Light Obscuration Particle Counter

Liquid-Borne Particle Counter

KL-04A
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), and Korean Pharmacopeia (KP) 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 trail 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

### JP: Standardization of "Light Obscuration Particle Counter"

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Calibration</th>
<th>Sample volume accuracy</th>
<th>Sample flow rate</th>
<th>Sensor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verify the calibration, the sample volume accuracy, the flow rate accuracy, and the counting accuracy at least once a year.</td>
<td>Verify the calibration, the sample volume accuracy, the flow rate accuracy, and the counting accuracy at least once a year.</td>
<td>Verify the calibration, the sample volume accuracy, the flow rate accuracy, and the counting accuracy at least once a year.</td>
<td>Verify the calibration, the sample volume accuracy, the flow rate accuracy, and the counting accuracy at least once a year.</td>
<td>Verify the calibration, the sample volume accuracy, the flow rate accuracy, and the counting accuracy at least once a year.</td>
</tr>
<tr>
<td>5 μm, 10 μm and 25 μm PSL particles are to be included.</td>
<td>Use the weighing method to measure volumes within 5 %</td>
<td>Use the weighing method to measure volumes within 5 %</td>
<td>Use the weighing method to measure volumes within 5 %</td>
<td>Use the weighing method to measure volumes within 5 %</td>
</tr>
<tr>
<td>Within the range specified by the manufacturer</td>
<td>Within the range specified by the manufacturer</td>
<td>Within the range specified by the manufacturer</td>
<td>Within the range specified by the manufacturer</td>
<td>Within the range specified by the manufacturer</td>
</tr>
</tbody>
</table>

### Criteria for JP, USP and EP Insoluble Particulate Matter Tests

<table>
<thead>
<tr>
<th></th>
<th>JP</th>
<th>USP/EP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Large volume</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 μm or more</td>
<td>No more than 25 particles/mL (100 mL or more)</td>
<td>No more than 25 particles/mL (over 100 mL)</td>
</tr>
<tr>
<td>25 μm or more</td>
<td>No more than 3 particles/mL (100 mL or more)</td>
<td>No more than 3 particles/mL (over 100 mL)</td>
</tr>
<tr>
<td><strong>Small volume</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 μm or more</td>
<td>No more than 6 000 particles/container (Less than 100 mL)</td>
<td>No more than 6 000 particles/container (100 mL or less)</td>
</tr>
<tr>
<td>25 μm or more</td>
<td>No more than 600 particles/container (Less than 100 mL)</td>
<td>No more than 600 particles/container (100 mL or less)</td>
</tr>
</tbody>
</table>

- Permissible sensor resolution: within 10 %
- Particle counting accuracy: 763 to 1 155 particles/mL
- Threshold setting accuracy: within 5 %
We can support your validation works (IQ, OQ, PQ) for KL-04A.

**Support for validation works**

1. Discussion with customers (Confirmation 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

**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
  - 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)
  - Measurement parameter (One aspiration action can be used for multiple measurements; within 25 mL)

**Measurement Parameter**

- Screen display examples
  - History data search screen
  - History data display
  - Operator management screen

**Required documents**
- Traceability system diagrams
- Test results reports
- Instruction manuals
- Calibration certificates
- Specification sheets

**Work flow chart**

1. Discussion with customers (Confirmation 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

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optical method</td>
<td>Light-obscuration method</td>
</tr>
<tr>
<td>Light source</td>
<td>Laser diode (rated output: 3 mW, wavelength: 780 nm)</td>
</tr>
<tr>
<td>Laser product class</td>
<td>Class1, IEC 60825-1: 2007</td>
</tr>
<tr>
<td>Light detector</td>
<td>PIN type photodiodes</td>
</tr>
<tr>
<td>Materials of parts exposed to sample</td>
<td>Sampling tube: PFA; Sensor area: Synthetic quartz, PFA, perfluoro (fluorocarbon rubber); Syringe pump: Borosilicate glass, Kel-F (PCTFE), PTFE, PFA; Tube/packing/connector: PTFE, PCTFE; Sample container plate: Polyacetal; Sampling tube: PFA, Synthetic quartz, PFA, perfluoro (fluorocarbon rubber);</td>
</tr>
<tr>
<td>Counting efficiency</td>
<td>100 ± 5%</td>
</tr>
<tr>
<td>Measurable particle size range</td>
<td>1.3 to 100 μm (when using PSL particles in pure water)</td>
</tr>
<tr>
<td>Allowable fluid type</td>
<td>Fluids which do not cause corrosion to the parts in contact with the fluid</td>
</tr>
<tr>
<td>Calibration</td>
<td>Using PSL particles (refractive index 1.6) in pure water</td>
</tr>
<tr>
<td>Size range</td>
<td>Selectable arbitrarily from 1 to 20 channels</td>
</tr>
<tr>
<td>Flow rate</td>
<td>25 mL/min (10 mL/min is the factory option)</td>
</tr>
<tr>
<td>Maximum number particle concentration</td>
<td>10 000 particles/mL (when the counting loss is 10% in the vicinity of 10 μm PSL particles in pure water)</td>
</tr>
<tr>
<td>Maximum sample pressure</td>
<td>30 kPa</td>
</tr>
<tr>
<td>Input/output connectors</td>
<td>PRINTER: Parallel interface to connect to a printer (IEEE 1284 compatible, 25 pin D-sub female type connector); Printer to be connected: Supporting PostScript Level 2 and above; USB: Interface to connect to equipment that supports USB devices (USB 2.0, type A, female type connector, 4 ports); 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. 363(H)×360(W)×236(D)mm (excluding protruding parts), Approx. 13 kg; Supplied accessories: PFA sampling tube (ø2mm×4mm, length 10 cm) set (includes a connector and a piece of packing), USB memory, Power code (2.5 m), Mouse, Keyboard, Cell cleaning brushes, Screw (for mounting electromagnetic stirrer)</td>
</tr>
</tbody>
</table>

### Optional Accessories

- Printer (PostScript Level 2 or above), Printer cable (parallel), Electromagnetic stirrer, stirrer bar
- PFA sampling tube (ø2mm×4mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S14)
- SUS sampling tube (ø2mm×3mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S12)
- SUS sampling tube (ø1mm×2mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S11)
- Seat, USB memory, USB-RS232C conversion cable

---

## Options

### 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 1000 rpm (single step switch)
- Stirring power: 3 W
- Environmental conditions: -10 to +55 °C (for less than 40% humidity), -10 to +95% RH (based on 140% RH)
- Weight of main body: Approx. 200 g
- Input power: Supplied through the attached control unit

- Includes one stirrer bar

---

### Compressing chamber XP-54

XP-54 added to the KL-04A 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 (max): 50 kPa
- Materials of parts exposed to sample: PTFE, PA, PP, FKM (Fluoro rubber)
- Dimension, weight: 340(H) × 245(W) × 245(D)mm, Approx. 12 kg

- Optional: External pump KZ-28M

---

### CLINTEX CTX10410

(standard particle concentration)

- Particle size: 10.14 μm
- Guaranteed particle concentration: 1000 particles/mL ± 10%

---

### PRINTER

- PostScript Level 2 or above, Monochrome laser printer

---

This leaflet is printed with environmentally friendly vegetable-based ink.

ISO 14001:2004 RION CO., LTD.
ISO 9001:2000 RION CO., LTD.

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

3-20-41, Higashimotomachi, Kokubunji, Tokyo 185-8533, Japan
Tel: +81-423-59-7878, Fax: +81-423-59-7458