

Technical requirements for medical device products

Medical alcohol pads

1. Product model/specification and its division description

1.1 Product composition

Medical alcohol pads is made of medical alcohol with the concentration of 70% ~ 80% (volume fraction) soaked in spunlaced nonwoven fabric.

1.2 Product specifications and division instructions

Product specifications are divided into 5cm×5cm(out size).
Inner swab size 3cm*6cm, 6cm*6cm

2. Performance index

2.1 physical property

2.1.1 Exterior

The pads should be uniform in thickness and free from defects such as damage.

2.1.2 Measure

The tolerance of product specifications and dimensions is 10%.

2.2 saturation ratio

saturation ratio>2

2.3 Disinfectant concentration

The concentration of medical alcohol in cotton tablets is 70% ~ 80% (volume fraction).

2.4 Microbial killing index

According to the quantitative germicidal test method of suspension in the Technical Specification for Disinfection (2002 edition) of the Ministry of Health, the germicidal effect should conform to Table 1.

Table 1 Technical Requirements for Killing Microorganisms

Object	min	Killing logarithmic value
escherichia coli	3	≥5.00
Staphylococcus aureus	3	≥5.00
pseudomonas aeruginosa	3	≥5.00
Candida albicans	3	≥5.00

2.5 Stability

Take medical alcohol pads products, and test the concentration of medical alcohol should be 70% ~ 80% (volume fraction).

According to the test method in 3.5, the degradation rate of ethanol is ≤10%.

3. Test method

3.1 Physical performance test

3.1.1 Exterior

Observed with normal vision or corrected vision, the results should meet the requirements of 2.1.1.

3.1.2 Size measurement experiment

Use the passing gauge to measure the specifications and dimensions, and the results shall meet the requirements of 2.1.2.

3.2 Saturation ratio test

Take 10 pieces of medical alcohol pads and weigh W_0 respectively. Extrude all the liquid in the cotton sheets into a volumetric flask and air dry the cotton sheets naturally. Weigh W_1 and calculate according to the following formula:

$$X = (W_0 - W_1) / W_1$$

The results shall meet the requirements of 2.2.

3.3 Disinfectant concentration test

According to 2.1 gas chromatography test in Appendix A of GB26373-2010, the results should meet the requirements of 2.3.

3.4 Indicator test for killing microorganisms

According to the method in Technical Specification for Disinfection of Ministry of Health (2002 edition), the results should meet the requirements of 2.4.

3.5 Stability test

With the accelerated test method, three boxes of medical alcohol sterilized cotton sheets were placed in a thermostat at 54°C for 14 days, and the ethanol content was measured before and after, and the average degradation rate was calculated. The results should meet the requirements of 2.5.

4. Terminology None