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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 38456-2020

Hygienic requirements for antibacterial and bacteriostatic lotion

抗菌和抑菌洗剂卫生要求

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Table of Contents

Foreword...	3
1 Scope...	4
2 Normative references...	4
3 Terms and definitions...	4
4 Requirements for raw materials...	5
5 Technical requirements...	6
6 Testing methods...	8
7 Packaging, transportation and storage...	9

1 Scope

GB 38456-2020 is the Chinese national standard on hygienic requirements for antibacterial and bacteriostatic lotion, in the field of health care technology. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 17 November 2020 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 December 2021. Classification: ICS 11.080, CCS C50. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

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.