indizo®

AUTOMATED NASAL SPRAY COLLECTION SYSTEM

Automated Test System for nasal spray devices from R&D to production

For R&D: Flexible programming streamlines method development to achieve desired target pump delivery and dose content uniformity.

For Production: Unattended automation eliminates manual processes for robust release testing and reproducible results.

Multiple tray configurations provide options for different testing needs

- 10 device capacity for pump delivery and spray content uniformity with 20 dose content collectors and 10 sample collectors (shown above)
- 20 device capacity for pump delivery with 20 sample collectors

Indizo® System features and benefits

- Fully automates dose content uniformity collection and pump delivery (shot weight) testing for vertically and side-actuated nasal sprays
- Integrates the high precision Vereo® NSx or SSx Automated Actuators
- Performs repeated tests across multiple product samples without operator intervention
- Capable of both delivered and metered shot weights
- Performs required release testing through life, beginning and end of life (BoL, EoL)

Viota® software features and benefits

- Viota® software provides sample traceability and compliance for 21 CFR Part 11
- Powerful, yet simple to use user interface with real time force and position feedback measured and displayed as actuation profiles
- Pre-method operational checks ensure error-free set up and execution

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Applicability to FDA Guidance

		FDA Required Test	Determination through Pump Delivery	Determination through SCU
Guidance for Industry: Nasal CMC Guidance	Specifications of the Drug	Pump Delivery	Yes	No
		SCU Collection	No	Yes
		Net Content	Yes	No
	Characterization Studies	Priming/Repriming	Yes	Yes
		Effect of Resting Time	No	Yes
		Temperature Cycling	Yes	Yes
		In Vitro Dose Proportionality	No	Yes
		Device Orientation	No	Yes
		Device Robustness	Yes (Shaking conditions)	Yes
		Profiling of Spray Near Exhaustion	Yes (Solution products)	Yes (Suspension products)
BA/BE Studies	*In Vitro* Tests	SAC	No	Yes
		Priming/Repriming	Yes	Yes

Available Indizo® System Models

Product No.	Model Name	Intended Usage/Application
3000-SCU	Indizo® System SCU NSP	10 device spray content and pump delivery for vertically actuated nasal sprays
3000-PD	Indizo® System PD NSP	20 device pump delivery for vertically actuated nasal sprays
3100-SCU	Indizo® System SCU SSP	10 device spray content and pump delivery for side actuated nasal sprays
3100-PD	Indizo® System PD SSP	20 device pump delivery for side actuated nasal sprays

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