



Original Research Article

Routine Control of Balances in the Pharmacy Department

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Abstract: Routine control of balances in the pharmacy department is essential for accurate pharmaceutical preparation, quality assurance, and regulatory compliance. Effective management ensures precision in weighing active pharmaceutical ingredients, minimizes errors, and supports Good Manufacturing Practice (GMP). This article explores the principles, procedures, maintenance schedules, documentation strategies, and regulatory standards vital to the routine control of balances. Best practices and graphical data are included for practical guidance.

Keywords: Pharmacy balances, weighing accuracy, GMP compliance, maintenance, documentation.

INTRODUCTION

Balances are core instruments in the pharmacy department, underpinning accurate weighing for formulation, compounding, quality control, and stock management. Because pharmacy operations demand high precision, a strict protocol for the control of balances—covering calibration, verification, maintenance, and documentation—is mandated by GMP and international regulatory standards^{[1][2][3]}. This article examines modern approaches, regulatory requirements, and practical steps to establish routine control for pharmacy balances.

Regulatory and Quality Standards

- **USP <41> and <1251>:** Require risk-based testing schedules and clear criteria for accuracy, repeatability, and minimum weight^[1]. Chapter <41> mandates accuracy checks using weights between 5–100% of balance capacity; repeatability and minimum weight determinations use smaller test weights.
- **GMP and GLP:** International authorities (FDA, EMA, WHO) enforce documented calibration and validation, with regular performance checks on all balances^{[3][4]}.
- **Certification:** Only balances with valid conformity declarations and certification may be used for pharmaceutical weighing.

Types of Balances and Their Applications

Balance Type	Sensitivity/Range	Typical Use
Analytical balance	0.01 mg – 200 g	API weighing, QC analysis

Top-loading balance	0.1 g – 5 kg	Bulk materials, excipient weighing
Two-pan balance	0.5 g – several kg	Load balancing (e.g., centrifuge)

Routine control procedures apply to all types but are most stringent for analytical balances due to their critical role in precise compounding^{[2][5][4]}.

Routine Control Protocols

1. Daily/Per-use Verification

- Perform daily checks using certified test weights, typically at the start of each shift or before critical weighing.
- Verify:
 - Zero balance reading.
 - Accurate reading for at least one known calibration weight (within defined allowable error margin).
 - Record findings in an equipment logbook, including user initials, date, time, and observed results^{[6][7]}.
- If checks fail, remove the balance from service and report for calibration/repair^{[2][8]}.

2. Scheduled Calibration and Maintenance

- **Annual Calibration:** Performed by qualified service technicians, usually annually, after repairs, or when a balance is moved to a new location. Calibration certificates must be retained for compliance^{[2][8]}.
- **Preventive Maintenance:** Regular internal cleaning, inspection, and level verification as per manufacturer recommendations, typically monthly or quarterly.
- **Predictive Maintenance:** Monitoring trends in daily checks to pre-empt potential failures or drifts in accuracy^{[6][9]}.

3. Documentation and Record Keeping

- Maintain comprehensive logs for every balance, including:
 - Calibration certificates and service reports
 - Daily verification records
 - Details of repairs, maintenance actions, and any adjustments
- Use clear labels on each balance indicating last calibration date and next scheduled check^{[6][9]}.

Good Weighing Practice (GWP)

- Always use balances within specified minimum and maximum weight limits.
- Avoid drafts, vibrations, and extreme temperatures during weighing.
- Clean weighing pans and surrounding areas to prevent contamination or residue errors^{[5][10]}.
- Employ safety factors above balance minimum weight to assure reliable readings.

Graph: Recommended Frequency of Balance Control Activities

Activity	Frequency
Daily verification	Daily/Per-use
Internal cleaning/inspection	Monthly
Calibration (external)	Annually
Preventive maintenance	Quarterly
Predictive data review	As needed

Table: Typical Balance Control Logbook Entry

Date	Activity	Weight Used	Result (mg)	Status	Initials
2025-07-21	Daily Check	50.000	50.002	Pass	KJ
2025-07-21	Cleaning	N/A	N/A	Complete	KJ
2025-06-01	Calibration	Cert #564	Passed	Pass	Service

Quality Risk Management

- Review historical logbooks for anomalies or recurring discrepancies.
- Initiate corrective actions promptly if deviations are noted.
- Conduct risk assessments to set the type and frequency of balance checks, tailored to each application's tolerance for error^{[1][3]}.

Common Errors and Troubleshooting

Error Type	Possible Causes	Corrective Actions
Zero drift	Temperature fluctuation, static build-up	Re-zero, address environment
Non-linearity	Overloaded pan, mechanical wear	Remove excess, service balance
Reproducibility	Damaged weighing surface, instability	Clean, check surface, recalibrate

Compliance and Auditing

- Regular audits ensure SOP adherence, calibration interval compliance, and correctness of records.
- Any nonconformity must trigger root-cause analysis and documentation of remedial action taken^[9].

CONCLUSION

Routine control of balances is foundational for accurate pharmacy operations, compliance, and product safety. Through structured daily verifications, periodic calibration, thorough documentation, and adherence to regulatory standards, pharmacy departments safeguard precision and meet stringent quality requirements. Well-maintained balances lead to consistent compounding, accurate dispensing, and ultimately, enhanced patient safety.

Recommendations

- Develop clear SOPs for all aspects of balance management.
- Institute comprehensive and traceable records for all verification, calibration, and repairs.
- Regularly train staff on weighing procedures, error prevention, and documentation.
- Integrate risk-based scheduling to optimize resources without compromising quality

REFERENCES

1. "USP Guidelines for weighing in Pharmaceutical Industry." METTLER TOLEDO.
2. "STANDARD OPERATING PROCEDURE." World Health Organization.
3. Total Pharmacy Supply. "Pharmacy Equipment Maintenance: Ensuring Accuracy and Safety."
4. "Procedure Of Weighing Balance In Pharmaceuticals." Flair Pharma Solutions, 2024.
5. "SOP for Calibration of Balance." Pharmaguideline, 2024.
6. "Good Weighing Practice in Pharmaceutical Industry." Scribd, 2025.
7. "Routine Testing of Balances and Scales Guide." METTLER TOLEDO.
8. "Weighing Scales for the Pharmaceutical Industry: Ensuring Precision, Compliance, and Quality Control." Shree Shree Weighing Solutions, 2025.