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**Test methods for particle contamination of infusion,
transfusion and injection equipment for medical use**

医用输液、输血、注射器具

微粒污染检验方法

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Test methods for particle contamination of infusion, transfusion and injection equipment for medical use

1 Scope

This Standard specifies test methods for particle contamination of intravenous infusion, blood transfusion, injection equipment.

This Standard is applicable to particle contamination inspection of intravenous infusion device. For other products, the particle contamination test method can refer to this Standard.

This Standard is not applicable to syringe for intramuscular injection with a nominal capacity of 1 mL or less.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 6682-2008, *Water for analytical laboratory use - Specification and test methods* (ISO 3696:1987, MOD)

GB/T 25915.1-2010, *Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness* (ISO 14644-1:1999, IDT)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 fluids for washing

liquids that have not been contacted with test sample and are used to elute particles contained in the test sample

3.2 fluids after washing

liquids that after the fluids for washing are in contact with the test sample, the particles contained in the sample have been eluted into the fluid for washing

6 Principle

Choose the right fluids for washing. Rinse the test piece by the specified method. Classify and count the particles in the fluids after washing (3.2) by a suitable counting method.

7 Instruments and materials

7.1 Fluids for washing

7.1.1 Fluid A for washing: purified water, filtered through a membrane with a pore size of not more than 0.22 μ m.

7.1.2 Fluid B for washing: isopropanol, analytically pure, filtered through a membrane of no more than 0.22 μ m.

7.1.3 Fluid C for washing: Tween-80 solution, 3g of commercially available high concentration polysorbate 80 (Tween-80) is dissolved in 10L of pure water (in accordance with GB/T 6682-2008 level 1 or 2).

7.2 Vacuum filter

The aperture is 0.45 μ m.

7.3 Erlenmeyer flask

The volume is 300mL.

7.4 Ultrasonic cleaner

The frequency is 40kHz.

7.5 Oscillating device

Move at a frequency of 300 times/min ~ 350 times/min on a horizontal circular path with a diameter of 12mm $\pm$ 1mm.

7.6 Particle counter

It uses extinction (light shading or light blocking) principle. And it can classify and count particles in the fluids after washing according to the categories defined in Table 1.

7.7 Microscope

Magnification is about 50 times, with proper direct illumination of 0°~10° with the microscope stage.

after washing to obtain at least 100mL of collected fluid.

10.3.2 For syringes with a nominal capacity greater than 10mL and less than or equal to 100mL, take 5 syringes. Respectively extract the fluids for washing of half nominal capacity. Pull the piston to the nominal capacity. Oscillate on the oscillating device (7.5) for 20s. Bring the fluids after washing from each syringe together. If the fluids after washing is less than 100 mL, repeat the above steps for the same 5 syringes. Combine the obtained fluids after washing to obtain at least 100mL of collected fluid.

10.3.3 For test syringes with a nominal capacity greater than 100mL, take 3 syringes. Respectively extract 100mL of fluids for washing. Move the piston to the nominal capacity. Place the cone head on the oscillating device (7.5) and oscillate for 20s to obtain 3 portions of 100mL unit washing fluid.

10.4 Containers

Take 3 containers for supply. Respectively fill the fluids for washing of nominal capacity through the filling tubing. Close container. Use ultrasonic cleaner to elute 2min. Collect the fluids after washing into the sampling cup to obtain 3 portions of unit washing fluid of test sample's nominal capacity.

10.5 Small entries

Take 10 test products. Place them in an Erlenmeyer flask (7.3). Add into 100mL of fluids for washing. Cover the top of the conical bottle with aluminum foil (or other suitable material). Place in an oscillating device (7.5) to oscillate for 20s to obtain 100mL of collected fluid.

10.6 Piercing devices

Take 5 test samples. Under 1m static head, make 100mL of fluids for washing flow through each of the 5 test samples. Collect 500mL of collected fluid in total.

10.7 Small die lumens

Take 10 test products for supply. Under 1m static-head, respectively use 50mL of fluids for washing to flush the lumen according to the maximum flow rate so as to obtain 500mL of collected fluid.

11 Particle counting method

11.1 Particle counter method

Use particle counter to determine the number of particles in fluids after washing. Stir for 1min on the particle counter (7.6). The sample volume is not less than

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