GMP Journals
Journal of Contemporary Chemistry
Volume 1, No. 1, P. 12 – 31
https://doi.org/10.5281/zenodo.24129115
www.gmpjournals.com

Systematic Review

Enhanced Mechanical Calibration Versus Chemical Verification for Dissolution Apparatus Suitability

Wondwossen Gebregergs Beyadgo[1*]

1. Ethiopian Food and Drug Authority, Addis Ababa, Ethiopia.

*** Corresponding Author e-mail:** wondea888@gmail.com

Submitted on: 24th October 2026
Published on: 11th November 2026

ABSTRACT

Introduction

Dissolution testing of solid oral dosage forms is highly sensitive to physical and hydrodynamic variables. Traditional qualification protocols heavily rely on chemical reference standards to verify system suitability, but these assays frequently suffer from operator-induced variability and environmental perturbations. They do not provide direct physical traceability.

Objectives

This study evaluates the metrological rigour, physical sensitivity, and cost-benefit profiles of chemical testing versus enhanced mechanical calibration to propose a risk-based harmonization framework for national regulatory laboratories.

Method

A systematic comparative analysis was executed across the mechanical and operational tolerances defined by the United States Pharmacopeia Dissolution Toolkit, the Dosage Form Performance Laboratory Guideline, and the American Society for Testing and Materials standard over a twenty-four-month period.

Results

The comparison revealed significant divergence in centering and verticality limits. While the mechanical standard pioneered dual-point centering, its verticality limit is twice as lenient as the pharmacopeial requirement. This leniency introduces substantial boundary-layer shear stress asymmetry. Tighter mechanical limits effectively stabilize the dissolution micro-environment.

Conclusions

Relying on chemical tests for routine calibration is a flawed metrological strategy. That is the only logical baseline for instrument suitability. By adopting a risk-based framework that utilizes enhanced mechanical calibration for semi-annual verification, laboratories can maintain compliance while eliminating costly, false-positive chemical failures.

Keywords

Dissolution, Metrology, Calibration, Harmonization, Compliance

1.0 Introduction

Why do regulatory laboratories experience frequent Out-of-Specification (OOS) investigations lacking any manufacturing defect? This systemic vulnerability stems directly from unstable fluid dynamics inside the dissolution vessel, where localized velocity gradients strictly control boundary-layer shear stress at the solid-liquid interface (McCarthy et al., 2003). Geometric alignment functions as the primary operational variable. A vessel tilt deviation of a single degree completely displaces the central vortex. This physical displacement introduces asymmetrical fluid flow that artificially accelerates dissolution rates by up to ten percent and compromises the in vitro kinetic profile (Cox et al., 1982).

Regulatory paradigms governing this physical environment remain fractured. Methodological consensus exists across distinct analytical disciplines regarding the necessity of spatial precision. Validating this requirement, researchers executing empirical physical stress-testing demonstrate that absolute geometric alignment prevents shear stress asymmetry (Cox et al., 1982). Complementing these empirical findings, scholars deploying computational hydrodynamic modeling theoretically corroborate these physical findings by mapping the exact velocity gradients disrupted by spatial deviations (McCarthy et al., 2003). Despite this unified theoretical alignment between physical and computational sciences, competing compendial frameworks enforce radically different dimensional tolerances. The American Society for Testing and Materials (ASTM) E2503-07 standard (American Society for Testing and Materials [ASTM], 2007) permits mathematical deviations that directly conflict with the restrictive physical limits mandated by the United States Pharmacopeia Dissolution Toolkit (United States Pharmacopeia [USP], 2010).

These localized, non-harmonized compendial mandates force multi-market National Regulatory Authority (NRA) laboratories to maintain redundant verification programs. Compounding this operational burden, the execution of chemical Performance Verification Testing (PVT) routinely generates false-positive system suitability failures. These analytical failures trigger mandatory OOS investigations under international regulatory frameworks. Applying Quality Risk Management (QRM) principles, as defined in the International Council for Harmonization Q9(R1), dictates the requirement that facilities shall implement control strategies that directly measure the physical sources of hydrodynamic variability (International Council for Harmonization [ICH], 2023). Consequently, this article quantifies the specific engineering deviations permitted under competing regulatory frameworks to establish a legally defensible mechanical harmonization strategy.

2.0 Materials and methods

Validation of in-vitro mass transfer kinetics cannot rely on qualitative assumptions. Such precision necessitates absolute dimensional control. Recognizing this requirement, this study executes a systematic, metrological comparison across three distinct regulatory frameworks and their companion implementation guides to establish the physical boundaries of dissolution qualification. By comparing mechanical tolerances through these frameworks, the specific engineering deviations that directly affect hydrodynamic symmetry are isolated. This analytical framework ensures these documents were not evaluated as isolated administrative mandates. Instead, they were analyzed as competing engineering designs that govern the physical micro-environment of the dissolution vessel. The material core of this comparative study consists of four distinct regulatory and technical standards:

1. *USP Dissolution Toolkit (Version 2.0, March 22, 2010): Represents the pharmacopeia's initial mechanical calibration pathway coupled with the 10.0 mg Prednisone PVT requirement.*
2. *USP Guideline (DEPTDOC-00276, Rev. 01, 2023): Mechanical Calibration and Performance Verification Test, USP Apparatus 1 and 2. Dosage Form Performance Laboratory (DFPL).*
3. *ASTM E2503-07 Standard Practice: Establishes the pure mechanical calibration paradigm with wider physical tolerances.*
4. *ASTM Implementation Guidance (Moore et al., 2010): Provides the diagnostic mathematical and physical procedures necessary to execute mechanical verification.*
5. *USP General Chapter <711> Dissolution (2023): Represents the official harmonized compendial standard establishing baseline physical dimensions and operational parameters.*

To reconcile the different parameters, all physical limits were compiled and normalized. Physical tolerances were evaluated across eight primary engineering indices: bench levelness, base plate levelness, shaft verticality, vessel verticality,

vessel-to-shaft centering, spindle runout (wobble), rotational velocity, and thermal distribution.

3.0 Results

3.1 Quantitative Risk-Based Calibration Framework

Implementing Quality Risk Management (QRM) principles under ICH Q9(R1) requires a systematic evaluation of physical failure modes. Quantifying these risks necessitates the isolation of mechanical variables impacting the Critical Quality Attributes (CQAs) of solid oral dosage forms. Recognizing this requirement, a Failure Mode and Effects Analysis (FMEA) shall be executed. This evaluative process assigns numerical values to Severity (S), Probability (P), and Detection (D), as detailed in Table 1, thereby establishing a baseline Risk Priority Number (RPN) for each mechanical parameter. The calculated RPN values determine the frequency of required calibration interventions.

Table 1: FMEA Matrix for Dissolution Apparatus Mechanical Deficiencies

Failure Mode	Impacted CQA	Severity (*S*)	Probability (*P*)	Detection (*D*)	Risk Priority Number (*RPN*)	Action Limit / Control Pathway
Vessel Tilt > 0.5°	Boundary-layer shear stress symmetry	8	4	2	64	Semi-annual dual-point verticality verification using calibrated digital inclinometers.
Spindle Wobble > 1.0 mm	Toroidal fluid velocity field	7	3	3	63	Mandatory runout checks using dial test indicators conforming to USP Guideline (2023b) tolerances.
Inter-vessel Temp Deviation > 0.4°C	Dissolution velocity constant (*k*)	9	2	2	36	Deployment of calibrated continuous dataloggers; integration of supply-voltage stabilizers.

Note: FMEA = Failure Mode and Effects Analysis; CQA = Critical Quality Attribute; S = Severity; P = Probability; D = Detection; RPN = Risk Priority Number; USP = United States Pharmacopeia.

Systematically assigning quantitative risk rankings to physical misalignments establishes a scientifically sound verification frequency that legally satisfies the requirements of 21 CFR 211.160(b) without requiring recourse to erratic, operator-dependent chemical performance verification assays (USP, 2017a). Analyzing the mechanical and operational tolerances establishes distinct dimensional divergence across the specified compendial and engineering frameworks. The USP (2023b) Guideline on Procedures for Mechanical Calibration and Performance Verification Test dictates highly restrictive physical limits. ASTM E 2503-07 permits wider mathematical deviations. Adhering to the US.FDA general requirement under 21 CFR 211.160(b), laboratory control mechanisms must utilize scientifically sound analytical methods to verify system suitability (U.S. Food and Drug Administration [FDA], 2017). This validated state directly correlates with these structural boundaries. The normalized comparison of these mechanical and operational tolerances is compiled in Table 2.

Representing the most severe evolutionary shift across the guidelines, centering metrology represents the most severe evolutionary shift across the guidelines. The older USP Toolkit (2010) evaluated centering at only a single point near the vessel flange. Contrasting with this approach, ASTM E2503-07 and the newer USP (2023b) guideline Mechanical Calibration and Performance Verification Test, require dual-point vertical centering. This dual-point evaluation captures the angular tilt of the vessel. For example, a lateral displacement of 1.0 mm at the upper measurement plane over a vertical distance of 65.0 mm yields an angular deflection of 0.88°. Operating under the ASTM standard, this vessel is deemed compliant because it remains within the Not More Than (NMT) 1.0° vessel verticality limit. Despite this regulatory compliance, this exact physical alignment fails the strict USP verticality limit of NMT 0.5°. The ASTM standard permits severe physical misalignment.

Extending this comparative analysis, rotational speed and temperature controls exhibit similar discrepancies. At a standard setpoint of 50.0 rpm, the ASTM speed

tolerance of ± 2.0 rpm permits a rotational speed range of 48.0 to 52.0 rpm. Constraining this variance, the USP speed tolerance of ± 1.0 rpm restricts this range to 49.0 to 51.0 rpm. Paralleling this divergence, the ASTM temperature control allows a range of 36.5 °C to 37.5 °C, permitting a total inter-vessel temperature spread of up to 1.0 °C. In contrast, recognizing the risks of thermal instability, the USP guidelines restrict the total inter-vessel temperature range to 0.4 °C. These wider ASTM limits directly increase hydrodynamic and kinetic variability. The USP limits actively establish reproducible dissolution micro-environments.

Table 2: Comparison of mechanical and operational tolerances across calibration frameworks

Parameter	USP <711> (USP, 2023a)	USP Toolkit (v2.0) (USP, 2010)	USP Guideline (USP, 2023b)	ASTM E2503
Bench/Surface Levelness	Not specified	1.0° surface inclination in two orthogonal directions	Supporting Bench Top: 1.0° inclination	No specific measurement
Horizontality/Vessel Plate Levelness	Not specified	0.5° inclination in two orthogonal directions	Vessel Support Plate: 0.5° inclination	0.5° deviation
Shaft Verticality	Not specified	0.5° deviation from 90.0°	0.5° deviation from 90.0°	Vertical in two directions 90.0° apart
Vessel Verticality	Not specified	0.5° deviation from 90.0°	0.5° deviation from 90.0°	1.0° from vertical
Vessel Centering (Limit)	2.0 mm from vertical axis	2.0 mm total difference over 360.0°	2.0 mm total difference over 360.0°	1.0 mm from centreline (2.0 mm equivalent)
Vessel Centering (Location)	Measured 2.0 cm below rim of vessel	Single Point: 2.0 cm below vessel flange	Dual Point: 2.0 cm below flange and at 500.0 mL fill level height	Dual Point: Top rim and directly above the basket or paddle blade
Basket/Shaft Wobble	No significant wobble	1.0 mm total deflection	1.0 mm total deflection	1.0 mm total runout

Basket/Paddle Height	25.0 mm± 2.0 mm	23.0 mm to 27.0 mm	25.0 mm ± 2.0 mm (23.0 mm to 27.0 mm)	Within 8.0% of desired height (± 2.0 mm for a 25.0 mm target)

Continued…

Rotational Speed	± 4.0% (tested at 50.0 and 100.0 rpm)	± 1.0 rpm (tested at 50.0 and 100.0 rpm)	± 1.0 rpm (tested at 50.0 and 100.0 rpm)	Within 2.0% or ± 2.0 rpm of the stated rate (whichever is larger)
Vessel Temperature	37.0°C ± 0.5°C	Inter-vessel agreement within 0.4°C range	Inter-vessel agreement within 0.4°C range	± 0.5°C from target value (37.0°C)
Deaeration (Dissolved Oxygen)	Must be removed before testing	6.0 ppm	6.0 ppm	Not specified
Mechanical and PVT	Required	Recommended to support qualification	Every 6.0 months	Not required
Serialization of Parts	Return parts to the same position	Return parts to same position	Return parts to same position	Parts must be traceable to Certificate of Analysis or Conformance

Note: USP = United States Pharmacopeia; ASTM = American Society for Testing and Materials; PVT = Performance Verification Test; cGMP = Current Good Manufacturing Practice; rpm = revolutions per minute; ppm = parts per million.

4.0 Discussion

The fundamental conflict between physical metrology and chemical verification concerns the nature of analytical control. Prioritizing absolute geometric parameters over unstable organic calibrators underscores the necessity for reproducible hydrodynamics. Analyzing the compiled data reveals that minor physical deviations permitted under the ASTM standard actively distort the boundary-layer shear stress, directly compromising the mass transfer profile. Methodological consensus exists across distinct analytical disciplines regarding this vulnerability. Researchers executing physical Design of Experiments (DOE) on prednisone kinetics demonstrate that borderline centering deviations consistently trigger validation failures (Han et al., 2015). Scholars utilizing computational fluid dynamics theoretically corroborate these empirical findings. Specifically, Perivilli et al. (2022) mathematically map how the impeller offset parameter (*pdl_off*) exerts a non-linear influence on local velocity magnitudes near the hemispherical vessel bottom. Any shift in *pdl_off* directly deforms the lower toroidal recirculation loop.

Notwithstanding these hydrodynamic findings, physical metrology exhibits absolute theoretical boundaries. Enhanced Mechanical Calibration (EMC) cannot verify the biochemical properties of the testing media. It cannot identify issues such as gelatin capsule cross-linking, which are analytical parameters that chemical verification theoretically captures. However, historical data suggest that Performance Verification Testing (PVT) predominantly functions as an indicator of operator proficiency rather than a diagnostic metric of instrument alignment (Brown et al., 2009; Salt & Glennon, 2011). When a chemical suitability run fails, laboratories rarely adjust the physical apparatus. Instead, they achieve passing results by manipulating media degassing procedures. Relying on an analytical method so highly sensitive to operator variables to qualify a stable physical assembly violates the US.FDA regulation under 21 CFR 211.160(b) requirements for scientifically sound laboratory controls (US.FDA, 2017).

Global pharmacopeial misalignment fragments the execution of chemical verification within international regulatory networks. Deep structural disparities exist between the United States, European, Japanese, and Chinese pharmacopoeias regarding dissolution testing standards (Gray et al., 2022). To bypass these conflicting regional chemical mandates, National Regulatory Authority (NRA) laboratories must transition to a standardized, physical metrology-based model. Implementing a harmonized, risk-based EMC framework provides a uniform baseline of instrument suitability. Transitioning to an exclusive EMC pathway must be justified by quantitative economic data. Smith and Davis (2021) directly modeled the costs of chemical reference standards against the long-term capital expenditure of mechanical qualification tooling. While traditional USP qualification protocols require approximately ten hours of labor per instrument per six-month cycle, performing an ASTM E2503-compliant enhanced mechanical calibration requires only six hours (Salt & Glennon, 2011). This labor optimization directly offsets the initial capital expense of specialized metrological measurement tools.

Vessel centering and verticality strictly govern the symmetry of the toroidal flow field. When a vessel is aligned solely at a single point near the flange, as permitted by the USP Toolkit (2010), there is no guarantee of vertical alignment. A tilted vessel shifts the central vortex of the rotating spindle. This asymmetry causes localized shear stresses at the bottom of the hemispherical vessel to vary dramatically, directly altering the convective mass transfer rate. Consequently, two vessels can yield significantly different dissolution profiles purely due to three-dimensional geometric misalignment, even if their upper flanges remain centered. This phenomenon is documented across multiple research paradigms. Physical perturbation studies reveal that asymmetrical fluid flow artificially accelerates dissolution rates (Cox et al., 1982), while advanced computational simulations confirm that these identical geometric offsets permanently alter the convective mass transfer rate (McCarthy et al., 2003).

Applying Quality Risk Management (QRM) principles to these physical boundaries allows laboratories to establish pragmatic compliance windows. Because centering values between 1.0 mm and 1.5 mm do not statistically distort the convective mass transfer profile, NRA laboratories should adopt a dual-tier action limit. Centering values greater than 1.0 mm but less than 1.5 mm obtained during routine calibration shall require mechanical adjustment. They must not trigger a formal Out-of-Specification (OOS) laboratory investigation. Any deviation equal to or exceeding 1.5 mm must be treated as a critical action limit requiring a mandatory laboratory investigation and Corrective and Preventive Action (CAPA) implementation.

Rotational speed and thermal regulation further dictate the kinetic energy of the dissolution micro-environment. The thickness of the stagnant diffusion boundary layer surrounding the solid dosage unit is highly dependent on spindle rotational velocity. Under the more lenient ASTM standard, a ± 2.0 rpm speed variance can significantly modify boundary-layer thickness (Qureshi, 2004). Dissolution remains a thermally activated process governed by the Arrhenius equation. Consequently, the 1.0 °C temperature spread allowed under the ASTM standard alters the dissolution velocity constant (k). The tight 0.4 °C inter-vessel temperature range established by the USP is superior because it actively stabilizes the kinetic rate across all testing positions (Cox et al., 1982).

The transition from chemical PVT to physical metrology introduces a strict regulatory requirement for tool-level verification. Physical calibration is not self-authenticating. The mechanical devices used to execute EMC must possess uninterrupted metrological traceability to international standards. In compliance with ISO/IEC 17025 regulations (International Organization for Standardization [ISO], 2017). These auxiliary measurement devices shall undergo annual calibration against national standards. Using uncalibrated physical tools to qualify a dissolution system violates Current Good Manufacturing Practice (cGMP) requirements (World Health Organization [WHO], 2011).

Metrological traceability to international standards requires strict containment of laboratory environmental variables. While physical calibration frameworks assume a static laboratory environment, contemporary testing facilities operate under highly variable conditions. Subtle shifts in ambient parameters silently degrade the alignment of high-precision components over extended operational cycles. NRA laboratories in low-and-middle-income countries frequently contend with unstable infrastructure characterized by recurring power grid fluctuations and structural micro-vibrations from nearby heavy machinery (Liddell et al., 2007). These structural irregularities directly threaten physical alignment. Mechanical vibrations induce progressive drift in spindle centering metrics, completely shifting the alignment out of the calibrated tolerance. Unmitigated relative humidity fluctuations promote microscopic corrosion on the drive-head gears of the dissolution apparatus, increasing spindle runout and disrupting rotational velocity stability (Qureshi, 2004). Voltage fluctuations in the power supply destabilize the heater-circulator unit. This destabilization introduces localized thermal gradients that easily exceed the strict pharmacopeial inter-vessel limit of 0.4 °C.

Implementing environmental controls in resource-limited settings requires rigorous verification protocols. Structural micro-vibrations and erratic voltage supplies cannot be mitigated by simple procurement. Laboratories must validate all protective infrastructure under Installation Qualification (IQ) and Operational Qualification (OQ) protocols. Vibration levels shall be quantitatively assessed using calibrated accelerometers. These measurements must confirm that residual structural displacement remains NMT 0.01 g. Without these documented engineering controls actively isolating the physical micro-environment of the dissolution vessel from external infrastructural shocks, dimensional data compiled during EMC remains scientifically indefensible.

The execution of physical metrology demands absolute procedural control over the measurement equipment itself. Yan et al. (2011) demonstrate that base plate levelness operates as the primary driver of verticality non-compliance. However, the accuracy of digital inclinometers depends entirely on the selected zero-reference point. If a digital device is zeroed on the instrument's own base plate rather than a verified horizontal bench surface, the measurement protocol fails to capture systemic inclinations. Operating protocols shall mandate that all digital measuring devices are zeroed on a certified earth-level surface.

Preventative maintenance procedures must explicitly address the physical movement of the vessel within its support ring. Glass dissolution vessels frequently rotate within their plastic ring holders during routine handling and cleaning cycles (Han et al., 2015). This rotation shifts the physical orientation of the vessel relative to the spindle axis. To mitigate this operational risk, calibration protocols shall require metrology engineers to identify the optimal rotational position of each vessel and permanently etch matching alignment marks on both the glass vessel and the support ring. Analysts must visually verify that these alignment marks are synchronized before each dissolution run. Facilities must redefine ambient laboratory conditions as Critical Process Parameters (CPPs) within their Analytical Instrument Qualification (AIQ) protocols (USP, 2017). Environmental monitoring shall be integrated into the preventive maintenance program. In accordance with 21 CFR 211.160(b), laboratory controls must rely on scientifically sound parameters (US.FDA, 2017). Stabilizing the ambient environment constitutes the only logical path toward liberating analytical laboratories from the systemic burdens of chemical suitability testing.

5.0 Conclusions

The persistent reliance on operator-dependent chemical assays to qualify dissolution architecture directly contradicts modern Quality Risk Management (QRM) paradigms. Transitioning to a physical metrology framework resolves this systemic vulnerability. To execute a legally defensible metrological transition

within a highly regulated environment, national regulatory laboratories must mandate a strict, dual-stage change-control qualification sequence. A final, documented chemical verification must historically close the legacy era of the specific apparatus. This event must be immediately followed by a baseline physical calibration to initiate the metrology era, ensuring that historical dissolution data generated under the chemical model remains fully defensible and preventing compliance gaps during regulatory audits.

Stabilizing the ambient physical environment constitutes the exclusive path toward liberating analytical laboratories from the burdens of systemic suitability testing. National regulatory bodies must amend their respective pharmacopeias to recognize continuous environmental monitoring and dual-point centering metrology as Critical Process Parameters (CPPs). This structural revision actively neutralizes false-positive analytical failures.

Yet, as international standardizing organizations meticulously establish these highly precise mechanical parameters, a broader disruption emerges within pharmaceutical manufacturing. The rapid deployment of in silico computational fluid dynamics completely automates physical prediction models. One must question whether the regulatory sector is investing vast capital to perfect the physical metrology of an analytical tool precisely at the moment the tool itself faces systemic obsolescence. A fading paradigm.

Acknowledgements

The authors acknowledge the technical contributions of the metrology and analytical development departments.

Financial support

This research received no external funding.

Conflict of interest

The authors declare no conflict of interest.

Ethical approval

This study did not involve human or animal subjects.

References

American Society for Testing and Materials. (2007). *Standard practice for qualification of basket and paddle dissolution apparatus* (ASTM E2503-07). ASTM International.

Brown, C. K., Buhse, L., Friedel, H.-D., Keitel, S., Kraemer, J., Morris, J. M., Stickelmeyer, M., Yomota, C., & Shah, V. P. (2009). FIP position paper on qualification of paddle and basket dissolution apparatus. *Dissolution Technologies, 16*(4), 6-9. https://doi.org/10.14227/DT160409P6

Cox, D. C., Wells, C. E., Furman, W. B., Savage, T. S., & King, A. C. (1982). Systematic error associated with apparatus 2 of the USP dissolution test II: Effects of deviations in vessel curvature from that of a sphere. *Journal of pharmaceutical sciences*, 71(4), 395–399. https://doi.org/10.1002/jps.2600710405

Gray, V., Abend, A., Alasandro, M., Armenante, P., Carducci, T., Crist, B., Li, F., Lu, X., Marques, M., Moore, K., & Nickerson, B. (2022). Dissolution best practices and international harmonization: AAPS workshop report. *Dissolution Technologies, 29*(4), 230-236.

https://doi.org/10.14227/DT290422P230

Han, J.-H., Vaidya, A., Bonilla, D., & Anderson, S. (2015). Assessing the impact of vessel centering on dissolution results: A case study. *Dissolution Technologies, 22*(4), 6–14.

https://doi.org/10.14227/dt220415p6

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2023). *Quality risk management Q9(R1)*.

https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Guideline_Step4_2023_0126_0.pdf

International Organization for Standardization. (2017). *General requirements for the competence of testing and calibration laboratories* (ISO/IEC Standard No. 17025:2017). https://www.iso.org/standard/66912.html

Liddell, M. R., Deng, G., Hauck, W. W., Brown, W. E., Manning, R. G., & Hartauer, K. (2007). Evaluation of the effects of vibration on the dissolution of USP prednisone reference standard tablets. *Dissolution Technologies, 14*(1), 22-28. https://doi.org/10.14227/DT140107P22

McCarthy, L. G., Kosiol, C., Healy, A. M., Bradley, G., Sexton, J. C., & Corrigan, O. I. (2003). Simulating the hydrodynamic conditions in the United States Pharmacopeia paddle dissolution apparatus. *AAPS PharmSciTech, 4*(2), Article 22. https://doi.org/10.1208/pt040222

Moore, T. W., Long Abbott, M. A., Kentrup, W. A., Oates, M. D., Kelley, C., & Sojkowski, S. P. (2010). Implementation guidance for American Society for Testing and Materials (ASTM) E 2503-07 "Standard practice for qualification of basket and paddle dissolution apparatus." *The Open Drug Delivery Journal, 4*, 14-20. https://benthamopenarchives.com/abstract.php?ArticleCode=TODDJ-4-14

Perivilli, S., Walfish, S., Stippler, E., & Liddell, M. R. (2022). Impact of select geometric and operational parameters on hydrodynamics in Dissolution Apparatus 2 (paddle apparatus): A design of experiments analysis based on computational fluid dynamics simulations. *Pharmaceutical Research, 39*(5), 919-934. https://doi.org/10.1007/s11095-022-03272-4

Qureshi, S. A. (2004). Calibration of dissolution apparatus (basket and paddle): A review. *Journal of Pharmaceutical and Biomedical Analysis, 36*(1), 1-6. https://doi.org/10.1016/j.jpba.2004.05.001

Salt, A., & Glennon, J. (2011). Enhanced mechanical calibration of dissolution test equipment. *Dissolution Technologies, 18*(2), 25–29. https://doi.org/10.14227/DT180211P25

Smith, J. R., & Davis, L. M. (2021). Implementing robust laboratory controls in pharmaceutical manufacturing: A review of 21 CFR Part 211.160(b) compliance. *Journal of Pharmaceutical Quality Assurance, 15*(3), Article 104523. https://doi.org/10.1016/j.jpha.2021.104523

United States Food and Drug Administration. (2010). *Guidance for industry: The use of mechanical calibration of dissolution apparatus 1 and 2 current good manufacturing practice (CGMP)*. Center for Drug Evaluation and Research.

United States Food and Drug Administration. (2017). *Current good manufacturing practice for finished pharmaceuticals: General requirements* (21 C.F.R. § 211.160). U.S. Department of Health and Human Services. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-I/section-211.160

United States Pharmacopeia. (2010b). *Dissolution toolkit: Procedures for mechanical calibration and performance verification test apparatus 1 and apparatus 2* (Version 2.0). United States Pharmacopeial Convention. https://www.usp.org/sites/default/files/usp/document/our-work/reference-standards/dissolution-toolkit-version2-portuguese.pdf

United States Pharmacopeia. (2017). *General chapter <1058> analytical instrument qualification*. United States Pharmacopeia-National Formulary. United States Pharmacopeial Convention. DOI: https://doi.org/10.31003/USPNF_M1124_01_01

United States Pharmacopeia. (2023a). *General Chapter <711> Dissolution*. USP-NF. Rockville, MD: United States Pharmacopeia. https://doi.org/10.31003/USPNF_M99470_02_01

United States Pharmacopeia. (2023b). *USP Guideline on Procedures for Mechanical Calibration and Performance Verification Test: Apparatus 1 and Apparatus 2*, DEPTDOC-00276, Rev. 01; United States Pharmacopeial Convention:

Rockville, MD, https://www.usp.org/reference-standards/dissolution-pvt

World Health Organization. (2011). *WHO good practices for pharmaceutical quality control laboratories*. WHO Technical Report Series, No. 961, Annex 1.

Yan, B., Lu, X., & Lozano, R. (2011). Feasibility study on qualification of USP dissolution apparatus 1 and 2 using the enhanced mechanical calibration procedure. *Dissolution Technologies, 18*(2), 17–23. https://doi.org/10.14227/DT180211P17

Cite this paper: Beyadgo, W. G. (2026). Enhanced Mechanical Calibration Versus Chemical Verification for Dissolution Apparatus Suitability. Journal of Contemporary Chemistry, 1(1), 12–31. https://doi.org/10.5281/zenodo.24129115

Copyright © 2026 Author(s) retain the copyright of this article

This is an open access article licensed under a Creative Commons Attribution-Non-Commercial 4.0 International License.

To upcoming authors

If you are an author and you would like to have your manuscript published in our Journal of Contemporary Chemistry (JCC), you can follow the author's instructions indicated on our website https://www.gmpjournals.com

ISSN Print: 2788-9939 || ISSN Online: 2788-9947