**APQR Report** [APQR Report Reference Number]

**PRODUCT** [Name, Dosage Form, Strength, Product Code, APQR Reference Number]

**REVIEW PERIOD** [DD.MM.YYYY-DD.MM.YYYY]

**Document approval**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Date** | **Signature** |
| **Reviewer’s designation**  **e.g., QC Head** |  |  |  |
| **Reviewer’s designation**  **e.g., Manufacturing Head** |  |  |  |
| **Reviewer’s designation**  **e.g., Regulatory Affairs Head** |  |  |  |
| **Reviewer’s designation**  **Qualified Person** |  |  |  |
| **Approver’s designation**  **e.g., Quality Management Director** |  |  |  |

**Table of Contents**

[1 General Information 3](#_Toc125733713)

[2 Summary 3](#_Toc125733714)

[3 Activities from previous APQR 3](#_Toc125733715)

[4 Conclusions and recommendations 3](#_Toc125733716)

[5 Starting Materials 3](#_Toc125733717)

[5.1 New Material sources 3](#_Toc125733718)

[5.2 List of Components 3](#_Toc125733719)

[6 Manufacturing 3](#_Toc125733720)

[6.1 Batches manufactured 3](#_Toc125733721)

[6.2 Rework or reprocessing 4](#_Toc125733722)

[7 Data analysis and trending 4](#_Toc125733723)

[7.1 Testing Monographs 4](#_Toc125733724)

[7.2 Evaluation and assessment of analytical results 4](#_Toc125733725)

[8 Deviations and Nonconformities 4](#_Toc125733726)

[8.1 Deviations and Nonconformities overview 4](#_Toc125733727)

[8.2 Deviations and Nonconformities list 4](#_Toc125733728)

[9 Out-of-Specification results 5](#_Toc125733729)

[10 Process and Analytical Changes 5](#_Toc125733730)

[10.1 Starting Materials changes 5](#_Toc125733731)

[10.2 Manufacturing Process changes 5](#_Toc125733732)

[10.3 Analytical changes 5](#_Toc125733733)

[11 Qualification status of relevant equipment and utilities 5](#_Toc125733734)

[12 Validation 5](#_Toc125733735)

[13 Quality agreements 6](#_Toc125733736)

[14 Stability program 6](#_Toc125733737)

[15 Medical Complaints (Adverse Events) 6](#_Toc125733738)

[16 Technical Complaints (Supply Chain) 6](#_Toc125733739)

[17 Returned Products 6](#_Toc125733740)

[18 Recalls and Rapid Alert Notifications 7](#_Toc125733741)

[19 Marketing Authorization variations and post-marketing commitments 7](#_Toc125733742)

[19.1 Marketing Authorization variations 7](#_Toc125733743)

[19.2 Post-marketing commitments 7](#_Toc125733744)

# General Information

# Summary

# Activities from previous APQR

# Conclusions and recommendations

# Starting Materials

## New Material sources

*Table 1: New sources of Starting Materials*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Material Number** | **Material Name** | **Supplier Number** | **Supplier Name** | **Manufacturer Number** | **Manufacturer Name** | **Manufacturer Status** | **Last Audit Date** |
|  |  |  |  |  |  |  |  |

## List of Components

*Table 2: Raw material received*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Material number** | **Material Name** | **Manufacturer Number** | **Manufacturer Name** | **Manufacturer Status** | **Number of batches Received** | **Number of batches rejected** | **Audit information** |
|  |  |  |  |  |  |  |  |

# Manufacturing

## Batches manufactured

*Table 3: Batches manufactured*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Material Number** | **Material Name** | **No of Batches Manufactured** | **No Batches Released** | **No of Batches Rejected** | **No of Batches Aborted** | **Comment / Remark** |
|  |  |  |  |  |  |  |

## Rework or reprocessing

*Table 3: Batches manufactured*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Material Number** | **Material Name** | **Batch Number** | **Description of the Rework / Reprocess Operation** | **Procedure Reference** | **Material Status** | **Deviation reference** |
|  |  |  |  |  |  |  |

# Data analysis and trending

## Testing Monographs

*Table 4: Testing Monographs*

|  |  |  |  |
| --- | --- | --- | --- |
| **Material Name** | **Material Number** | **Document Code** | **Implementation Date** |
|  |  |  |  |

## Evaluation and assessment of analytical results

Analytical results evaluation review

# Deviations and Nonconformities

## Deviations and Nonconformities overview

*Table 5: Deviations and Nonconformities overview*

|  |  |  |
| --- | --- | --- |
| **Material Number** | **Material Name** | **Number of Deviations and Nonconformities Closed during the Review Period** |
|  |  |  |

## Deviations and Nonconformities list

*Table 6: Deviations* *and Nonconformances list*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Material Number** | **Material Name** | **Deviation Ref.** | **Short Description** | **CAPA Ref.** | **CAPA Short Description** | **CAPA Due Date** | **CAPA Status** | **Effective ness Assessment** |
|  |  |  |  |  |  |  |  |  |

# Out-of-Specification results

*Table 7: Out-of-Specification results*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Material Number** | **Material Name** | **OOS Ref.** | **Short Description** | **Deviation Ref.** |
|  |  |  |  |  |

# Process and Analytical Changes

## Starting Materials changes

*Table 8: Summary of Starting Material changes*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Change Number** | **Change Type** | **Short description** | **Date of approval** | **Status** | **First batch affected / Implementation date** |
|  |  |  |  |  |  |

## Manufacturing Process changes

*Table 9: Summary of Manufacturing Process changes*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Change Number** | **Change Type** | **Short description** | **Date of approval** | **Status** | **First batch affected / Implementation date** |
|  |  |  |  |  |  |

## Analytical changes

*Table 10: Summary of analytical changes*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Change Number** | **Change Type** | **Short description** | **Date of approval** | **Status** | **First batch affected / Implementation date** |
|  |  |  |  |  |  |

# Qualification status of relevant equipment and utilities

*Table 11: Summary of qualified equipment & utilities*

|  |  |  |  |
| --- | --- | --- | --- |
| **Equipment / Utility** | **Qualification Status** | **Year of last qualification review** | **Changes / Deviations** |
|  |  |  |  |

# Validation

*Table 12: Summary of Process validation status*

|  |  |  |  |
| --- | --- | --- | --- |
| **Process step** | **Validation document reference** | **Validation Date** | **Status** |
|  |  |  |  |

# Quality agreements

*Table 13: Quality (technical) agreements list*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Contractor/ Agreement scope** | **Reference number** | **Date of Review** | **Valid (yes/no)** | **Comment** |
|  |  |  |  |  |

# Stability program

*Table 14: Results of the stability monitoring program*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Material name** | **Material number** | **Batch number** | **Sample storage date** | **Planned duration** | **Storage conditions** | **Current status** | **Study reference number** |
|  |  |  |  |  |  |  |  |

# Medical Complaints (Adverse Events)

Adverse Events Complaints review summary

# Technical Complaints (Supply Chain)

*Table 15: Technical complaints*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Complaint ID** | **Short Description** | **Root cause** | **Country** | **Material Number** | **Material Name** | **Batch Number** | **CAPA** | **CAPA short description** | **CAPA**  **Status** |
|  |  |  |  |  |  |  |  |  |  |

# Returned Products

*Table 16: Summary of returns*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Material Name** | **Material Number** | **Batch Number** | **Reason** | **Final use status** |
|  |  |  |  |  |

# Recalls and Rapid Alert Notifications

*Table 17: List of Rapid Alert Notifications, Withdrawals, Recalls*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Activity Category** | **Type / Number** | **Date Issued** | **Summary** | **Lot Number(s)** | **CAPA** |
| Rapid Alert Notifications |  |  |  |  |  |
| Withdrawals |  |  |  |  |  |
| Recalls |  |  |  |  |  |

# Marketing Authorization variations and post-marketing commitments

## Marketing Authorization variations

*Table 18: Marketing Authorization variations list*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variation description** |  | | | |
| Countries | Submitted (Yes/No) | Granted (Yes/No) | Rejected (Yes/No) | Reason for rejection |
|  |  |  |  |  |

## Post-marketing commitments

*Table 19: Post-marketing commitments list*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No** | **Commitment description** | **Heath Authority** | **Comment** | **Status** |
|  |  |  |  |  |