1.0 Purpose

The purpose of this policy is to provide a uniform and documented calibration and preventative maintenance program to ensure that all instrumentation used in U.S. Pharmacopeia compendial testing is maintained at a high level of confidence. The plan states the basic elements of a comprehensive calibration and preventative maintenance program.

2.0 Scope

This policy applies to the calibration and preventative maintenance of all USP quality control laboratory instrumentation.

3.0 Responsibility

QA Lab personnel will be responsible for the calibration and preventative maintenance of all USP quality control laboratory instrumentation.

4.0 Safety Considerations

Proper PPE should be worn at all times including but not limited to safety glasses, steel-toed shoes, lab coat, and safety glasses.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

N/A

6.0 Policy

6.1 Definitions

Calibration: A comparison of two instruments or measuring devices one of which is a standard of known accuracy (traceable to national standards) to detect, correlate, report or eliminate by adjustment, any discrepancy in accuracy of the instrument measuring device being compared to the standard.

Calibration record: Record prepared for a specific item to show the actual value of the parameter(s) calibrated.

Traceability: Ability to relate individual measurement results to national standards or nationally accepted measurement systems through an unbroken chain or direct comparison.

6.2 Calibration Programs Required by Regulatory Authorities

US Code of Federal Regulations, 21 CFR 211.68: Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

US Code of Federal Regulations, 21CFR 211.67: Maintenance at appropriate intervals to prevent malfunction & shall be "preventative" not "reactive" maintenance.

Calibration requirements for Laboratory Instruments US Code of Federal Regulations, 21 CFR 211.67:

–Specific Directions
–Schedules
–Limits of accuracy & precision
–Remedial Actions
–Systems to prevent usage of instruments failing calibration

ICH Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients: Control, weighing, measuring, monitoring and test equipment that is critical for assuring the quality of intermediates or APIs should be calibrated according to written procedures and an established schedule.

6.3 Procedure

1. Calibration procedures that use traceable calibration standards or calibration equipment and describe the calibration requirements for each instrument will be maintained in the USP Testing Laboratory Calibration Log binder.

2. Preventive maintenance procedures will be maintained in the USP Testing Laboratory Maintenance Log binder.

3. Qualified individuals (having the appropriate education, training, background and experience) will be responsible for calibrating & maintaining instrumentation.

4. Calibration records and maintenance logs will be maintained and updated in the 'USP Testing Laboratory Calibration Log' and the 'USP Testing Laboratory Maintenance Log' binders. The calibration status of each instrument, the date of calibration or maintenance, the identification of the person performing calibration or maintenance, and, in the case of maintenance, a short description will be recorded.

5. Instruments that require annual calibration for traceability or factory recommended maintenance will be serviced once a year by an on-site visit from appropriate service personnel or by sending the instrument to an accredited laboratory for calibration.

6. Up-to-date calibration, verification, and service certificates from annual instrument service will be maintained in the USP Testing Laboratory Calibration Log binder.

7. Calibration stickers will be provided by service personnel indicating the calibration status of each instrument, the date of calibration, the next calibration date, and the identification of the person that performed the most recent calibration.

8. A qualified individual will be responsible for monitoring the calibration and maintenance program.

9. A schedule for all calibration and maintenance tasks will be maintained and followed.

6.4 Master USP Equipment List

Each Item on this list is assigned and marked with an identity number, denoting its use in USP procedures.

Item	Model	Serial Number	Identity #
Adjustable Pipette, 1000 µl	Eppendorf, Research Plus	269800A	G1
Adjustable Pipette, 5 ml	Eppendorf, Research Plus	210362A	G2
Adjustable Pipette, 10 ml	Eppendorf, Research Plus	M14602C	G3
Analytical Balance	Mettler Toledo, XS105DU	B139292316	G4
pH Meter	VWR, SB-20	00005645	G5
Drying Oven	Quincy Lab Inc., 20GC	G2-6409	G6
Muffle Furnace	Thermodyne, Type FB1300	1256081004135	G7
Laboratory Centrifuge	Drucker, 614B	160312-64	G8
UV-Vis Spectrophotometer	Hach, DR 5000	1396156	G9
ICP-OES Spectrometer	Teledyne Leeman Labs, Prodigy-H	122-00152-1 REV F	G10
Bottle-Top Burette	Brand Titrette, 50-ml	08L62300	G11

7.0 Reference Documents

N/A

8.0 Change Information

Updated to New Doc System format
Updated serial no. for the 10mL Eppendorf
Changed Author
Added reference to new USP Testing Laboratory Maintenance binder