HIAC 9703+
SUB-VISIBLE PARTICULATE TESTING

LIGHT OBSCURATION TESTING TO USP<787>, <788> AND EP 2.9.19

- Program your SOPs into the counter
- Microsoft Active Directory User Name and Password control
- Review and Approve Workflow in the counter
- Electronic Signatures supported
- Secure Electronic Records straight from the counter

CHARACTERIZED
by ingenuity.

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PharmSpec Software

Program your SOPs into the counter

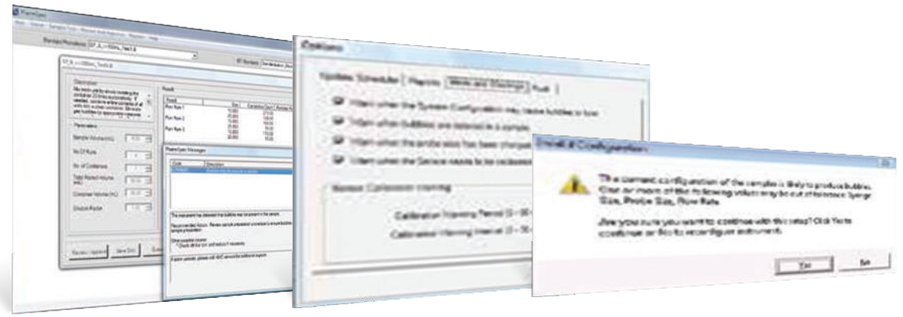
- Eliminate manual counter configuration and pass/fail calculations by using Procedure Builder to program your own SOPs into the counter so that they are available for the technician via a drop-down selection box

21CFR part 11 ALCOA Data Accuracy and Integrity

- User Name and Password credentials are controlled by your corporate IT Microsoft Active Directory
- Multi-level user rights
- Licensed software modules available to automate pass/fail compendial reporting:
  - USP<787>
  - USP<788>
  - EP 2.9.19
  - JP 11
  - JP 24
  - KP 52
- Sample result records include the technician's name, batch number, test result data, pass/fail result and SOP used for the test
- Review and Approve workflow with electronic signature to create secure electronic records straight from the counter
- Comprehensive Audit Trail included

Secure database

- You can choose to locate the database on a separate, secure networked location and the HIAC 9703+ will automatically save all records to that server across the Ethernet network
- Alternatively, you can choose to configure the 9703+ to periodically automatically back-up the database to a secure network location



Flexible sampling options

- The light obscuration sensor can be calibrated at multiple different flow rates to make sampling easier for large volume injectables/infusions testing as well as viscous fluids
- Small-bore, low tare volume sample probe available for Therapeutic Protein Injection testing and wide bore sample probe available for testing viscous samples

Use in laminar airflow cabinets

- Design allows HEPA filtered airflow from cabinet to pass over the top of the glassware/vial to help reduce the risk of sample particulate contamination from the air, reducing the possibility of false-positive results

Typical instrument configuration

PART NUMBER	DESCRIPTION
2089105-01	HIAC 9703+ sampler
2089250-150	Light Obscuration sensor
2086804-01	PharmSpec 3 software CD
700060GP	PharmSpec 3 software licence key
700057	USP Compendial Tests
700058	EP Compendial Tests
700055	SOP Procedure Builder software
2089007-025	Calibration @25mL/minute flow rate including certificate
DOC026.53.80099	IQ/OQ Validation document set on CD

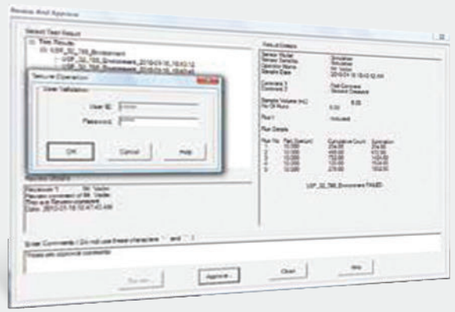
USP<787> Therapeutic Protein Injections

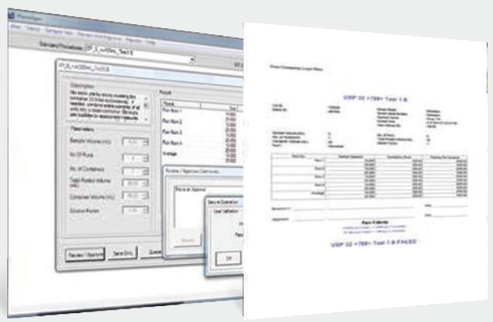
Save valuable product

- Small tare volume option of just 0.091mL allows you to get results to USP<787> with product sample volumes of just 0.2mL

Small vial clamp for conical vials

- Small vial clamp option holds conical vials in line with the sampling probe and upright for automated sampling





Specifications

9703+ Sampler

Temperature Range	5 to 40°C (40 to 104°F) 0 to 80% relative humidity, non-condensing
Temperature Range of Sample	5 to 40°C (40 to 104°F)
Viscosity Limit	<50 cP
Power Requirement	100/230 VAC, 50/60 Hz
Maximum Power	67 W at 115/230 VAC
Dimensions	343 W X 337 D X 482 H mm (13.5 X 13.3 X 19.0 inches)
Weight	10.7 kg (23.6 lbs)
Sample Bottle Clearance	153 mm (6.02 inches)
Volume Accuracy	> 95%
Flow Rate Accuracy	> 95%
Sample Flow Rate	10 to 100 ml/min; Actual flow rate for the system is determined by the sensor's flow rate with step-by-step instructions and Pass/Fail results.
Tare Volumes for Probes	0.091 ml for 81 L X 1.2 ID mm (3.2 X 0.047 inches) 0.172 ml for 154 L X 1.2 ID mm (6.1 X 0.047 inches) 1.57 ml for 140 L X 6.35 ID mm (5.5 X 0.25 inches) - large bore

PharmSpec 3 Software

Processor	1.0 GHz or faster processor
Operating System	Windows 10 Enterprise 64-bit
Memory	2GB of RAM
Hard Disk	2 GB of available hard-disk space
Drives	USB port or network connection is required for installation
Display	1024 x 768 or higher resolution
Power Supply	Uninterrupted power supply (UPS) or network server
Removable Drive	Removable drive for backing up data, such as a recordable CD or a network server that can back up the computer hard drive
Printer	Color printer capable of printing at 300 dpi
USB Port	USB port to connect to the particle counting sensor
Software	Modern web browser and Microsoft® Excel®, Word® or Adobe® Acrobat® (to access PharmSpec reports)

Standard Sensors	**Range**
HRLD-150	1.3 µm to 150 µm
HRLD-150JA	1.3 µm to 150 µm (chemical compatibility)
HRLD-400	2 µm to 400 µm
HRLD-600JS	2 µm to 600 µm (chemical compatibility)
Compliance Certifications	CE Compliant per EMC and Low Voltage Directives Class 1 Laser Product Complies with IEC/EN 60825-1 and 21 CFR 1040.10 pursuant to Laser Notice 50 **
	** Contact manufacturer for complete compliance details

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