Conforms to Method 1 "Light Obscuration Particle Count Test" in insoluble particulate matter test for injections conducted by the Japanese Pharmacopeia

Counts insoluble particulate matter in injections performed at pharmaceutical plants, etc.

Features

- Data management principles as specified by Japanese Pharmacopeia (JP), United States Pharmacopeia (USP), European Pharmacopeia (EP), Korean Pharmacopeia (KP) and Chinese Pharmacopoeia (ChP) can be selected (option)
- Can be connected to an external system, such as LIMS (Laboratory Information Management System), to output measurement data (option) (USB-RS232C conversion cable required)
- USB memory is used for data output and system back up
- Conforms to 21 CFR Part 11 by the American FDA Enhanced audit trial and operator management functions
- Measurable particle size range: 1.3 to 100 μm, flow rate: 25 mL/min (10 mL/min is factory option), size range: enables setting of up to 20 channels
- Supports automatic measurement and pass/fail evaluation according to pharmacopeia specifications
- Small volume ampoule measurement is possible with the setting range of measurement volume from 0.2 mL
- Fully integrated system comprising sampler, sensor, controller and data storage
- Built-in hard disk can hold over ten years worth of measurement data

| Instrument | Verify the calibration, the sample volume accuracy, the flow rate accuracy, and the counting accuracy at least once a year.
| Calibration | 5 μm, 10 μm and 25 μm PSL particles are to be included.
| Sample volume accuracy | Use the weighing method to measure volumes (within 5 %)
| Sample flow rate | Within the range specified by the manufacturer
| Sensor | Particle Count Reference Standard Suspension Using (10 μm PSL particle, within 1 000 particle/mL ± 10 %) to conduct the following tests:
  - Permissible sensor resolution: within 10 %
  - Particle counting accuracy: 763 to 1 155 particles/mL
  - Threshold setting accuracy: within 5 %

| Criteria for JP, USP, EP, KP and ChP Insoluble Particulate Matter Tests |
| Large volume | JP/KP/ChP | USP/EP |
| 10 μm or more | No more than 25 particles/mL (100 mL or more) | No more than 25 particles/mL (over 100 mL) |
| 25 μm or more | No more than 3 particles/mL (100 mL or more) | No more than 3 particles/mL (over 100 mL) |

| Small volume | JP/KP/ChP | USP/EP |
| 10 μm or more | No more than 6 000 particles/container (Less than 100 mL) | No more than 6 000 particles/container (100 mL or less) |
| 25 μm or more | No more than 600 particles/container (Less than 100 mL) | No more than 600 particles/container (100 mL or less) |
Support for validation works
We can support your validation works (IQ, OQ, PQ) for KL-04A.

Audit Trail Function
This function records information about time stamp (local time), operator, and operation event. History data can be displayed, printed, and searched.

Operator Management Function
Functions such as deletion and modification of measurement data and display and printing of audit trail data can be access controlled by operator management.

Screen display examples
Screen language can be switched to Japanese or English

JP performance test data example
Measurement parameter (One aspiration action can be used for multiple measurements; within 25 mL)

Automatic conversion for unit container and 1 mL
Measurement parameter (Selection of performance test data)
Optical method  Light-obscuration method
Light source  Laser diode (rated output: 3 mW, wavelength: 780 nm)
Laser product class  Class1, IEC 60825-1
Light detector  PIN type photodiodes
Materials of parts exposed to sample
Sampling tube  PFA
Sensor area  Synthetic quartz, PFA, perfluoro (fluorocarbon rubber)
Syringe pump  Borosilicate glass, Kel-F (PCTFE), PTFE, PFA
Sample container plate  Polycrystalline
Counting efficiency  100 ± 5 %
Measurable particle size range  1.3 to 100 μm (when using PSL particles in pure water)
Allowable fluid type  Fluids which do not cause corrosion to the parts in contact with the fluid
Calibration  Using PSL particles (refractive index 1.6) in pure water
Size range  Selectable arbitrarily from 1 to 20 channels
Flow rate  25 mL/min (10 mL/min is the factory option)

Rapidly rotating the stirrer bar that is mounted on the sample stand of the KL-04A enables you to equalize the samples.

Specifications

<table>
<thead>
<tr>
<th>Maximum particle number concentration</th>
<th>10 000 particles/mL (when the counting loss is 10 % in the vicinity of 10 μm PSL particles in pure water)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum sample pressure</td>
<td>50 kPa</td>
</tr>
<tr>
<td>Input/Output connectors</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRINTER</th>
<th>Parallel interface to connect to a printer (IEEE 1284 compatible, 25 pin D-sub female type connector)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USB</td>
<td>Interface to connect to equipment that supports USB devices (USB 2.0, type A, female type connector, 4 ports)</td>
</tr>
<tr>
<td>Power</td>
<td>100 to 240 V AC, 50/60 Hz, approx. 100 VA</td>
</tr>
<tr>
<td>Environmental conditions for operation</td>
<td>+15 to + 30 °C, 20 to 80 % RH (no condensation)</td>
</tr>
</tbody>
</table>

Dimensions, weight
Approx. 305(H)×286(W)×110(D)mm (excluding protruding parts), Approx. 15 kg

Supplied accessories
PFA sampling tube (ø2 mm×4 mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S14)
SUS sampling tube (ø2 mm×3 mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S12)
SUS sampling tube (ø1 mm×2 mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S11)
Seat, USB memory, USB-RS232C conversion cable

Optional Accessories
- Printer (PostScript Level 2 or above).
- Printer cable (parallel).
- Electromagnetic stirrer, stirrer bar
- PFA sampling tube (ø2 mm×4 mm, length 10 cm) set (includes a nut) (KL-04-S14)
- SUS sampling tube (ø2 mm×3 mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S12)
- SUS sampling tube (ø1 mm×2 mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S11)
- Seat, USB memory, USB-RS232C conversion cable

Electromagnetic Stirrer Unit
Rapidly rotating the stirrer bar that is mounted on the sample stand of the KL-04A 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 XP-54 (Custom-made product)
XP-54 added to the KL-04A enables you to measure samples during pressurization.

Chamber pressure (inside)  50 kPa
Materials of parts exposed to sample  PTFE, PAF, PTF, FKM (Fluoro rubber)
Dimensions, weight  340(H)×245(W)×245(D)mm, Approx. 12 kg

Supported types of sample fluid
Fluids where the fluid or its gases will not corrode the materials of the unit

PrINTER
- PostScript Level 2 or above
- Monochrome laser printer

Printer to be connected
Supporting PostScript Level 2 and above
USB Interface (USB 2.0, type A, female type connector)
Power  100 to 240 V AC, 50/60 Hz, approx. 100 VA
Environmental conditions for operation  +15 to + 30 °C, 20 to 80 % RH (no condensation)
Dimensions, weight  Approx. 305(H)×286(W)×110(D)mm (excluding protruding parts), Approx. 15 kg

Supplied accessories
PFA sampling tube (ø2 mm×4 mm, length 10 cm) set
SUS sampling tube (ø2 mm×3 mm, length 10 cm) set (includes a nut and 2 pieces of packing)
SUS sampling tube (ø1 mm×2 mm, length 10 cm) set (includes a nut and 2 pieces of packing)
Seat, USB memory, USB-RS232C conversion cable

ISO 14001 RION CO., LTD.
ISO 9001 RION CO., LTD.

http://www.rion.co.jp/english/

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