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GB/T 26372-2020

Replacing GB 26372-2010

Hygienic requirements for glutaraldehyde disinfectants

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1 Scope

GB/T 26372-2020 is the Chinese national standard on hygienic requirements for glutaraldehyde disinfectants, in the field of health care technology. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 2 June 2020 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 January 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 material requirements, technical requirements, application scope, use methods, packaging, transportation, storage, and identification of glutaraldehyde disinfectants Requirements and inspection methods. This standard applies to glutaraldehyde, and glutaraldehyde plus synergist as the main component of glutaraldehyde disinfectant.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this article Pieces. For undated references, the latest version (including all amendments) applies to this document.

GB/T 191 Packaging, storage and transportation pictorial signs

GB 27949 General requirements for disinfectants for medical devices

GB 30689 Hygienic requirements for automatic endoscope cleaning and disinfection machine

WS507-2016 Technical Specification for Cleaning and Disinfection of Soft Endoscope Pharmacopoeia of the People's Republic of China (2015 Edition, Part Two) Disinfection Technical Specifications (2002 Edition) [Ministry of Health (Health Law Jianfa [2002] No. 282)]

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Synergist It does not have a certain specific activity or is low in activity, but when mixed with a substance with such activity, it can greatly increase the active substance The performance of a class of substances.

Note. The synergist specified in this standard refers to a chemical substance that uses a specific mechanism to enhance the bactericidal activity of glutaraldehyde when used in combination with glutaraldehyde, such as fatty alcohol polyoxyethylene Vinyl ether, dodecyl dimethyl benzyl ammonium chloride, dodecyl dimethyl benzyl ammonium bromide, etc.

3.2 pH regulator Used to maintain or change the pH of the solution required acidifiers, alkaline agents and buffering salts.

4 Raw material requirements

4.1 Glutaraldehyde. It should meet the requirements of raw materials for medicine, and the content should be greater than or equal to 50.0%.

4.2 Synergist. It should meet the requirements of raw materials for medicine.

4.3 pH regulator. should meet the requirements of raw materials for medicine.

4.4 Anti-rust agent. should meet the requirements of raw materials for medicine.

4.5 Water for production. it should comply with the requirements of purified water in the Pharmacopoeia of the People's Republic of China (2015 Edition, Part Two).

7 How to use

7.1 Soaking and disinfection of medical equipment See GB 27949 for usage. Soak the cleaned instruments in the glutaraldehyde disinfectant solution to completely submerge them, and then add the disinfection container The cover, according to the requirements of the instruction manual, acts for a certain time at room temperature (<=60min). Rinse with

sterile water before use.

7.2 Immersion sterilization of medical devices See GB 27949 for usage. Soak the cleaned instruments in 2.0%~2.5% glutaraldehyde to completely submerge them, and then disinfect Cover the container for 10 hours at room temperature. Rinse with sterile water before use.

7.3 Disinfection of Endoscope

7.3.1 For the disinfection of the automatic endoscope washer-disinfector, follow the requirements of GB 30689 and the product manual.

7.3.2 For manual endoscope disinfection treatment, according to WS507-2016, "Disinfection Technical Specification" (2002 Edition) and product instruction manual requirements get on.

8 Packaging, transportation and storage

8.1 Packaging The packaging should be dust-proof, moisture-proof and sealed. Packaging materials should meet the requirements of non-toxic packaging materials. The outer packaging should be tied firmly, transported normally, and packed Do not loosen when unloading.

8.2 Transportation Do not turn upside down during transportation to prevent pressure, collisions, crowding, exposure to the sun and rain. Vehicles should always be kept dry.

8.3 Storage The product should be stored in a cool, dry and ventilated place. Do not store it in the open air, or mix it with other toxic substances.

9 Marking requirements

9.1 The packaging label should meet the requirements of GB/T 191.

9.2 The label and product instructions should comply with the relevant specifications and standards in the label instructions of disinfection products.

9.3 The instructions should indicate the following precautions.

--- Disinfectant for external use, oral administration is prohibited;

---For those who are allergic to aldehydes;

---Should be prepared and used in a well-ventilated place, pay attention to personal protection, wear protective masks, protective gloves and protective glasses. If accidentally touched, Immediately rinse with drinking water continuously, and seek medical attention as soon as possible if the eyes are injured;

---The container used for soaking instruments should be clean, covered, and disinfected or sterilized before use;

--- During continuous use, ensure that the concentration of glutaraldehyde meets the requirements of the product instructions;

--- Disinfected or sterilized instruments, remove them in a sterile manner before use, rinse them repeatedly with sterile water to remove residual glutaraldehyde, and use sterile Wipe dry with gauze, etc. before using;

---Not suitable for wiping or spray disinfection of indoor surfaces, indoor air disinfection, hands, skin and mucous membrane disinfection.

10 Inspection method

10.1 The appearance inspection shall be tested in accordance with the relevant methods in

2.2.3.1 of the "Technical Specification for Disinfection" (2002 Edition).

10.2 The physical and chemical tests are carried out in accordance with the relevant methods in

2.2.3 of the "Technical Specifications for Disinfection" (2002 Edition), and the content determination is shown in Appendix A.

10.3 The laboratory quantitative (qualitative) sterilization test shall be conducted in accordance with the relevant methods in

2.1.1 of the "Technical Specification for Disinfection" (2002 Edition).

10.4 The continuous use stability test shall be tested in accordance with the relevant methods in

2.1.2 of the "Technical Specification for Disinfection" (2002 Edition).

10.5 The medical device disinfection simulation field test shall be conducted according to the relevant methods in

2.1.2 of the "Disinfection Technical Specification" (2002 edition).

Appendix A

(Normative appendix) Determination of glutaraldehyde content A.1 Determination of glutaraldehyde ($C_5H_8O_2$) content A.1.1 Principle The glutaraldehyde reacts with the triethanolamine solution, and the neutral solution of hydroxylamine hydrochloride is used as the indicator, and the remaining triethanolamine solution is titrated with sulfuric acid standard solution. Solution, calculate the content of glutaraldehyde based on the amount of sulfuric acid standard solution. A.1.2 Reagent preparation 65g/L triethanolamine solution, 1% hydrochloric acid solution, 10g/L sodium hydroxide solution, 0.4g/L bromophenol blue ethanol solution and hydroxylamine hydrochloride Solution (17.5g hydroxylamine hydrochloride added 75mL distilled water to dissolve, and add isopropanol to dilute to