

Liquid

Particle

Counting

System for

SVI and LVI

HIAC 9705

accurate • innovative • efficient



Compendial tests for life sciences including USP <788> and cleaning validation





UNIFORM PARTICLE DISPERSION: ACCU-SWIRL™

If you're conducting particle counting tests on your pharmaceutical parenterals, injectibles, or other liquid products, you know that most liquid particle counting systems include a magnetic stir bar to distribute particles throughout a sample. This presents two problems for accurate sampling. First, due to the intrusive nature of the stir bar and the difficulty in removing microscopic particles, contamination between samples may occur. Second, the purely circular motion of most stir bars can create a highly symmetrical velocity profile, distributing particles unequally throughout the sample. The USP recommends hand-swirling to create a more homogenous solution in USP <788>.

The HIAC 9705 Liquid Particle Counting System introduces the patent-pending Accu-Swirl stirring mechanism, a revolutionary non-invasive design for particle suspension. No stir bar means no possibility of cross-contamination. The Accu-Swirl moves the entire bottle in an elliptical motion carefully calculated to provide uniform particle dispersion. This motion replicates the only stirring method specifically referenced by USP <788>, hand-swirling, but eliminates all user variability.

The Accu-Swirl works in combination with the HIAC 9705's unique sample delivery system. To eliminate potential for contamination after samples have been taken, samples are septa-sealed for purity. Once placed in the 9705, the sample is drawn while the Accu-Swirl is in motion to ensure uniform particle dispersion. When the sample bottle is removed, the self-cleaning needle eliminates cross-contamination between samples.

The best part of this breakthrough technology? The 9705 comes with the reliability and confidence you've come to expect from the HIAC brand name.

Why your lab nee

Compendial testing at the push of a b

HIAC quality and reliability take new shape in the 9705 with revolutionary developments in liquid particle sampling technology. An innovative sampling process, housed within the 9705's streamlined case, provides consistent dispersion and highly pure sampling. The 9705 sets new standards for accuracy and efficiency in the analysis of injectables, precision cleaning, parenteral particle counting and verification of WFI / PW / DI waters per USP testing guidelines.



100% Satisfaction Guarantee

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Full compliance

Supports USP, EP, JP, and KP. Interfaces with PharmSpec 2.1 software for 21 CFR Part 11 compliance support. USB port on back allows easy connection to PC.

Intuitive operation

Icon-driven operating system with touch commands simplifies operation.

Local spot checks

Verify sample ranges or other tests before running fully with a PC and software.

Internal printer, located on left side, gives immediate results.

Innovative sample delivery

Provides 10 - 60 mL/min flow rate.

Small tare volume

Minimizes sample waste and reduces sampling time. Save costs particularly when working with expensive or rare samples.

Septa-sealed samples

Accommodate most sample sizes. No need for placement in laminar flow hood.

Non-coring, self-cleaning needles

Offer fail-safe sampling and reduced cross-contamination.

Accu-Swirl stirring mechanism

Uniformly disperses particles and prevents cross contamination.

PHARMSPEC 2 SOFTWARE

USP, EP, JP and KP Compendial Tests: Key compendial tests offered include: USA, Europe, Japan and Korea (KP VIII <52>). PharmSpec 2 only lists the tests required by the application.

Tools for Validation: Manage 9705 data acquisition and analysis with PharmSpec software. Collect and analyze information based on USP, EP, JP or KP procedural standards. PharmSpec also supports 21 CFR Part 11 compliance with password, audit trail and security options.

Unique User ID: PharmSpec employs a 3-element identification method consisting of a user ID, password, and a public name which appears in reports, other general documents or screens. This public element helps to protect the security of the actual User ID and Password elements.

Administrators control password expiration dates, minimum lengths for User IDs and Passwords. The system automatically prevents duplication of user names.

Audit Trails: A secure audit trail database records user actions and automatic system actions. Review and search the database by the type of action, by specified dates or by user name. Information may be printed but cannot be altered or removed.

Database Security: The protected SQL database prohibits operator access or alteration. Back up or permanently archive the database for additional security.

Network Support: Archive and backup data to mapped network drives or the local computer drive. Print to both local and network printers.



SAMPLE SIZES BOTH SMALL AND LARGE

The large volume adapter, consisting of an adjustable height stand and stainless steel tube intake, enables sampling from vessels greater than 125 mL. Easily accommodate IV bags and Large Volume Injectables (LVI) with this included accessory. For the tare volume, the adapter adds 0.054 mL per inch of tubing.

HIAC 9705 Liquid Particle Counting System

Specifications

Temperature Range 10 to 40 °C, 20 to 80% relative humidity, non-condensing

Temperature Range of Sample 5 to 40 °C Viscosity Limit < 15 cp

Voltage 100 to 240 VAC, 50/60 Hz

Dimensions 40.5 H x 30.1 W x 34.3 D (16.0" x 11.9" x 13.5")

Weight 10.7 kg (23.5 lbs) Sample Bottle Clearance 11.8 cm (4.6') Volume Accuracy $\pm 2\%$

Volume Accuracy $\pm 2\%$ Flow Rate Accuracy $\pm 3\%$

Sample Flow Rate 10 - 60 mL/min (specify when ordering, 20 mL/min default)
Concentration Limit 10% coincidence loss at 10,000 p/mL (10 µm PSL)

Sizing Range 1.3 to 150 µm

Sample Vial Sizes 5, 10, 20, 30, 50, 60, 100, 125 mL

Large Volume Adapter Sample sizes greater than 125 mL including LVI

Tare Volume 0.54 mL

Accessories Included

Large Volume Adapter
Sensor Cleaning Brush
Standard Needle for 30 - 125 mL Bottles
USB Cable, 2 m
Adapter Rings (20, 100 mL rings)
Power Cord
Syringes (10 mL)
Printer Paper
Needle Removal Tool
Operator Manual

Stylus

Optional Accessories/Spares

Large Volume Adapter with integrated stirrer

Sample Vials (5, 10, 20, 30, 50, 60, 100, 125 mL)

Vial Adapter (5, 10, 20, 30, 50, 60, 100, 125 mL)

Adapter Rings (20 mL for USP standards, 100 mL for LVA)

Removable Vent Needle (5-30 mL vial, 50-125 mL vial)

Sample Preparation Kit (5, 10, 20, 30, 50, 60, 100, 125 mL)

Syringes (1, 25 mL)

Sample V

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Sample Vial Seals
Sample Vial Crimp Ring
Sample Vial Crimp Tool
Sample Vial Decapping Tool
PharmSpec Calibration Kit
Pharm-Trol™ Reference Particles
USB Cable (1, 2, 3 m, A to B Type)

PharmSpec 2 Software

Computer Requirements

Intel Pentium III or higher processor, 450 MHz Microsoft® Windows 2000, NT or XP system Microsoft Internet Explorer 5.5 or higher USB Communications Port 128 MB RAM 500 MB free hard disk space

Video, 1024 x 768

License and Ordering Information

PharmSpec 2 License
JP Compendial Test <11>, <24> License
EP Compendial Test <2.9.19> License
USP Compendial Test <788> License

KP Compendial Test <52> License
Procedure Builder for Custom Tests License
User Manual and CD
PharmSpec 2 Validation (IQ/OQ) Documents/CD

Service

Comprehensive local and onsite Hach Ultra service programs with multiple field service offices and authorized distributors available throughout the world. Contact your representative for additional information.

Global Headquarters

6, route de Compois, C.P. 212, CH-1222 Vesenaz, Geneva, Switzerland, Tel 41 22 855 91 00 Fax 41 22 855 91 99

Americas Headquarters

481 California Avenue, Grants Pass, Oregon 97526 USA, Tel 1 800 866 7889 1 541 472 6500 Fax 1 541 479 3057

www.hachultra.com



