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Replacing GB/T 27950-2011

General requirements for hand disinfectant

手消毒剂通用要求

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General requirements for hand disinfectant

1 Scope

This standard specifies the raw material requirements, technical requirements, inspection methods, methods of use, identification of hand disinfectants.

This standard applies to disinfectants for sanitary hand disinfection and surgical hand disinfection.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this standard.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB 15982 Hygienic standard for disinfection in hospitals

WS/T 313 Standard for hand hygiene for healthcare workers in healthcare settings

Pharmacopoeia of the People's Republic of China (2015 edition)

Technical specifications for cosmetic safety (2015 edition)

Technical specification for disinfection (2002 edition) [Ministry of Health (WJF [2002] No.282)]

Hygienic code for disinfection products manufacturers (2009 edition) [Ministry of Health (WJF [2009] No.53)]

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Hand antisepsis

Treatment process of killing or removing hand microorganisms and

achieving a harmless state.

Note: It can be divided into sanitary hand antisepsis and surgical hand antisepsis.

3.2

Hand disinfectant

Chemical preparation applied to hand antisepsis.

3.3

Alcohol-based hand rub

Hand disinfectant containing alcohol and skin care ingredients.

Note: The dosage form includes liquid, gel, foam.

3.4

Waterless antiseptic agent

Hand disinfectant which is mainly used for disinfection of surgical hands and does not need to be washed with water after disinfection.

Note: The dosage form includes liquid, gel, foam.

3.5

Hygienic hand antisepsis

The process of rubbing your hands with a hand disinfectant to reduce the temporary bacteria in the hands.

3.6

Surgical hand antisepsis

The process that, before the surgery, the medical staff rubbed and washed hands with running water and hand washing liquid, then used hand disinfectant to remove or kill temporary resident bacteria and reduce resident bacteria.

4 Requirements for raw material

4.1 The raw materials shall meet the quality requirements of the Pharmacopoeia of the People's Republic of China (2015 edition) or medical

Carry out the test according to "Technical specifications for disinfection" (2002 edition).

6.5.2 Determination of lead, arsenic, mercury content

6.5.2.1 Lead

It is tested according to the test method of " Technical specifications for cosmetic safety " (2015 edition).

6.5.2.2 Arsenic

It is tested according to the test method of " Technical specifications for cosmetic safety " (2015 edition).

6.5.2.3 Mercury

It is tested according to the test method of " Technical specifications for cosmetic safety " (2015 edition).

7 Method of use

7.1 Hygienic hand antisepsis method

Take an appropriate amount (about 2.0 mL) of hand disinfectant on the palm. Rub your hands together to evenly coat each part. Rub and disinfect for 1.0 min.

7.2 Surgical hand antisepsis method

The surgical hand antisepsis method shall be carried out according to the requirements of WS/T 313.

8 Identification

8.1 The marking shall comply with the provisions of GB/T 191.

8.2 The label and instruction manual shall mark the validity period of the product and the validity period after the product is put into use. It shall comply with the relevant codes and standards of the label instruction manual of the disinfected product.

8.3 At the same time, the product manual shall indicate the precautions:

- a) Disinfectant for external use shall not be taken orally and shall be placed out of the reach of children;
- b) Avoid use with antagonists;

Appendix A

(Normative)

Testing method of validity period of use after product put into use

A.1 Purpose

Observe the validity period of use of the hand disinfectant product after it is put into use.

A.2 Scope of application

This test method is applicable to the test of the validity period of use of the hand disinfectant product after it is put into use.

A.3 Test equipment

Biosafety cabinet or clean laboratory (cleanliness level above 1000), graduated pipette (1.0 mL, 2.0 mL, 5.0 mL), diluent, nutrient agar medium, plate, neutralizer, electric mixer, content testing instrument, as shown in the corresponding standard method or "Technical specification for disinfection" (2002 edition).

A.4 Test method

A.4.1 Select the representative room (in the hospital or simulated hospital conditions) as the test room. Take 3 batches, 3 bottles per batch, totally 9 bottles of disinfectants which had finalized package. Place them in the test room. Use hand disinfectant 5 times a day for 5 time periods, each time interval is about 1 h. The amount and method of use is according to the product instructions (when the disinfectant balance is less than 10%, stop taking samples). At the day 0 , the day (T - 30), the day T (T is the effective period of use after the product is put into longest use in the instruction manual), respectively, use 2 sterilized test tubes for aseptic operation to take 2 mL. Number it and fill in the sampling record. Send it to the laboratory within 4 h for testing. One sample is used to test the total number of bacteria, whilst the other sample is used to test the content of active ingredients in the disinfectant.

A.4.2 In the biosafety cabinet or clean laboratory, follow the requirements of GB 15982 to test the total number of bacteria; take the average value as result. Follow the corresponding standard of the disinfection product or "Technical specification for disinfection" (2002 edition), to test the content of the active ingredient; take the average value as result. Calculate the rate of decline in active ingredients.

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