Premium Waters, Inc.
bottled water solutions

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SQF Element: 2.2.2 Document Control			

1.0 Purpose

1.1 The purpose of this document is to describe the GOOD LABORATORY PRACTICES (GLP) to be followed to obtain reliable and reproducible results meeting regulatory standards with effective usage of time, manpower, and resources.

1.2

2.0 Scope

2.1 All Premium Waters, Inc. Sites.

2.2 All Premium Waters, Inc. Co-Manufacturing sites.

3.0 Responsibility

3.1 It is the responsibility of each site QA Manager to ensure that the site labs are following the current Good Laboratory Practices.

3.2 It is the responsibility of the Laboratory Director or designee to ensure that the corporate lab is following all applicable GLP.

4.0 Definition

4.1 GLP stands for Good Laboratory Practices

4.2 SOP stands for Standard Operating Procedure

4.3 AHU stands for Air Handling units

4.4 IQ stands for Installation Qualification

4.5 PQ stands for Performance Qualification

4.6 OQ stands for Operations Qualification

5.0 **MISCELLENEOUS**

5.1 Good Laboaratory Practice

5.1.1 Good Laboratory Practices embodies a set of principles that provides a framework within which laboratory studies (Activities) are planned, performed, monitored, recorded, reported, and archived.

5.1.2 GLP helps to assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk based decisions.

5.2 Raw data that may be the results of general observations and other activities.

5.2.1 Raw data refers to the laboratory Worksheet

5.2.2 Notebooks or analysis sheet

5.2.3 Records

5.2.3.1 Handwritten data

5.2.3.2 Electronic data

5.2.4 Memorandums

5.2.5 Notes or Extract copies

5.2.5.1 Handwritten

5.2.5.2 Electronically composed
5.2.6 Photographs
5.2.7 Drawings
5.2.8 Computer Printouts
5.2.9 Charts
5.2.10 Environmental Monitoring
5.2.11 Calibration
5.2.12 Records of instruments / equipment
5.2.13 Integrator output from Analytical equipment

6.0 **PROCEDURE:**

6.1 Quality Management

6.1.1 The attainment of quality objectives, product quality, efficacy, and safety is the responsibility of senior management but requires the participation and commitment of all staff which is vital to the success of the laboratory mission.
6.1.2 There must be comprehensive and effectively implemented Quality Control Systems that should be fully documented, and its effectiveness monitored.
6.1.3 Ensure the Quality Systems should be adequately resourced with competent personnel and proper premises, equipment, and facilities to ensure that the Quality Control Functions is effective at meeting the requirements.
6.1.4 Written Job responsibilities of Quality Control Personnel should be laid out and followed according to GOOD LABORATORY PRACTICES
6.1.5 The structure of the organization which is fundamental to the satisfactory operation of Quality Control should be appropriately defined. See organizational chart for the Central Lab.
6.1.6 The QA Lab should be independent of the production department and warehouse
6.1.7 The QA Lab should be under the authority of a QA Manager for site laboratories and a Laboratory Director for the Central lab.
6.1.7.1 Possess the appropriate qualifications and experience
6.1.7.2 The reporting structure should be aligned to best accomplish regulatory requirements.
6.1.7.3

6.2 REFERENCE DOCUMENTS

6.2.1 N/A

6.3 APPROVALS

APPROVALS:		
Preparer of Document	*Gregory S. Pluimer*	Date:
Quality Manager / SQF Practitioner		Date:
Plant Manager		Date:
		Date
		Date

6.4 REVIEWS/REVISIONS

CHANGE HISTORY

Revision	Date	Responsible Person	Description of Change
00	8/4/2011	Greg Pluimer	Initial Issue
01	8/31/2019	Sabrina Minter	General Formatting and Content Review