

Certificates USP 41 & Ph. Eur. 2.1.7

Comply with Pharmacopoeias



What is a Pharmacopoeia?

A Pharmacopoeia is a reference work for pharmaceutical drug specifications containing test procedures and acceptance criteria. USP and Ph. Eur. chapters are legally binding for all pharmaceutical companies in the US and Europe and those importing into them.



Scope of USP and Ph. Eur.

USP 41 and Ph. Eur. 2.1.7 chapters focus on lifecycle management of analytical balances used for quality control of drugs and state that calibration is mandatory. The chapters are not applicable to the manufacturing of pharmaceuticals.



How to ensure compliance

The Accuracy Calibration Certificate (ACC) and the Certificates USP 41 and/or Ph. Eur. 2.1.7 provide physical evidence of fulfilment of the requirements stipulated by these chapters. Plus, GWP® Verification provides a calibration and routine testing plan.



METTLER TOLEDO Expertise

By choosing calibration services from METTLER TOLEDO you benefit from our global expertise. Many of our calibration laboratories are accredited to ISO 17025 and our ACC calibration certificate is based on EURAMET cg-18.



US and EU Pharmacopoeia Chapters

General Chapters USP 41 and Ph. Eur. 2.1.7 address equipment performance and introduce three measures that must be carried out periodically to optimize the performance of analytical balances:

- Calibration documented in a calibration certificate (incl. measurement uncertainty)
- Performance checks (routine testing) between calibration intervals
- Adjustment by built-in weights

Our Good Weighing Practice Program (GWP®) supports the balance chapters of these Pharmacopoeias, providing a clear and detailed plan of how to specify, test and calibrate balances.

Our Service Offering for Pharmacopoeias Compliance

GWP® - Good Weighing Practice™

The balance chapters of USP 41 and Ph. Eur. 2.1.7 are aligned with our Good Weighing Practice Program (GWP®), which covers:

- Calibration
- Routine testing (performance checks)
- Internal adjustment (by built-in weights)

GWP® supports you to implement the regulations on weighing, including calibration and routine testing (performance checks).

Learn more: www.mt.com/gwp



Calibration – Accuracy Calibration Certificate (ACC)

The Accuracy Calibration Certificate (ACC) quantifies the performance (measurement uncertainty) of your balance over its entire weighing range. Various annexes are available to analyze the calibration results depending on your needs or local applicable regulations.

Learn more: www.mt.com/calibration-acc

Assessment of Repeatability and Accuracy – Certificates USP 41 and/or Ph. Eur. 2.1.7

We also offer the certificates USP 41 and Ph. Eur. 2.1.7 to fully comply with USP and Ph. Eur. General Chapters. These certificates document the assessment of the balance against the stipulated tests (repeatability & accuracy) and include a compliance statement concerning the acceptance criteria of 0.10%.

Learn more: www.mt.com/balances-ep

Routine Testing (Performance Checks) – GWP® Verification

GWP® Verification helps you to define the appropriate intervals for calibration and performance checks based on your own quality considerations and the risk of specific applications. It provides you with a calibration and routine testing plan and gives guidance on routine testing methods, frequency, test weights and tolerances.

Learn more: www.mt.com/gwp-verification



Accuracy Calibration Certificate (ACC)



Certificate USP/Ph. Eur



GWP® Verification



METTLER TOLEDO Group

Laboratory Weighing
Local contact: www.mt.com/contacts

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