

Standard Operating Procedure

Title: Annual Product Review

Department	Quality Management	Document no	QMS-060
Prepared by:		Date:	Supersedes:
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Document Owner

Quality Assurance Manager

Affected Parties

All Quality Assurance, Technical Service, Laboratory and operation's colleagues

Purpose

This procedure provides a guideline to annual product review which is required to be performed for each product produced for the commercial market to evaluate data, trends and to identify any preventative or corrective action that would lead to product quality improvements and report them to management.

Scope

An APR will be required for all products manufactured or packed. Contract manufacturers should have a comparable system of product review and this will be checked during periodic audits.

Definition

N/A	
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Related Documents

N/A	
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EHS Statement

There is no EHS impact.

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Procedure

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- The QA manger or the delegate will provide a summery report of Deviation Reports. In addition the QA department will provide any reworks/ reprocessed / returned drug products and salvaged materials for the review period, number of lots produced, rejected or uncompleted (including partial lot rejection) and the list of lot numbers reviewed in the APR.
- The laboratory manager or delegate will provide the raw materials control information, all finished product release and stability test results, Deviation report summaries and retention sample review results. The laboratory manger will also provide information on all relevant method validation activities.
- The technical service manager or delegate will provide a summery of the manufacturing /packaging validation activities and an evaluation of critical equipment changes during the review period. These evaluations must assess the impact of changes on the product. Technical service will also be responsible for summarizing change control information and investigations not captured in the discussion of Deviation reports.
- The engineering manager or delegate will provide summery data on equipment evaluation carried out by engineering department. This data must be accompanied by an assessment of the impact on the product.
- The operations manager or delegate will provide information on all recalls executed and product complaints received during the review period for the product under evaluation together with a summery of correspondence conducted with regulatory bodies.
- The Operations manager or delegate will provide a list of lots assigned for manufacture during the review period, lot yielded data, in-process results and product reconciliation information
- The regulatory manager will provide a summery of regulatory changes or requirements for the review period that affected the product.

3. APR report evaluation and final Report retention- Responsibilities

- The QA staff will circulate the APR draft report to the appropriate department manager or designee for review and comments as follows
 - QA
 - Regulatory
 - Manufacturing
 - Technical Service
 - Laboratory
 - Other support department as applicable
- Comments and/or recommendations must be addressed to the QA staff on or before the next scheduled quality meeting. The recommendations will be assessed in the meeting and included in the APR if necessary.
- A summery of the APR report should be presented to the management team for review and approval. The summery should be attached to the final report for filing.
- The QA department should track completion of the recommendations.

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<ul style="list-style-type: none"> List of active ingredients and excipients with their specifications and test report, issue number, approved manufacturer or supplier, implementation date, and source of change. 	<p>progress during the review period.</p> <ul style="list-style-type: none"> Stability data from laboratory 		
<p>Validation</p> <ul style="list-style-type: none"> Gather information regarding periodic maintenance of critical systems and equipments Identify lots manufactured after significant changes and assess the change in quality 	<ul style="list-style-type: none"> Validation reports (Technical Service and Laboratory) Maintenance of equipments (Engineering) Assess the changes made to critical process parameters, equipments, facilities, and utilities 	None	Tabulate and/or summarize
<p>Product recall and returned goods evaluation</p>	<ul style="list-style-type: none"> Review relevant Deviation Reports. If applicable Obtain a list of returned goods from QA department 	None	Tabulate and/or summarize
<p>Deviations</p> <ul style="list-style-type: none"> Deviation number, lot number, Date issued/closed, category, stage, deviation description Evaluate and denote the corresponding section of the APR that reports any trend in deviations. 	<ul style="list-style-type: none"> Batch records Packaging records Obtain the summary of deviations that includes all investigations during the review period 	<ul style="list-style-type: none"> Pareto Analysis Pie chart 	Tabulate and/or summarize
<p>Analytical Results – results listed include but not limited to:</p> <ul style="list-style-type: none"> Assay test %RSD %LOD identify lots released, pending, cancelled, rejected, validation Intermediate and finished product test results Evaluate trends Comparison of results against limits 	<ul style="list-style-type: none"> C of A Raw Material specification and test report Finished Product Specification and Test Report Controlled methods 	<ul style="list-style-type: none"> Average Range Standard deviation Process capability analysis providing the results are normally distributed. Graph results Slope 	Tabulate and/or summarize

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<p>evaluation</p>	<p>evaluation conducted for critical equipment during the review period from the Technical Service and engineering department.</p>	<p>None</p>	<p>Tabulate and/or summarize</p>
<p>Regulatory compliance</p> <ul style="list-style-type: none"> • Review any commitment pending from the previous period • Evaluate corrective actions for closure 	<ul style="list-style-type: none"> • Review available information regarding regulatory filing changes, inspection observations, Product certifications as applicable. 	<p>None</p>	<p>Tabulate and/or summarize</p>
<p>Evaluation/recommendation and/or comments</p> <ul style="list-style-type: none"> • Evaluate all information obtained during the APR preparation • Present if product quality characteristics shows a particular trends • Comment on activities, accomplishments, enhancement conducted during the review period, if any • Determine the need for changes, if any based on the report evaluation • If changes are recommended as a result of this evaluation they should be minimally agreed by the site management team. 	<ul style="list-style-type: none"> • Previous APR • Documents reviewed • Management evaluation 	<p>N/A</p>	<p>Tabulate and/or summarize</p>

5. Summary of Changes

Version #	Revision History
QMS-060	New