\_Other | NA | 3 | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | IEC\_Pre-Peak | NA | 25 | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | IEC\_R-1\_Peak | NA | 3 | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | IEC\_Sub-1\_Peak | NA | 20 | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | IEC\_Sub-2\_Peak | NA | 10 | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | pH | 5.5 | 6.5 | NONE |
| Actemra DS\_tocilizumab G5.2 (SC) | Potency\_Bioassay | 0.7 | 1.3 | 10E3U\_MG |
| Actemra DS\_tocilizumab G5.2 (SC) | Protein\_Conc | 162 | 198 | MG\_ML |
| Actemra DS\_tocilizumab G5.2 (SC) | PS\_80 | 0.1 | 0.3 | MG\_ML |
| Actemra DS\_tocilizumab G5.2 (SC) | SEC\_Dimer | NA | 1.3 | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | SEC\_Monomer | 98 | NA | PERCENT |
| Actemra DS\_tocilizumab G5.2 (SC) | SEC\_Other | NA | 0.5 | PERCENT |

The production period selected for performance analysis are listed in Table below. These timeframes represent all available data at the time from [LIMS, data source].

**Table 2. Date Range in Performance Analysis**

|  |  |  |  |
| --- | --- | --- | --- |
| Product | Analysis Year | Date Range | Number of Batches |
| Actemra DS\_tocilizumab G5.2 (SC) | 2016 | 2016-01-01 To 2016-08-11 | 96 |

The Method Monitoring data used for Rho calculation is from Analysis Year 2016 .

##### .

**Table 3. Performance Analysis Summary for Actemra DS\_tocilizumab G5.2 (SC)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Attribute | 2015 APQR Rpk \* | 2016 APQR Rpk | SME Assigned Risk | Overall OOS | Rationale for SME Assigned Risk | Recommended action |
| Potency\_Bioassay | Invalid APQR year | 0.61 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| pH | Invalid APQR year | 0.47 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IEC\_Pre-Peak | Invalid APQR year | 0.35 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| PS\_80 | Invalid APQR year | 0.28 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IC\_His | Invalid APQR year | 0.23 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IC\_Arg | Invalid APQR year | 0.22 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| CE-SDS\_Main\_Peak | Invalid APQR year | 0.21 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| Protein\_Conc | Invalid APQR year | 0.21 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IC\_Met | Invalid APQR year | 0.20 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IEC\_1Q-H\_Peak | Invalid APQR year | 0.20 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IEC\_Main\_Peak | Invalid APQR year | 0.20 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IEC\_R-1\_Peak | Invalid APQR year | 0.15 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IEC\_Sub-1\_Peak | Invalid APQR year | 0.10 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| CE-SDS\_Other | Invalid APQR year | 0.09 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IEC\_Other | Invalid APQR year | 0.08 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| IEC\_Sub-2\_Peak | Invalid APQR year | 0.06 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| SEC\_Dimer | Invalid APQR year | 0.04 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| SEC\_Monomer | Invalid APQR year | 0.02 | [assign risk] | 0.000 | [insert rationale] | [insert action] |
| SEC\_Other | Invalid APQR year | 0.00 | [assign risk] | 0.000 | [insert rationale] | [insert action] |

The \* indicates number of batches N < 20

[add notes as needed]

[Please change this page orientation to the landscape and delete this sentence.]

##### .

## 3. APPENDIX:

