1. ­­ **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.

1. **Scope**

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

1. **Responsibility**

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

1. **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.

1. **Materials/Equipment**

N/A

1. **Policy**
   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.

* 1. **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.

* 1. **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.
   1. **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 |

1. **Reference Documents**

N/A

1. **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