1.0 PURPOSE

1.1 To provide guidelines for conducting

1.1.1 an annual Product Quality Review

1.1.2 an annual review of quality metrics

2.0 SCOPE

2.1 Applies to the annual product review of {*products*} manufactured by {*Company*}.

2.2 Applies to purified water systems used to manufacture {*products*}.

2.3 Applies to periodic review of the following quality metrics:

2.3.1 Deviations

2.3.2 OOS investigations

2.3.3 Customer complaints

2.3.4 Internal audit observations

3.0 GENERAL

3.1 The Code of Federal Regulations 21 CFR 211.180(e) recommends quality reviews at least annually. The specific issues to be reviewed are included in section 5.0 of this SOP.

4.0 RESPONSIBILITIES

4.1 Quality Assurance conducts and documents the annual reviews

4.2 Management approves the reports

5.0 PROCEDURE

5.1 Prior to data analysis, spreadsheets used to collect data from production records for each product shall be verified for accuracy.

5.2 The following areas shall be reviewed:

5.2.1 Number of batches manufactured and their yields

5.2.2 Critical process parameters,

5.2.3 In-process and finished test results,

5.2.4 Change control documents (process, analytical methods, raw materials, container/ closure system, etc.)

5.2.5 Rework or reprocessed batches

5.2.6 Complaints and returned goods

5.2.7 Rejected batches

5.2.8 Deviation or Non-conformance including (OOS) reports

5.2.8.1 Adequacy of corrective actions should be assessed

5.2.9 Master formula changes or modifications

5.2.10 Approved vendors used for raw materials

5.2.11 Cleaning Validation and annual assessment

5.2.12 Stability summary

5.2.13 Retained samples

5.2.13.1 Samples should be reviewed for deterioration as per 21 CFR 211.170(b)

5.2.14 Validation Status for all product lines

6.0 REPORT CONTENTS – PRODUCT REVIEW

6.1 Executive Summary

6.1.2 The summary should include how many batches were made, any processing changes and how many investigations, complaints and returns occurred throughout the year, and an assessment of whether corrective action or any revalidation studies are needed.

6.2 A summary of each of the items reviewed in section 5.2 should be written.

6.3 Tables

6.3.1 Spreadsheet of data for each product

6.3.2 Stability Summaries for each product

6.4 Charts

6.4.1 Critical parameters should be graphed i.e. yields, assay and/or impurity results etc.

7.0 PURIFIED WATER SYSTEM

7.1 Prior to data analysis, spreadsheets used to collect data from the records for the purified water system shall be verified for accuracy.

7.2 The following areas shall be reviewed:

7.2.1 USP Testing

7.2.2 Microbial Testing

7.2.3 Change control documents (analytical methods, testing procedures, sampling procedures etc.)

7.2.4 Deviations

7.2.5 Out of Specifications

7.2.6 Records for sampling and servicing

8.0 REPORT CONTENTS – PURIFIED WATER REVIEW

8.1 Executive Summary

8.1.1 The summary should include any testing or sampling changes and how many investigations occurred throughout the year, and an assessment of whether corrective action or any revalidation studies are needed.

8.2 A summary of each of the items reviewed in section 7.2 should be written.

8.3 Tables

8.3.1 Spreadsheets of data

8.4 Charts

8.4.1 Critical parameters should be graphed i.e. TOC, pH, and Conductivity.

10.0 ANNUAL REVIEW – QUALITY METRICS

10.1 The following quality metrics will be reviewed and trended at least once per year. The review will be documented in writing.

10.1.1 Internal audit observations

10.1.1.1 Review should look for repeated observations and those not closed before the next audit.

10.1.2 Deviations or Non-Conformances

10.1.2.1 Review should determine the categories of each deviation as per the Deviation SOP as well at the cause (i.e. personnel error, process, etc.)

10.1.3 Out of Specifications

10.1.3.1 Reviews should determine number of OOS results and causes of OOS results.

10.1.4 Customer Complaints

10.1.4.1 Review should include number of complaints as well as number of quality versus business complaints.

10.1.5 Number of batches manufactured

10.1.5.1 Review should include total number of batches made

11.0 Attachments

11.1 Annual Review Checklist – Products

11.2 Annual Review Checklist – Water System

PRODUCT NAME:_____

Completed	Item
	Summary Number of Batches Manufactured:_____ Number of Investigations:_____ Validation Date:_____
	Yield Range Range of Product Yield:_____ Are all batches manufactured within range?_____ List all batches that are not in range?_____ _____ _____
	Test Results Are all in-process and final product results in specification?_____ List all batches that are not in specification:_____ _____ _____ Review impurity data. Any batches have unknown impurities? If yes, list batches _____ _____ Were all unknowns within specification limits?_____
	List all Change Controls for this product: _____ _____ _____

Completed	Item
	_____ _____
	List all Reprocessed/Reworked batches for this product: _____ _____ _____ _____ _____
	List all Customer Complaints batches for this product: _____ _____ _____ _____ _____
	List all Rejected batches for this product: _____ _____ _____ _____ _____
	List all Deviations batches for this product: _____ _____ _____ _____ _____

Completed	Item
	List all Out of Specification (OOS) batches for this product: _____ _____ _____ _____ _____
	List the current version of the batch record for this product: _____ _____ _____ _____ _____
	List all vendors used for raw materials for this product. Review qualifications and make sure they are up to date. _____ _____ _____ _____ _____
	List all Cleaning validations for this product. Have any of the equipment changed since the original validation. Have annual cleaning assessments been conducted to monitor cleaning processes? _____ _____ _____ _____ _____

Completed	Item
	List all completed and on-going stability studies for this product, this year: _____ _____ _____ _____ _____
	Review retain samples for this product: _____ _____ _____ _____ _____

WATER SYSTEM NAME:_____

Completed	Item
	Test Results Are all USP test results in specification?_____ List all samples that are not in specification:_____ _____ _____ Are all microbial test results in specification?_____ List all samples that are not in specification:_____ _____ _____
	List all Change Controls for this system: _____ _____ _____ _____ _____
	List all Deviations for this system: _____ _____ _____ _____ _____
	List all Out of Specification (OOS) results for this system: _____

Completed	Item
	_____ _____ _____ _____
	List date of last validation of this system: _____ _____