**<company name and address>**

**<YEAR> Annual Product Quality Review - Summary**

**Product**:

**Article code(s)**:

**Review period:**

**I. SIGNIFICANT OR CONTINUING ADVERSE TRENDS**

*(Example language; to be replaced with the actual content) There are no significant or continuing adverse trends for this product.*

**II. SUMMARY OF SIGNIFICANT DEVIATIONS**

*(Example language; to be replaced with the actual content)*

*<Article code>; batch CW6348 was restricted to reprocessing (PSD OOS).*

*<Article code>; batch DX0679 was rejected (wire pieces from broken metal sieve screen).*

**III. VALIDATION**

*(Example language; to be replaced with the actual content) Based on a review of the information presented in this APQR and in the change control and deviation systems, it is concluded that the process remains in a state of control.*

**IV. ACTION ITEMS FROM PREVIOUS APQR**

*(Example language; to be replaced with the actual content) One (1) action item from the previous review period remains open and will be followed up in the next review period.*

**V. SUMMARY OF RECOMMENDATIONS/FOLLOW UP ITEMS**

*(Example language; to be replaced with the actual content) Eight (8) action items from the current review period remain open and will be followed up in the next review period.*

**VI. OTHER RELEVANT ITEMS**

*(Example language; to be replaced with the actual content) None to be reported.*

**VII. CONCLUSIONS**

*(Example language; to be replaced with the actual content) Based on the Annual Product Quality Review the overall process and product are determined to have remained in a validated state of control. Aside from any recommendations indicated in the above****,*** *it is the conclusion of this review that no additional changes in product specifications or**manufacturing or control procedures are needed at this time.*

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<**author name and title**>