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Replacing GB/T 26368-2010

Hygienic requirements for iodine disinfectants

含碘消毒剂卫生要求

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Hygienic requirements for iodine disinfectants

1 Scope

This Standard specifies raw material requirements, technical requirements, scope of application, method for use, packaging, transport and storage, marking requirements and inspection methods for iodine disinfectants (iodine tincture, iodophor) and compound iodine disinfectants.

This Standard is applicable to iodine tincture, iodophor and compound iodine disinfectants that use available iodine as the main bactericidal ingredient, are used for skin, mucous membrane and hand disinfection.

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 27950, *Hygienic requirements for hand antiseptic agents*

GB 27951, *Hygiene requirements for skin disinfectant*

GB 27954, *General requirements for disinfectant of mucous membrane*

Pharmacopoeia of the People's Republic of China (Volume II, 2015)

Pharmacopoeia of the People's Republic of China (Volume IV, 2015)

Technical standard for disinfection (2002) [Ministry of Health (issued by Department of Legal Supervision, Ministry of Health [2002] No. 282)]

Technical specification for cosmetic safety (2015) (Announcement No. 268 of China Food and Drug Administration [2015])

3 Terms and definitions

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

7 Method for use

7.1 Iodine tincture

Use a sterile cotton swab to dip this product. Wipe the skin on the disinfected area. Then use a cotton swab to dip in 75% medical ethanol to wipe and diiodine. The action time shall meet the requirements of GB 27950 and GB 27951.

7.2 Iodophor and compound iodine disinfectants

According to the use concentration required in iodophor or compound iodine disinfectant instructions, directly rinse or wipe the disinfected part. The action time shall meet the requirements of GB 27950, GB 27951 and GB 27954.

7.3 Povidone iodine powder

According to the dilution method required by the product manual, use purified water to dilute. Then rinse or wipe the disinfected part. The action time shall meet the requirements of GB 27950, GB 27951 and GB 27954.

8 Packaging, transport and storage

8.1 Packaging materials shall meet the requirements of non-toxic packaging materials. Use corrugated cardboard packaging box for external packaging. It shall be tied firmly. Use normal transportation. Do not loose when loading-unloading.

8.2 According to packaging requirements, conduct regular transportation. If there are special requirements in storage, packaging, and transportation, it must be indicated in the product manual or on the packaging box.

8.3 This product shall be stored in a cool and dark place at room temperature.

9 Marking requirements

9.1 Marks, labels and manual

The mark identification shall meet the requirements of GB/T 191. Label and manual shall comply with the requirements of relevant specifications and standards for label manual of disinfection products. Indicate the product name, factory name and address, trademark, specifications, quantity, expiration date, and storage conditions.

9.2 Precautions for manual

Annex A

(normative)

Determination method for available iodine content

A.1 Method One: Chemical titration method (arbitration method)

A.1.1 Test principle

In acid solution, use sodium thiosulfate titrant to directly titrate free iodine. According to the dose of sodium thiosulfate, calculate the available iodine content in the disinfectant. The reaction equation is:

$$I_2 + 2Na_2S_2O_3 = 2NaI + Na_2S_4O_6$$

A.1.2 Test reagents and equipment

A.1.2.1 Test reagents

Sodium thiosulfate titrant, 36% acetic acid solution, 5g/L starch solution (prepared when required).

A.1.2.2 Test equipment

Pipette, acid burette, iodine measuring flask, electronic balance (resolution is 0.0001g).

A.1.3 Test method

Accurately weigh or draw an appropriate amount of iodine disinfectant, to make it equivalent to 0.25g of available iodine. Place it in a 250mL iodine measuring flask. Add 5 drops of acetic acid. Use sodium thiosulfate titrant to titrate. Shake well while dripping. When the solution is light yellow, add 10 drops of 5g/L starch solution (the solution immediately turns blue). Continue to titrate until the blue color disappears. Record the total amount of sodium thiosulfate titrant used. Conduct a blank test to correct the titration result. Test the sample twice. Take the average of two times to calculate.

Because 1mL of 1mol/L sodium thiosulfate titrant is equivalent to 0.1269g of available iodine, the available iodine content can be calculated according to formula (A.1) and formula (A.2):

Annex B

(normative)

Determination method for polyvinylpyrrolidone content

B.1 Test principle

Polyvinylpyrrolidone has retention behavior on C_{18} reversed-phase chromatography column. It can be separated from other components in the sample. It has obvious UV absorption at 205nm wavelength. Therefore, an ultraviolet absorption detector is used for detection. Based on the quantitative relationship between the peak area and the concentration, determine the content of the substance in the disinfectant.

B.2 Test reagents and equipment

B.2.1 Test reagents

Acetonitrile (chromatographic grade), ultrapure water.

B.2.2 Test equipment

High performance liquid chromatograph, electronic balance (resolution is 0.0001g), pipette, volumetric flask.

B.3 Chromatographic conditions

B.3.1 Chromatographic column: C_{18} column (4.6mm×150mm, 5μm).

B.3.2 Mobile phase: acetonitrile: water = 5: 95 (volume ratio).

B.3.3 Flow rate: 1.0mL/min.

B.3.4 UV detection wavelength: 205nm.

B.3.5 Column temperature: 20°C.

B.3.6 Injection volume: 20μL.

B.4 Test steps

B.4.1 Preparation of reference substance solution

Precisely weigh 0.1g of polyvinylpyrrolidone K30 reference substance in a 100mL volumetric flask. Add water to dissolve. Set constant volume to the scale. Shake well to obtain the standard solution of which the concentration is

Annex C

(normative)

Identification method for polyoxyethylene fatty alcohol ether

C.1 Method principle

When using infrared to irradiate organic molecules, the chemical bond or functional group in the molecule can absorb vibration. Different chemical bonds or functional groups have different absorption frequencies. They will be in different positions on the infrared spectrum, so as to get information about what kind of chemical bond or functional group contained in the molecule.

C.2 Instruments and equipment

Fourier transform infrared spectrometer, rotary evaporator, eggplant bottle, decompression pump, water bath.

C.3 Sample pretreatment and sample preparation

Take proper amount of sample in an eggplant-shaped bottle. Conduct vacuum distillation to remove water so as to obtain the test sample. Take about 1.0mg of dry test sample. Use KBr liquid film method tablet to determine infrared spectrum. And compare with the comparison chart of polyoxyethylene fatty alcohol ether-8.

C.4 Spectrum analysis

Figure C.1 is the infrared spectrum represented by polyoxyethylene fatty alcohol ether-8. 2924cm^{-1}, 2856cm^{-1}, 1466cm^{-1} and 1378cm^{-1} in the figure show alkyl absorption. −OH appears at 3476cm^{-1}. The characteristic absorption peaks of polyoxyethylene ether are 1350cm^{-1} (−CH_2−non-planar rocking vibration, medium intensity peak), 1116cm^{-1} (C−O−C asymmetric stretching, the strongest peak), 947cm^{-1} (symmetric stretching Vibration, weaker), 885cm^{-1} (end group−CH_2CH_2OH−CH_2−plane swing vibration), 844cm^{-1} (polyoxyethylene plane swing vibration in the middle).

The infrared spectra of polyoxyethylene fatty alcohol ethers with different ethylene oxide addition numbers (EO numbers) show regular changes. It is more obvious that the C−O−C asymmetric stretching band is a strong peak. It increases with the increase of EO number. The position is slightly shifted to the low wave number (from 1121cm^{-1} of EO number 3 to 1116cm^{-1} of EO number 11). The intensity of the symmetric stretch band also increases. The wave number is stable around 949cm^{-1}. In the alkyl group, 1378cm^{-1} peak wave

Annex D

(normative)

Identification of alkylphenol polyoxyethylene ether by infrared spectroscopy

D.1 Method principle

When using infrared to irradiate organic molecules, the chemical bond or functional group in the molecule can absorb vibration. Different chemical bonds or functional groups have different absorption frequencies. They will be in different positions on the infrared spectrum, so as to get information about what kind of chemical bond or functional group contained in the molecule.

D.2 Instruments and reagents

Fourier transform infrared spectrometer, rotary evaporator, eggplant bottle, decompression pump, water bath.

D.3 Sample pretreatment and sample preparation

Take proper amount of sample in an eggplant-shaped bottle. Conduct vacuum distillation to remove water to obtain the test sample. Take about 1.0mg of dry test sample. Use KBr liquid film method tablet to determine infrared spectrum. And compare with the comparison chart of nonylphenol polyoxyethylene ether-10.

D.4 Spectrum analysis

Figure D.1 is the infrared spectrum of nonylphenol polyoxyethylene ether-10 (NP-10). In addition to showing the characteristic absorption peaks of polyoxyethylene, there are also benzene ring vibration peaks 1609cm^{-1} and 1512cm^{-1} sharp peaks. Para-substitute 832cm^{-1} peak, aromatic ether C−O−C 1249cm^{-1} characteristic peak. The strong absorption peak of C−O−C in EO appears at 1116cm^{-1}. NP with different EO numbers is in the range of 1640cm^{-1}~600cm^{-1}. The absorption intensity of the correlation peak changes. It can be used to quantitatively calculate its EO number.

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