Liquid-Borne Particle Counter

KL-05
Conforms to Method 1 "Light Obscuration Particle Count Test" in insoluble particulate matter testing for injections in accordance with the Japanese Pharmacopeia

Serves for measurement of insoluble particles in injections, for example at pharmaceutical plants

Features

- Compliant with insoluble particulate matter testing for injections in accordance with the Japanese Pharmacopeia (JP), United States Pharmacopeia (USP), European Pharmacopeia (EP), Korean Pharmacopeia (KP) and Chinese Pharmacopoeia (ChP).
- Supports small volume measurement (USP 787). Special small size sample stand available as option, for 10 mL syringes and ampoules etc.
- Compliant with FDA’s 21 CFR Part 11. Comprehensive operator and password management functions, as well as electronic signature support.
- Serial communication function allows output of measurement data to a Laboratory Information Management Systems (LIMS) etc.
- Measurement results can be output as PDF or text file (tab delimited) format.
- Large 10.4 inch LCD panel provides information in an easy to read format.
- Integrated SSD storage improves data access speed.
- Measurable particle size range 1.3 μm to 100 μm, flow rate 25 mL/min (10 mL/min available as factory option), with up to 20 particle size range settings.
- Light source uses semiconductor laser with three-year guarantee. (under normal use and proper handling)
Sample display screens

Audit trail function

Produces a reliable record of who performed which operation at what time. Audit trail data can be displayed, printed, and searched.

Audit trail display sample screen

Audit trail search sample screen

Operator management function

Functions such as deletion and modification of measurement data, as well as display and printing of audit trail data can be accessed controlled by operator management.

Operator management sample screen

Specifications

| Optical system | Light-obscuration method |
| Light source   | Laser diode (rated output 4.5 mW, wavelength 790 nm) |
| Laser product class | Class 1, IEC 60825-1 |
| Light detector | Photodiode |
| Fluid-contacting materials | |
| Flow cell | Synthetic quartz |
| Syringe | Borosilicate glass, PTFE |
| Syringe pump | Kel-F (PCTFE), PTFE |
| Tube, packing, joint | PFA, PTFE, PCTFE, Perfluorine rubber (special fluorine rubber) |
| Particle size ranges | 1 to 20 ranges from 1.3 μm to 100 μm (in 0.1 μm steps) |
| Counting efficiency | 100 % ±5 % |
| Maximum particle number | 10,000 particles/mL (10 μm vicinity PSL particles, coincidence loss max. 10%) |
| Sampling volume accuracy | |
| 25 mL syringe, flow rate 25 mL/min | ±2 % (when measuring 10 mL) |
| 25 mL syringe, flow rate 10 mL/min | Factory option |
| 10 mL syringe, flow rate 10 mL/min | Factory option |
| 0.2 mL | Depending on sampling tube in use, dead volume must be added to aspiration |
| Minimum measurable volume | |
| Maximum sample fluid pressure | 50 kPa (gauge pressure) |
| Maximum sample fluid viscosity | 30 mPa-s (at 25°C) |
| Power requirements | 100 V to 240 V AC, 50/60 Hz, approx. 80 VA |
| Environmental condition for operation | 15°C to 30°C, 20% to 80% RH (no condensation) |
| Dimensions and weight | Approx. 369 (H) x 375 (W) x 236 (D) mm, approx. 10 kg |
| Supplied accessories | PFA sampling tube set (2 mm dia. x 4 mm dia., length 10 cm) |
| | Drain tube set (2 mm dia. x 3 mm dia., length 150 cm) |
| | USB flash drive (8 GB), power cord (Japan domestic, 2.5 m), mouse, Keyboard, ferrite core, |
| | cell cleaning brushes (in case), cable clamp |
| Optional accessories | |
| PFA sampling tube set (2 mm dia. x 4 mm dia., length 10 cm) | |
| 25 mL syringe 5ZSY60P0 | Capacity test required after replacement. |
| 10 mL syringe 5ZSY61P0 | Capacity test required after replacement. |
| USB flash drive (32 GB) | 5ZUBU200 |
| Printer LP-S280DN | Recommended model (alternative: HL-L2360DN) |
| USB cable for printer, Type A to Type B (2 m) | 5WUSB200 |
| External display (21.5 in) | E2282HD-B1 |
| Communication cable CC-61A, CC-63A | |

Automatic unit volume conversion

(example: 1 mL)

One aspiration action can be used for multiple measurements (within 25 mL)
**SUS sampling tube set**  
(with nut and 2 packings)

- **KL-04-S12**
  - φ2 mm × 3 mm, Length 100 mm
- **KL-04-S11**
  - φ1 mm × 2 mm, Length 100 mm

**Sample stand adapter for small volume containers**  
KL-05-S22

This sample stand is designed to hold small volume containers during measurement. Containers between 8 and 20 mm in width can be used.

**Electromagnetic stirrer unit**  
KL-05-S21

Rapidly rotating the stirrer bar that is mounted on the sample stand of the KL-05 enables you to equalize the samples.

- **Stirring capacity**: 1 to 800 mL
- **Rotational frequency**: 130 to 1,000 rpm (single step switch)
- **Stirring power**: 3 W
- **Environmental conditions**: -10 to +120 °C (for less than 40 % humidity)
  -10 to +95 °C (for 100 % humidity)
- **Dimensions of main body**: 16(H) × 48(W) × 48(D) mm
- **Weight of main body**: Approx. 200 g
- **Input power**: Supplied through the attached control unit

**Compressing chamber JCC-54**  
(Custom-made product)

JCC-54 added to the KL-05 enables you to measure samples during pressurization.

- **Supported types of sample fluid**
  - Fluids where the fluid or its gases will not corrode the materials of the unit
- **Chamber pressure (inside)**: 50 kPa
- **Materials of parts exposed to sample**
  - PTFE, PAF, PP, FKM (Fluoro rubber)
- **Dimension, weight**
  - 340(H) × 245(W) × 245(D) mm
  - Approx. 12 kg

**CLINTEX CTX10410**  
(standard particle concentration)

- **Particle size**: 10.14 μm
- **Guaranteed particle concentration**: 1,000 particles/mL ±10 %

**Support for validation works**

We can support your validation works (IQ, OQ, PQ) for KL-05.

1. Discussion with customers (Continuation of IQ, OQ and PQ)
2. Preparation and approval of IQ, OQ and PQ implementation plans
3. Implementation of IQ, OQ and PQ operations
4. Preparation of IQ, OQ and PQ implementation records

**Specifications subject to change without notice.**

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