

ICS 11.080
CCS C50



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

GB 27954-2020

Replacing GB 27954-2011

General requirements for disinfectant of mucous membrane

黏膜消毒剂通用要求

Issued on: April 9, 2020

Implemented on: November 1, 2020

**Issued by: State Administration for Market Regulation;
Standardization Administration of China**

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1 Scope

GB 27954-2020 is the Chinese national standard on general requirements for disinfectant of mucous membrane, 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 9 April 2020 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 November 2020. 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 material requirements, technical requirements, inspection methods, use methods and marking for disinfectant of mucous membrane. This Standard is applicable to disinfectants used by medical and health institutions to disinfect mucous membrane.

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 document.

GB/T 26367 Hygienic Standard for Biguanides Disinfectants

GB/T 26368 Hygienic Standard for Iodine Disinfectants

GB/T 26369 Hygienic Standard for Quaternary Ammonium Disinfectant

GB/T 27947 Hygienic Requirements for Phenol Disinfectant

GB 27951 Hygienic Requirements for Skin Disinfectant

WS 628 Technical Requirements for the Hygiene and Safety Evaluation of Disinfectant Products Pharmacopoeia of the People's Republic of China Technical Standard for Disinfection (2002 Edition) [Ministry of Health (WFJF [2002] No.282)] Hygiene Regulation for Disinfection Products Production Enterprises (2009 Edition) [Ministry of Health (WJDF [2009] No.53)] Notice on Provisions for the Limit Values of Some Ingredients for the Disinfectant of Skin Mucous Membrane Issued by the Ministry of Health [Ministry of Health (WFJF [2003] No.214)] Safety and Technical Standards for Cosmetics (2015 Edition) (State Food and Drug Administration)

3 Raw Material Requirements

3.1 Main germicidal ingredients Iodine-containing disinfectants used for mucous membrane disinfection shall meet the requirements of GB/T 26368; guanidine disinfectants shall meet the requirements of GB/T 26367; quaternary ammonium salt disinfectants shall meet the requirements of GB/T 26369; phenolic disinfectants shall meet the requirements of GB/T 27947. Other disinfectants used for mucous membranes shall comply with the Notice on Provisions for the Limit Values of Some Ingredients for the Disinfectant of Skin Mucous Membrane Issued by the Ministry of Health and other relevant national standards and regulations.

3.2 Prohibited substances All kinds of prescription drugs such as antibiotics, antifungal drugs, antiviral drugs, hormones and their raw materials with the same name, etc. and prohibited substances that is prescribed by the health administrative department.

3.3 Production water It shall meet the requirements of purified water specified in Pharmacopoeia of the People's Republic of China.

3.4 Other non-sterilizing factor ingredients or excipients It shall comply with the Hygiene Regulation for Disinfection Products Production Enterprises (2009 Edition) and other relevant national standards and regulations.

3.5 Limits of lead, mercury and arsenic Lead ≤ 10 mg/kg, mercury ≤ 1 mg/kg, arsenic ≤ 2 mg/kg.

4 Technical Requirements

4.1 Physical and chemical indicators The physical and chemical indicators of the disinfectant, such as effective ingredient equal to 10 CFU/mL; and hemolytic streptococcus, Staphylococcus aureus, Pseudomonas aeruginosa shall not be detected during routine test. When suspected of being contaminated by pathogenic microorganisms during use, the corresponding target microorganisms shall be tested and none must be detected.

5 Inspection Methods

5.1 Active ingredient content It shall be tested according to the corresponding standard methods of sterilization active ingredients.

5.2 Stability It shall be tested according to the provisions of Technical Standard for Disinfection (2002 Edition).

5.3 pH It shall be tested according to the provisions of Technical Standard for Disinfection (2002 Edition).

5.4 Determination of Limits of lead, mercury and arsenic It shall be tested according to the methods specified in Safety and Technical Standards for Cosmetics (2015 Edition)

5.5 Microbial killing test It shall be tested according to the provisions of Technical Standard for Disinfection (2002 Edition).

5.6 Safety test It shall be tested according to the provisions of Technical Standard for Disinfection (2002 Edition).

5.7 Microbial contamination test It shall be tested according to the method specified in GB 27951.