# Annual Product Quality Review (APQR) - US Template

Manufacturer: Bayer

Product: Aspirin 325 mg - Tablet

Review Period: [Start Date] to [End Date]

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Prepared by: [Name, Function] Date: [dd-mmm-yyyy]

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## 1. Objective and Scope

State the objective of the APQR and the scope (sites, markets, strengths, dosage forms).

## 2. Product Identification & Background

Product name, brand, generic, registration/licence numbers, formulation summary, pack sizes, shelf life, storage conditions, and manufacturing sites.

## 3. Executive Summary

High level summary of manufacturing performance, quality status, and any major issues during the review period.

## 4. Manufacturing & Batch Records Summary

Number of batches manufactured, yields, reworks, rejections, deviations per batch, critical process parameter summary. Include table(s).

[Insert Batch Summary Table / Link to Appendix A]

## 5. Quality Control / QC Results Summary

Summary of analytical results, conformance to specification, OOS/OOT results and their disposition.

[Insert QC Summary Table / Link to Appendix B]

## 6. Trend Analysis and Statistical Review

Statistical analysis of key quality attributes, control charts, impurity trends, assay degradation, dissolution trends etc. Attach charts in appendix.

[Insert Trend Charts / Link to Appendix C]

## 7. Deviations, OOS/OOT and CAPA Summary

Summarize major deviations, OOS/OOT investigations, CAPA status, effectiveness checks and timelines.

[Insert Deviations & CAPA Table / Link to Appendix D]

## 8. Stability Program and Results

Summarize ongoing stability program, any failures or out-of-trend results, proposed or executed stability actions.

[Insert Stability Summary / Link to Appendix E]

## 9. Supplier and Materials Review

Review of critical starting materials, API and excipient supplier performance, change notifications, supplier audits.

[Insert Supplier Performance Table / Link to Appendix F]

## 10. Change Control and Regulatory Commitments

List of all change controls affecting the product, post-approval commitments and regulatory variations during the review period.

## 11. Validation and Equipment Qualification Summary

Process validation status, cleaning validation, analytical method revalidations, equipment qualification activities and outcomes.

## 12. Complaints, Recalls and Market Actions

Summary of product complaints, field actions, recalls, medical information trends and any market surveillance data.

## 13. Inspection and Audit Findings

Summary of any regulatory inspections, internal/external audits, observations and closure status.

## 14. Conclusions and Recommendations

Overall suitability of current specifications and controls, recommendation for revalidation, specification changes, supplier changes or other quality improvements.

## 15. Action Plan (Owners & Timelines)

Table of required actions, owners, target due dates and status.

[Insert Action Plan Table / Link to Appendix G]

## 16. Appendices / Attachments

Appendix A: Batch Summary Table  
Appendix B: QC Data  
Appendix C: Trend Charts  
Appendix D: Deviations & CAPA Details  
Appendix E: Stability Data  
Appendix F: Supplier Performance  
Appendix G: Action Tracking Log  
Appendix H: Relevant SOPs and References

## Regulatory & Standards Notes (tailored)

Template aligned with US FDA expectations (21 CFR 211.180(e)). Include review of production and control records, returned or salvaged product reviews, and trend analysis as applicable. Reference: 21 CFR Part 211, ICH Q7/Q9/Q10.

## Template Checklist

* Cover page with manufacturer, product, review period, and approvals
* Batch count and yield summary
* QC pass/fail and OOS/OOT disposition summaries
* Trend charts for key attributes
* Summary of deviations and CAPAs with effectiveness
* Stability trending and proposed actions
* Supplier performance review
* Change controls and regulatory commitments list
* Validation & qualification summary
* Appendix with raw data and charts
* Signature block and document control metadata

## Document Control

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Distribution: QA, Site Head, Manufacturing, QC, Regulatory Affairs, Supply Chain