

## **Attachment 18**

### **Balances and Weigh Scales**

The use of balances and weigh scales has a far greater direct effect on the quality of pharmaceuticals, from research laboratory to manufacturing, weighing of raw materials to final analysis of the product, than any other instrument. It is therefore evident that particular attention should be paid to the calibration of these instruments. The importance to the pharmaceutical of balances and weigh scales may be seen in the documents on the use of these instruments e.g. U.S. Pharmacopeia

#### **Balance, Weigh Scale Specification**

The following are factors that must be considered when purchasing and installing a balance or weigh scale to ensure calibration is not affected:

- Weighing Range
- Repeatability
- Resolution
- Linearity
- Temperature Sensitivity
- Minimum Weight Reading
- Uncertainty of Measurement
- Installation Location

#### **Performance Qualification**

As with all instrumentation written procedures must be maintained for qualifying the performance and calibration of balances and weigh scales. These should specify what testing regime is carried out, the standards to be used (certified or check weights), the acceptance criteria and the frequency.

There are calibration software programmes available to assist with the recording of calibration information and providing pass/fail criteria that include the uncertainties of the constituent parts for the calibration process.

#### **Certified Weights**

Manufactured to an approved specification for its design and tolerance from organisations such as the OMIL, ASTM and NIST, these weights must be certified to National Standards by an accredited calibration house.

#### **Check Weights**

Check weights are checked against certified weights by the comparison method on the balance or weigh scale they are to be used. If the check weights are to be used on more than one balance or weigh scale, then comparison weight readings must be kept for all of these instruments. The check weights must be compared against the

certified weights at appropriate intervals. These weights are manufactured from a material suitable for their intended use.

### Weighing Test

The weighing test should take place at two or more points over the range of the instrument increasing in weight, so as not to reset to zero between points. Typically if two points were chosen these would be done 25 and 75% of the maximum load of the balance or weigh scale.

### Repeatability Test

A single weight should be added and removed a minimum of five times, after each removal of the weight, the indication should be set to zero, ensuring that the maximum deviation is within specified limits. The positioning of the weight should be in the same spot with a minimum of variation.

### Eccentricity Test

Single weight of 50% of the maximum load of the balance or weigh scale is normally used for this test. This is then applied, repeating at the measurement periphery of the balance or weigh scale pan, after each removal of the weight, the indication should be reset to zero. Each test completed should be compared so that the maximum deviation is within specified limits.

### Minimum Weight Test

The USP requires that the smallest allowable weight that can be measured by a balance or weigh scale is determined. The minimum weight test consists of repeated placing of a weight on the balance or weigh scale a minimum of ten times. After each removal of the weight the indication should be set to zero.

The minimum weight may be calculated from the following method;

Take 10 weight reading from the balance or weigh scale

Determine the standard deviation from the 10 reading recorded

Calculate the minimum sample weight by using the following formula:

$$[\text{Standard Deviation} * 3] * 1000 = \text{Minimum Sample Weight}$$

### References:

Guide to the Measurement of Mass and Weight

The Institute of Measurement and Control / National Physical Laboratory

ISBN 0 904457 27 3

Published 1998

Calibration in the Pharmaceutical Laboratory

Tony Kowalski  
ISBN 1 57491 092 2  
Published 2001

Ultimate Calibration  
Beamex OY  
Published 2009

Glossary Notes:

OMIL  
Organisation Internationale de Metrologie Legale

NIST  
National Institute of Standards and Technology

ASTM  
American Society for Testing and Materials