kinaero cx™

PMDI COLLECTION SYSTEM

Automated shaking, actuation, and sample collection for delivered dose uniformity (DDU) and aerodynamic particle size distribution (APSD)

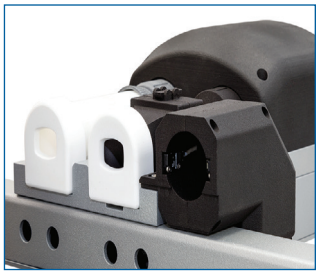
proveris SCIENTIFIC

Inherent human error found in manual testing processes increases the variability of results and decreases the sensitivity for detecting potential performance differences throughout OINDP development and among products. To ensure consistency and sensitivity of findings, the FDA recommends the use of automated actuation systems. The Kinaero Cx Automated pMDI Collection System provides precise reproducible control of shaking, actuation, and sample collection for development and quality control testing. Time savings provided by Kinaero Cx allows more variables to be evaluated during development, helping you create robust products. Performing delivered dose uniformity and aerodynamic particle size distribution with Kinaero Cx eliminates manual variability, increases efficiency, and reduces the risk for OOS events.

Kinaero Cx pMDI Collection System

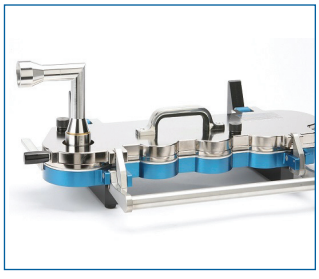
Built around the gold standard Vereo® Automated Actuator, the Kinaero Cx provides the benefits of consistent shaking, shake-to-fire intervals and actuation with added automated sample collection. Integrated flow sensor and controlled values ensure the desired flow rate, eliminating the need for manual flow adjustments.

Automated shaking, shake-to-fire intervals, and actuation



Automated wasting and sample collections

Compatible with apparatus A for DDU testing

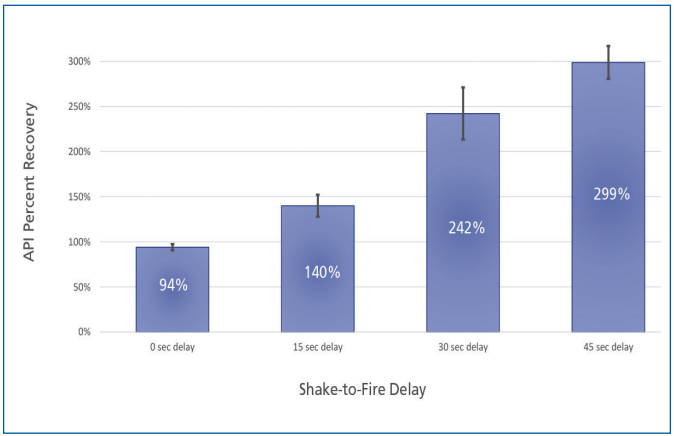


Compatible with Anderson and Next Generation Impactors for APSD

Controlling human variables

Vereo Automated Actuators provide precise and reproducible control of stroke length, actuation velocity and acceleration, hold time and return velocity, and acceleration. Control of these variables is ideal for translating results of human actuation studies to consistent actuation performance. Realistic simulation of patient specific actuation provides a better indication of product performance and reduces the risk of late-stage failures.

Shake-to-fire interval timing is critical to delivered dose of suspension pMDIs and can cause variations in results from 75-320% of label claim. Kinaero Cx ensures that the correct dose is delivered, every time.



Consistent results

APSD and DDU are required Critical Quality Attributes (CQAs) for pMDIs. Their results depend greatly on consistent and accurate dose delivery. Without automated control of shaking, shake-to-fire actuation, and sample collection, there is an increased risk of an OOS event which can increase testing costs and time. When compared to manual testing, Kinaero Cx provides more consistent results regardless of the operator.

Efficiency throughout R&D and QC

Kinaero Cx's control of parameters contributing to CQAs makes it the ideal tool for R&D following a Quality by Design strategy. The consistency and walk-away functionality that Kinaero Cx provides increases efficiency and saves analysts fatigue from repetitive tasks.

Depending on the regulatory agency, life testing requires testing at three life stages - beginning, middle, and end-of-life. Kinaero Cx provides consistent dose delivery for wasting tasks, maintaining product performance, and avoiding tail-off effects from improper dose delivery during wasting.

Combined workflows for every phase

Wasting between tests can be performed on a single sample using the Kinaero Cx. Testing throughput can be increased by including the Kinaero Fire-Down System to through life testing workflows. The fire down system accommodates 10 devices providing the same level of shaking, shake to fire intervals, and actuation. Fire down between beginning, middle, and end of life ensures consistent dose delivery and prevent tail-off ideal for release testing.

Kinaero High-Throughput Fire-Down System can be used alongside the Kinaero Cx for increased throughput.

Traceability

Kinaero Cx is the first automated DDU and APSD solution that employs software guided by 21 CFR Part 11 compliance that allows for easy instrument control, data storage, and report generation. User-friendly software provides the regulatory framework for ensuring data integrity, security, and compliance when working with electronic records and signatures.

Complete pMDI solutions

The addition of Kinaero Cx completes Proveris Scientifics *in vitro* pMDI testing solutions. Regardless of development stage Proveris Scientific instruments provide the consistency, traceability, and adaptability needed to accelerate successful development of orally inhaled drug products.

System overview

System	– Kinaero Cx Automated pMDI Collection	Part Number: 8600
	– Vereo SFMDx Actuator for Kinaero Cx	Part Number: 8650
	– Kinaero Cx Configured Windows 10 Workstation (ask about requirements if providing your own workstation)	Part Number: 010300-00
	– Kinaero Cx Cascade Impactor Kit	Part Number: 010145-00
Size	– Benchtop Operation – Height: 23.4 in (59.5 cm); Width: 21.9 in (55.6 cm); Depth: 24.6 in (62.4 cm) – Weight: 80 lbs (36 kg). Weight with Actuator: 95 lbs (43.1 kg)	
Electrical	– 100-240 VAC, 50/60Hz, 3 A (480 W)	
Regulatory	– In accordance with FDA 21 CFR Part 11	

The Proveris advantage

Complete Solution
Proveris offers a complete suite of testing solutions that covers the lifetime of your OINDP product from early development to manufacturing release.

Scientific Focus
Our line of instruments and lab service offerings help you uncover the true performance of your combination drug product and get to market faster!

Industry Leader
Our experts collectively bring more than 25 years of experience in the field of OINDPs and have helped to shape the regulatory landscape for bioequivalence studies.

Unmatched Customer Support
Global service organization offering world-class support and additional value-add services to help you maximize the benefits from your instruments.

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