



InnovaSystems, Inc.

Technology Engineering

- **Automated Nasal Spray Products Testing**
- NSP DW – Automates FDA Recommended Tests:
 - Dose (Shot) Weights
 - Priming/Repriming
 - Tail-Off
- Increases Throughput and Productivity
- Improves the Accuracy and Reproducibility of Results
- Insures Reproducible Actuation Force

NSP DW - Automated Actuations, Weights

NSP DW...

Automates the routine Actuation (waste sprays) and Weighing of your Nasal Spray Product. Processes up to 20 sample bottles, unattended, and provides a documented sample history.

Transports bottles, with the XYZ gantry, to the actuator station, bottle shaker and balance. Waste sprays will be contained and drained into a waste vessel.

Supports 21 CFR Part 11 Compliance and simplifies validation with the IQ/OQ documentation.

Includes

- Dose Weight Station with Transport, Gripper and Controller
- MightyRunt Actuator
- Analytical Balance
- Bottle Shaker
- Bottle Tray
- Enclosure
- Validation Protocols, IQ/OQ
- NSP DW Application Software

PRODUCT PARAMETERS

The screenshot shows the 'Product Editor' window. The 'Prod file' is '35_00_10_00_1_50_05 F-2098'. The 'Last edited' and 'Approved' fields are both 'estevens_applic' on 'Apr-29-2003'. The 'NSP Type' dropdown is set to 'F-2098'. The parameters are as follows:

Actuation force (Kg):	3.5	Min travel distance (mm):	5.0
Force rise time (sec):	0.0	Max travel time (sec):	0.5
Release delay (sec):	1.0	Min spray weight (mg):	0
Force Fall time (sec):	0.0	Max spray weight (mg):	999
Actuation delay (sec):	1		

DATA OUTPUT

The screenshot shows the 'Data Output' window with the following text:

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Actuation force (kg): 3.5
Force rise time (sec): 0.0
Release delay (sec): 1.0
Force Fall time (sec): 0.0
Actuation delay (sec): 1
Product / RIC #: 234324325
LSL (mg): 88.35
USL (mg): 97.65

# of observations 50
omitted observations 0
Mean (mg) 91.67
Std. Dev. 6.07
Min (mg) 89.04
Max (mg) 97.30
Range (mg) 8.26

NSP Average Shot weight summary Report
MS # / Run Id: 1234 1342:12 Aug-18-2003
Product / RIC #: F-1524 Inspector: dgarbern

NSP ID Start weight Final weight # sprays Avg Shot weight
1 16.4540 12.4950 10 89.04 MIN
2 14.5458 12.6112 10 97.30 UL MAX
.....
50 14.5458 12.6112 10 91.25

UL - unusable or unstable weight reading Mean (mg) 91.67
UL - Less than LSL value Std. Dev. 6.07
UL - Greater than USL value Min (mg) 89.04
MIN - Max of all Avg Shot weights Max (mg) 97.30
MAX - Min of all Avg Shot weights Range (mg) 8.26
    
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Specifications

Space	Height	Width	Depth
Station	84in	54in	32in
	Power	Air	
Utilities	110/220 VAC 50/60 Hz	100-120 PSI	

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