Printed on: Sat Aug 31 2024, 19:09:17 pm
Printed by: Tina huang
Status: Currently Official on 31-Aug-2024
Official Date: Official as of 01-Aug-2019
Document Type: GENERAL CHAPTER
Docld: GUID-0778059F-4B53-414F-B496-2195C1D8C7FB_4_en-US
DOI: https://doi.org/10.31003/USPNF_M98780_04_01
DOI Ref: z12nj
Do not distribute



41 BALANCES

This chapter states the requirements for balances used for materials that must be accurately weighed (see <u>General Notices, 8.20 About</u>). Unless otherwise specified, when substances must be "accurately weighed", the weighing shall be performed using a balance that is calibrated over the operating range and meets the requirements defined for repeatability and accuracy. For balances used for other applications, the balance repeatability and accuracy should be commensurate with the requirements for its use.

For a discussion of the theoretical basis of these requirements, see <u>Weighing on an Analytical Balance (1251)</u>, which may be a helpful—but not mandatory—resource.

Change to read:

© 2024 USPC

REPEATABILITY

Repeatability is assessed by weighing one test weight NLT 10 times. [Note—The test weight must be within the balance's operating range, but the weight need not be calibrated. Because the standard deviation is virtually independent of sample mass within the balance's capacity, use of a small test weight, which may be difficult to handle, is not required.]

Repeatability is satisfactory if $^{\blacktriangle}$ twice $_{\blacktriangle}$ (USP 1-Aug-2019) the standard deviation of the weighed value, $^{\blacktriangle}$ s $_{\blacktriangle}$ (ERR 1-Aug-2019) (USP 1-Aug-2019) divided by the desired smallest net weight (i.e., smallest net weight that the users plan to use on that balance), does not exceed 0.10%. $^{\blacktriangle}$ The repeatability measurement establishes the smallest net amount of material that may be weighed on the balance in conformance with the 0.10% limit. The minimum weight, M_{min} is described by the inequality $M_{min} \ge 2000^{\blacktriangle}$ s $_{\blacktriangle}$ (ERR 1-Aug-2019). For example, if $^{\blacktriangle}$ s is found to be 0.00015, then M_{min} must be ≥ 0.30000 g or 300.00 mg. $_{\clubsuit}$ (ERR 1-Aug-2019) $_{\clubsuit}$ (USP 1-Aug-2019) If the standard deviation, s, obtained is less than 0.41d, where d is the scale $^{\blacktriangle}$ interval of the balance, then the inequality becomes $M_{min} \ge 2000$ (0.41d). For example, for a 4-place analytical balance, d is 0.0001 so that M_{min} must be ≥ 0.0820 g or 82 mg. $_{\clubsuit}$ (USP 1-Aug-2019)

ACCURACY

The accuracy of a balance is satisfactory if its weighing value, when tested with a suitable weight(s), is within 0.10% of the test weight value. A test weight is suitable if it has a mass between 5% and 100% of the balance's capacity. The test weight's maximum permissible error (mpe), or alternatively its calibration uncertainty, shall be NMT one-third of the applied test limit of the accuracy test.

[Note—Applicable standards are the following: American Society for Testing and Materials (ASTM) E617 (available from http://www.astm.org) and International Organization of Legal Metrology (OIML) R 111 (available from http://www.oiml.org).]

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
<41> BALANCES	Yang Liu Manager, Product Quality and Analytical Methods	GCMDQ2020 General Chapters - Measurement and Data Quality

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 50(5)

Page Information:

USP43-NF38 - 6449 USP42-NF37 1S - 9011 USP42-NF37 - 6382

Current DocID: GUID-0778059F-4B53-414F-B496-2195C1D8C7FB_4_en-US

DOI: https://doi.org/10.31003/USPNF_M98780_04_01

DOI ref: z12nj