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**Hygienic requirements for antibacterial and bacteriostatic
lotion**

抗菌和抑菌洗剂卫生要求

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Hygienic requirements for antibacterial and bacteriostatic lotion

1 Scope

This Standard specifies the raw materials, technical requirements, testing methods, packaging, transportation, storage, label and instructions requirements for antibacterial and bacteriostatic lotion.

The Standard applies to antibacterial and bacteriostatic lotion products for use on intact skin, vaginal and oral mucosa.

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 191, *Packaging and storage marks*

GB 15979, *Hygienic standard for disposable sanitary products*

GB 38598, *General requirement for label and instruction book of disinfection products*

Pharmacopoeia of the People's Republic of China

*Technical specification for cosmetics safety*¹

*Technical specification for disinfection*² (Edition 2002)

*Hygienic standard for manufacturers of disinfection products*² (Edition 2009)

3 Terms and definitions

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

3.1 antibacterial lotion

A liquid preparation that is directly contact with human skin or mucous membranes (excluding human feet, eyes, nails, armpits, scalp, hair, nasal mucous membranes,

¹ The document was issued by the former State Food and Drug Administration.

² The document was issued by the former Ministry of Health of the People's Republic of China.

anorectal and other specific parts), not for the purpose of treating diseases or improving symptoms of skin and mucous membranes, with certain sterilization effect, and the killing rate is greater than or equal to 90%.

3.2 bacteriostatic lotion

A liquid preparation (except suppository and soap) that is directly contact with human skin or mucous membranes (excluding human feet, eyes, nails, armpits, scalp, hair, nasal mucous membranes, anorectal and other specific parts), not for the purpose of treating diseases or improving symptoms of skin and mucous membranes, with certain sterilization effect, and the inhibition rate is greater than or equal to 50%.

3.3 killing rate

In the microbial killing test, the value of the reduction of microorganisms expressed as a percentage.

[WS/T 466-2014, definition 4.27]

3.4 inhibition rate

In the microbial inhibition test, the value of the microbial antibacterial effect expressed as a percentage.

4 Requirements for raw materials

4.1 Raw materials shall meet the quality requirements of the currently valid *Pharmacopoeia of the People's Republic of China* for food level, medical level, cosmetics and other corresponding standards.

4.2 Production water shall meet the requirements of *Hygienic standard for manufacturers of disinfection products (Edition 2009)*.

4.3 Product formulations must not contain:

- a) Drugs and raw materials with the same names listed in the currently effective *Pharmacopoeia of the People's Republic of China*;
- b) Preparations made from microorganisms, cells, animal or human-derived tissues and body fluids and biological techniques for the prevention, treatment and diagnosis of human diseases, such as vaccines, blood products, biotechnological drugs, probiotics, immune Regulators, diagnostic products, etc. (except deep castor enzyme and lysostaphin);
- c) Prohibited substances listed in the currently valid *Technical specification for cosmetics safety* (except iodine);

6.4.1 Testing of total number of bacterial colonies

Test according to the method in GB 15979.

6.4.2 Testing of coliform bacteria

Test according to the method in GB 15979.

6.4.3 Testing of staphylococcus aureus

Test according to the method in GB 15979.

6.4.4 Testing of hemolytic streptococcus

Test according to the method in GB 15979.

6.4.5 Testing of pseudomonas aeruginosa

Test according to the method in GB 15979.

6.4.6 Testing of total fungal colonies

Test according to the method in GB 15979.

6.5 Test methods for toxicological safety

Test according to the method in *Technical specification for disinfection (Edition 2002)*.

7 Packaging, transportation and storage**7.1 Packaging**

The packaging shall be tight to prevent moisture. Packaging marks shall meet the requirements of GB/T 191.

7.2 Transportation

It shall be airtight during transportation. Shipping containers shall be anti-corrosive. Loading and unloading shall be handled with care. Throwing is strictly prohibited. It shall be protected from sun, rain and moisture during transportation.

7.3 Storage

7.3.1 Store in a cool, dry and dark place.

7.3.2 Stacking shall be more than 10 cm above the ground. Stack height shall not exceed 12 boxes. The distance from the wall shall be more than 20 cm.

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