

ICS 11.020
CCS C 50

WS

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

WS/T 535-2017

**Rapid detection methods on site for disinfectant used in
medical and health
(English Translation)**

Issued on: August 11, 2017

Implemented on: February 1, 2018

**Issued by: National Health and Family Planning Commission of the
People's Republic of China**

Table of Contents

- Foreword
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Method for determination of active ingredient content
 - 4.1 Test paper semi-quantitative determination method
 - 4.2 Instrumental method

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

Drafting organizations of this standard. Health and Family Planning Supervision Center of National Health and Family Planning Commission, China Center for Disease Control and Prevention Product Safety Institute, Chinese People's Liberation Army Disease Control and Prevention Institute, Jiangsu Provincial Health Supervision Institute.

1 Scope

This standard specifies the method, result determination and method for on-site rapid detection of the content of effective ingredients and related indicators of commonly used disinfectants in medical and health institutions Precautions.

This standard applies to the use of disinfectant concentration test paper method to determine peracetic acid, chlorine dioxide, chlorine, bromine, iodine-containing disinfectants, acid oxygen the content of the effective ingredients of common disinfectants such as electrochemically charged water, glutaraldehyde and o-phthalaldehyde, and the limit value of the concentration in use, as well as the quick Rapid detection equipment quantitatively determines active ingredients and related indicators such as acidic oxidation potential water and ethanol.

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 26373 Hygienic Standard for Ethanol Disinfectants Disinfection Technical Specification

Former Ministry of Health.2002 Regulations on Sanitation and Safety Evaluation of Disinfection Products National Health and Family Planning Commission.2014

3 Terms and definitions

The following terms and definitions apply to this document.

The test paper semi-quantitatively determines that the specific chemical substance on the test paper reacts with the effective ingredients in the corresponding disinfectant, and the color of the test paper changes compared with the standard Color card comparison is a rapid detection method to determine the content of effective ingredients in disinfectants.

Active ingredients

In disinfectant formulations, substances that have the effect of killing or inhibiting pathogenic microorganisms.

Limited value

In the use of disinfectants, the minimum active ingredient content that allows safe and effective use.

4.1.1 Scope of application

Suitable for peracetic acid, chlorine dioxide, chlorine-containing, bromine-containing, iodine-containing disinfectants, acidic oxidation potential water, glutaraldehyde, o-phthalaldehyde Rapid determination of the content of active ingredients in poisons and application solutions.

4.1.2 Operation method

4.1.2.1

At room temperature, take an appropriate amount of the disinfectant to be tested in a 25mL beaker as a sample. Take a piece of corresponding disinfectant concentration test paper, Part of the test paper is immersed in the sample, and the disinfectant concentration test paper is taken out after the time specified in the instruction manual.

4.1.2.2

Under natural light, compare the test paper with the standard colorimetric card for the time specified in the disinfectant concentration test paper, and read the concentration.

Degree value or determine whether the concentration of disinfectant meets the requirements.

4.1.2.3

If the effective ingredient content or concentration of the tested disinfectant sample is higher than the maximum limit value that can be tested by the test paper used, the sample can be used After diluting with the dilution water specified by the disinfectant manufacturer, test according to the above method, and multiply the read disinfectant concentration value by the dilution factor to obtain the original disinfectant.

The active ingredient content or concentration value of the sample.

4.1.3 Results judgment

4.1.3.1

Disinfectants for peracetic acid, chlorine dioxide, chlorine, bromine, iodine, acid oxidizing potential water, glutaraldehyde and their applications If the content or concentration of the active ingredient in the tested disinfectant sample meets the range specified in the relevant national standards and instructions for disinfection products, it is considered the effective ingredient content or concentration of the disinfectant sample meets the requirements; if the effective ingredient content or concentration of the disinfectant sample tested does not meet the corresponding country According to the scope specified in the standards and instructions, the disinfectant sample is preliminarily determined to not meet the product quality requirements, and further according to the "Disinfection Technical Specification" to determine whether the content or concentration of the effective ingredient of the product meets the corresponding requirements.

4.1.3.2

For glutaraldehyde disinfectant, if the color reaction of the tested sample on the test paper does not reach 1.8% glutaraldehyde concentration during sterilization use the standard color of the degree limit value is determined to be too low for the disinfectant to continue to be used.

4.1.3.3

For o-phthalaldehyde disinfectant, if the initial concentration of o-phthalaldehyde in the tested sample is within the range specified in the instructions, the the disinfectant sample meets the requirements; if the concentration of the tested sample does not meet the range specified in the instruction manual, it is preliminarily determined that the disinfectant sample does not meet the requirements the product quality requirements should be further tested in accordance with the requirements of Appendix A to finally determine whether the product content meets the requirements; if the product is inspected in use the color reaction of the test sample on the test paper does not reach the standard color of the o-phthalaldehyde concentration limit value specified in the instruction manual, then the disinfectant is judged the concentration is too low to continue to use.

4.1.4 Matters needing attention

4.1.4.1

The disinfectant concentration test paper shall meet the requirements of the "Regulations on Sanitation and Safety Evaluation of Disinfectants" and other requirements, and be used within the validity period.

4.1.4.2

The method of using the disinfectant concentration test paper of different products is slightly different, and the method should be operated according to the method specified in the product manual.

4.1.4.3

The concentration range of the disinfectant tested by different products is different. When the concentration is close to the upper or lower limit, the error is large. When the concentration is close to the median value, the measurement result the result is more accurate.

4.1.4.4

After opening and using, the package should be closed in time, do not contact with acid or alkali substances, and be careful not to take out the desiccant.

4.1.4.5

The disinfectant concentration test paper should be stored in a sealed, dark, dry and cool place.

4.1.4.6

When taking the test paper for detoxification agent concentration, avoid contaminating it.

4.2.1.1 Sampling requirements

Before testing, a water sample should be taken at the outlet of the acidic oxidation potential water, and the pH value and the oxidation reduction potential (ORP) value should be measured on site.

And available chlorine concentration (follow the method in 4.1).

4.2.1.2 PH value measurement (pH meter method)

The pH value of the stock solution of acidic oxidation potential water is 2~3, and the pH meter is calibrated with potassium hydrogen phthalate standard buffer solution (pH4.00, 20°C), Take about 60mL of the stock solution of acidic oxidation potential water in a 100mL beaker, put the pH meter probe into the stock solution of acid oxidation potential water, and read the pH after stabilization value.