

3. Standards and Specification

(1) Ethanol Preparations

Definition Ethanol preparations contains Ethanol as an active ingredient. However, Diluent, stabilizers, dissolving agents, etc. can be added for dilution or stability in quality.

Compositional Specifications of Ethanol preparations

Description Ethanol preparations is colorless~pale yellow liquid with characteristic odor.

Identification Pipet about 0.6 g of ethanol preparations and add acetone to bring the volume to 25 ml, test solution. Shake the sample until it is completely dispersed, if necessary, centrifuge it and use the supernatant. Separately, add acetone to 0.6 g of ethanol standard material to make 25 ml, standard solution. Gas chromatography is carried out with both solutions under the following operation conditions. Retention time of the main peak of Test Solution should be identical to that of Standard Solution.

Operation Condition

Column : DB WAX(30m×0.53mm ID, coating thickness 1.0 μ m)or its equivalent

Detector : Hydrogen Flame Ionization Detector (FID)

Column Temperature : 60~150℃

Temperature at injection port : 150~200℃

Detector Temperature: 150~200℃

Carrier gas and Flow rate : N₂ or He, flow rate 1ml/min

Test of Bactericidal Activity When ethanol preparations is tested by Test Method of Bacterial Suspension or Test Method of Bacterial Surface in Test of Bactericidal Activity, it should be appropriate.

Storage Standard of Ethanol preparations and Ingredients Containing it

Ethanol preparations should be stored in a hermetic container in a cold dark place which is inflammable.

(2)N-Decyl-N,N-dimethyl-1-decanaminium Chloride Preparations

Definition It contains N-decyl-N,N-dimethyl-1-decanaminium Chloride as an active ingredient. However, Diluent, stabilizers, dissolving agents, etc. can be added for dilution or stability in quality.

Compositional Specifications of N-decyl-N,N-dimethyl-1-decanaminium Chloride preparations

Description N-decyl-N,N-dimethyl-1-decanaminium Chloride preparations is liquid with characteristic odor.

Identification (1) N-decyl-N,N-dimethyl-1-decanaminium Chloride preparations responds to the tests for Ammonium Salt and Chlorides.

(2) Pipet 1 g of N-decyl-N,N-dimethyl-1-decanaminium Chloride preparations and dilute to volume of 100 ml with water, test solution. Separately, when adding 5 ml of test solution to the mixture of 2~3 drops of brom phenol blue · sodium hydroxide solution, 5 ml of 0.1N sodium hydroxide solution, and 5 ml of chloroform, the chloroform layer of the solution appears blue.

Test of Bactericidal Activity When N-decyl-N,N-dimethyl-1-decanaminium Chloride preparations is tested by Test Method of Bacterial Suspension in Test of Bactericidal Activity, it should be appropriate.

Storage Standard of N-decyl-N,N-dimethyl-1-decanaminium Chloride preparations and Ingredients Containing it

N-decyl-N,N-dimethyl-1-decanaminium Chloride preparations should be stored in a hermetic container in a cold dark place which is inflammable.

(3) n-Alkyl(C₁₂-C₁₈)benzyldimethylammonium Chloride Preparations

Definition n-alkyl(C₁₂-C₁₈)benzyldimethylammonium Chloride Preparations contains Quaternary ammonium compounds, n-alkyl(C₁₂-C₁₄)benzyl-dimethyl chlorides or 1 or more of Quaternary ammonium compounds, n-alkyl(C₁₂-C₁₈) dimethyl ethylbenzyl ammonium chloride (average molecular weight 377~384), n-alkyl(C₁₂-C₁₈) dimethyl ethylbenzyl ammonium chloride (average molecular weight 384), Quaternary ammonium compounds, di-n-alkyl(C₈-C₁₀) dimethyl ammonium chloride (average molecular weight 332 to 361), or Poly (hexamethylene biguanide) hydrochloride contained to Quaternary ammonium compounds, alkyl(C₁₂-C₁₄) benzyl-dimethyl chlorides as an active ingredient. However, Diluent, stabilizers, dissolving agents, etc. can be added for dilution or stability in quality.

Compositional Specifications of n-Alkyl(C₁₂-C₁₈)benzyldimethylammonium Chloride

Description n-alkyl(C₁₂-C₁₈)benzyldimethylammonium Chloride Preparations is liquid with characteristic odor.

Identification (1) n-alkyl(C₁₂-C₁₈)benzyldimethylammonium Chloride Preparations responds to the tests for Ammonium Salt and Chlorides.

(2) Pipet 1 g of n-alkyl(C₁₂-C₁₈)benzyldimethylammonium Chloride Preparations and dilute to 100 ml with water, test solution. Separately, when adding 5 ml of test solution to the mixture of 2~3 drops of Brom phenol blue · Sodium hydroxide solution, 5 ml of 0.1N sodium hydroxide solution, and 5 ml of chloroform, the chloroform layer of the solution becomes blue.

Test of Bactericidal Activity When n-alkyl(C₁₂-C₁₈)benzyldimethylammonium Chloride Preparations is tested by Test Method of Bacterial Suspension in Test of Bactericidal Activity, it should be appropriate.

Storage Standard of n-Alkyl(C₁₂-C₁₈)benzyldimethylammonium Chloride Preparations and Ingredients Containing it

It should be stored in a hermetic container in a cold dark place which is inflammable.

(4) Sodium Dichloroisocyanurate Preparations

Definition Sodium Dichloroisocyanurate preparations contains Sodium Dichloroisocyanurate and Sodium Dichloroisocyanurate 2 hydrate as active ingredients. However, Diluent, stabilizers, dissolving agents, etc. can be added for dilution or stability in quality.

Compositional Specifications of Sodium Dichloroisocyanurate preparations

Description Sodium Dichloroisocyanurate preparations is white crystallite, white granular powder or tablet with odor of chlorine.

Identification (1) When diluted hydrochloric acid is added to Sodium Dichloroisocyanurate preparations, gas with odor of chlorine is generated.

(2) Gas in (1) make the colour of potassium iodide starch paper (wetted with water) blue.

(3) Sodium Dichloroisocyanurate preparations responds to the tests for (1) Sodium Salt in Identification.

Purity (1) Iron : 1 g of Sodium Dichloroisocyanurate preparations, ignited by the procedure in Residues on Ignition, and then the residue is generated. To the residue, add 2 ml of diluted hydrochloric acid(1→2), dissolve, and evaporate to dryness it in a water bath. Dissolve it in 1 ml of hydrochloric acid and dilute to 50 ml with water. Pipet 10 ml of this solution, dilute to 40 ml with water, add 40 mg of ammonium persulfate and 10 ml of ammonium thiocyanate solution., then red or pink color develops. That color should not be deeper than the color appeared when 3 ml of iron standard solution is taken instead of test solution and proceeded in the same manner as test solution. (not more than 150 ppm).

(2) Lead : When 2.0 g of Sodium Dichloroisocyanurate Preparations is tested by Atomic Absorption Spectrophotometry or Inductively Coupled Plasma Emission Spectroscopy, its content should not be more than 10 ppm.

Test of Bactericidal Activity When Sodium Dichloroisocyanurate preparations is tested by Test Method of Bacterial Suspension in Test of Bactericidal Activity, it should be appropriate.

Storage Standard of Sodium Dichloroisocyanurate preparations and Ingredients Containing it

Sodium Dichloroisocyanurate preparations should be stored in a hermetic container in a cold dark place which is inflammable.

(5) Sodium Hypochlorite Preparations

Definition This item contains Sodium Hypochlorite preparations as active ingredient and includes acquiring saline solution by electrolysis. However, Diluent, stabilizers, etc. can be added for dilution or stability in quality.

Compositional Specifications of Sodium Hypochlorite preparations

Description Sodium Hypochlorite preparations is colorless to light green-yellow liquid or powder having an odor of chlorine.

Identification (1) Sodium Hypochlorite preparations is diluted with water so that 50~100 μ g of active chlorine is contained per ml of Sodium Hypochlorite preparations, test solution. Separately, pipet 0.5 ml of sodium stock standard solution and dilute to 100 ml with water, sodium standard solution. When Sodium standard solution and test solution are tested by Atomic Absorption Spectrophotometry, the peak of sodium should be identified.

(2) To 5 ml of test solution in (1), add 1 ml of sodium hydroxide solution(1 \rightarrow 2,500) and 0.2 ml of potassium iodine solution, the color of the solution turns yellow. Again add 0.5 ml of starch solution, then the solution becomes deep blue.

(3) To 5 ml of test solution in (1), add 0.1 ml of potassium permanganate solution(1 \rightarrow 300) and add 1 ml of sulfuric acid(1 \rightarrow 20) to this solution, then the red violet of solution doesn't fade.

(4) To 90 ml of test solution in (1), add 100 ml of sodium hydroxide (1 \rightarrow 5), then the solution shows maximum absorption band at 290~294nm.

Test of Bactericidal Activity When Sodium Hypochlorite preparations is tested by Test Method of Bacterial Suspension in Test of Bactericidal Activity, it should be appropriate.

Storage Standard of Sodium Hypochlorite preparations and Ingredients Containing it

Sodium Hypochlorite preparations should be stored in a hermetic container in a cold dark place which is inflammable.

(6) Hypochlorous Acid Water Preparations

Definition Hypochlorous Acid Water preparations is obtained by electrolysis of hydrochloric acid or saline solution. The aqueous solution contains Hypochlorous Acid as an active ingredient. This item includes strongly acidic hypochlorous acid water (aqueous solution obtained from both poles by electrolyzing sodium chloride (not more than 0.2%) in an electrolytic bath with septum composed of anode and cathode, which are separated by septum) and slightly acidic hypochlorous acid water (aqueous solution obtained by electrolyzing 2~6% hydrochloric acid water in an aseptic electrolytic bath composed of anode and cathode, which are not separated by septum).

Compositional Specifications of Hypochlorous Acid Water preparations

Description Hypochlorous Acid Water preparations is colorless, odorless or with slight odor of chlorine.

Identification (1) To 5 ml of Hypochlorous Acid Water preparations, add 1 ml of sodium hydroxide(1→2,500) and 0.2 ml of potassium iodide, then yellow color develops. When adding 0.5 ml of starch solution to this solution, deep blue color develops.

(2) To 5 ml of Hypochlorous Acid Water preparations, add 0.1 ml of potassium permanganate solution(1→300) and add 1 ml of sulfuric acid(1→20) to this solution, then red violet color doesn't fade.

(3) To 90 ml of Hypochlorous Acid Water, add 100 ml of sodium hydroxide(1→5), then the solution exhibits an absorption maximum at a wavelength of 290~294 nm.

Purity (1) pH : When pH is determined by glass electrode method, not more than 2.7 for strongly acidic Hypochlorous Acid Water preparations, and 5.0~6.5 for slightly acidic Hypochlorous Acid Water.

(2) Evaporation Residue : When pipetting 20.0g of Hypochlorous Acid Water preparations and drying it for 2 hours at 110°C after evaporating water, the residue should not be more than 0.25%.

Test of Bactericidal Activity When Hypochlorous Acid Water preparations is tested by Test Method of Bacterial Suspension in Test of Bactericidal Activity, it should be appropriate.

(7) Poly(hexamethylenebiguanide)hydrochloride Preparations

Definition Poly (hexamethylenebiguanide) hydrochloride preparations contains Poly (hexamethylenebiguanide) hydrochloride or Quaternary ammonium compounds, Poly (hexamethylenebiguanide) hydrochloride containing di-n-alkyl(C₈-C₁₀) dimethyl ammonium chloride (average molecular weight 332 to 361) as active ingredient . However, Diluent, stabilizers, dissolving agents, etc. can be added for dilution or stability in quality.

Compositional Specifications of Poly(hexamethylenebiguanide)hydrochloride preparations

Description Poly(hexamethylenebiguanide)hydrochloride preparations is liquid with characteristic odor.

Identification (1) Poly(hexamethylenebiguanide)hydrochloride preparations responds to the tests for Ammonium Salt and Chlorides.

(2) Pipet 1 g of Poly(hexamethylenebiguanide)hydrochloride preparations and dilute to 100 ml with water, test solution. Separately, add 5 ml of test solution to the mixture of 2~3 drops of Brom phenol blue · Sodium hydroxide solution, 5 ml of 0.1N sodium hydroxide solution, and 5 ml of chloroform, then the chloroform layer of the solution becomes blue.

Test of Bactericidal Activity When Poly(hexamethylenebiguanide)hydrochloride preparations is tested by Test Method of Bacterial Suspension in Test of Bactericidal Activity, it should be appropriate.

Storage Standard of Poly(hexamethylenebiguanide)hydrochloride preparations and Ingredients Containing it

It should be stored in a hermetic container in a cold dark place which is inflammable.

(8) Hydrogen Peroxide Preparations

Definition It contains Hydrogen Peroxide preparations as active ingredient. However, Diluent, stabilizers, dissolving agents, etc. can be added for dilution or stability in quality.

Compositional Specifications of Hydrogen Peroxide preparations

Description Hydrogen Peroxide preparations is a colorless, clear liquid. It has a slight odor.

Identification (1) When adding 5 ml of dilute sulfuric acid and 1 ml of potassium permanganate solution to an aqueous solution of Hydrogen Peroxide (1→10), bubbles are formed and the color of the solution disappears.

(2) Hydrogen Peroxide preparations shows the peroxide reaction in Identification.

Purity (1) Free acid : Add freshly boiled and cooled water to 3 ml of Hydrogen Peroxide preparations and make to 50 ml. When adding 1 ml of 0.02 N sodium hydroxide solution and 3 drops of phenolphthalein solution, the solution should turn red.

(2) Arsenic : Mix 0.25 ml of Hydrogen Peroxide preparations with 10 ml of water. Add a small amount of this solution in small portions to a platinum crucible in a water bath to evaporate the liquid to dryness. Add a small amount of water to the residues and use the entire solution as a Test Solution. This Test Solution is tested for arsenic and its content should be appropriate (Not more than 4ppm).

(3) Lead : Add 10 ml of water to 5 g of Hydrogen Peroxide preparations. And add a small amount of this solution in small portions to a platinum crucible in a water bath to warming it until forming bubbles is ended. Add 0.5N of nitric acid to make to 25ml. This solution is used as a Test Solution. When test solution is tested by Atomic Absorption Spectrophotometry or Inductively Coupled Plasma Emission Spectroscopy, its content should not be more than 4.0 ppm.

(4) Tin : Add 10 ml of water to 5 g of Hydrogen Peroxide preparations. And add a small amount of this solution in small portions to a platinum crucible in a water bath to warming it until forming bubbles is ended. Add 1N of hydrochloric acid to make to 25ml. This solution is used as a Test Solution. When test solution is tested by Atomic Absorption Spectrophotometry or Inductively Coupled Plasma Emission Spectroscopy, its content should not be more than 10 ppm.

(5) Iron : Add 10 ml of water to 5 g of Hydrogen Peroxide preparations. And add a small amount of this solution in small portions to a platinum crucible in a water

bath to warming it until forming bubbles is ended. Add 0.5N of nitric acid to make to 25ml. This solution is used as a Test Solution. When test solution is tested by Atomic Absorption Spectrophotometry or Inductively Coupled Plasma Emission Spectroscopy, its content should not be more than 0.5 ppm.

- (6) Residue on evaporation : To 10 ml of Hydrogen Peroxide, add about 20 ml of water. Add this solution in small portions to a platinum crucible. Evaporate it to dryness by gently heating in a water bath and cool down. Dry the residues for 1 hour at 105°C and the amount should not be more than 3 mg.
- (7) Phosphate Salt : To 8 ml of Hydrogen Peroxide, add 10 ml of water and 3 ml of hydrochloric acid. Then evaporate it to dryness by gently heating in a water bath. Add about 30 ml of warm water to dissolve the residues, which is then cooled down. Dilute the solution to 50ml with water, Test Solution. Transfer 5 ml of Test Solution into a Nestler tube, where 4 ml of dilute sulfuric acid (1→6) and 1 ml of ammonium molybdate solution (1→20) are added. Then mix it well by shaking and allowed to stand for 3 minutes, where 1 ml of 1-amino-2-naphthol-4-sulfonate solution is added. Heat it for 30 minutes in a water bath at 60°C and cool down in running water. The resulting blue color should not be deeper than that of the solution prepared by the same procedure with 5 ml of phosphate salt standard solution.

Test of Bactericidal Activity When Hydrogen Peroxide preparations is tested by Test Method of Bacterial Suspension (Test Method of Spore Suspension when used for sterilization of food container and packaging) in Test of Bactericidal Activity, it should be appropriate.

Storage Standard of Hydrogen Peroxide preparations and Ingredients Containing it

Hydrogen Peroxide preparations should be stored in a hermetic container in a cold dark place which is inflammable.

(9) Peroxyacetic Acid Preparations

Definition Peroxyacetic Acid preparations is obtained by reaction of hydrogen peroxide and acetic acid, containing peroxyacetic acid, hydrogen peroxide and acetic acid as active ingredient or it is obtained by reaction of hydrogen peroxide, acetic acid, and octanoic acid containing peroxyacetic acid, peroxyoctanoic acid, hydrogen peroxide, octanoic acid, and acetic acid as active ingredient. However, Phosphoric acid, (1-hydroxyethylidene)bis-, phosphoric acid or 1-Octanesulfonic acid, sodium salt can be added for dilution or stability in quality.

Compositional Specifications of Peroxyacetic Acid preparations

Description Peroxyacetic Acid preparations is a colorless, clear liquid. It has a characteristic pungent odor.

Purity (1) Arsenic : Pipet 0.25 ml of Peroxyacetic Acid preparations and mix it with 10 ml of water. Add a small amount of this solution in small portions to a platinum crucible in a water bath to evaporate the liquid to dryness. Add a small amount of water to the residues and use the entire solution as Test Solution. This Test Solution is tested for arsenic and its content should be appropriate (Not more than 4ppm).

(2) Lead : Add 10 ml of water to 5 g of Peroxyacetic Acid preparations. And add a small amount of this solution in small portions to a platinum crucible in a water bath to warming it until forming bubbles is ended. Add 0.5N of nitric acid to make to 25ml. This solution is used as a Test Solution. When test solution is tested by Atomic Absorption Spectrophotometry or Inductively Coupled Plasma Emission Spectroscopy, its content should not be more than 4.0 ppm.

Test of Bactericidal Activity When Peroxyacetic Acid preparations is tested by Test Method of Bacterial Suspension(Test Method of Spore Suspension when used for sterilization of food container and packaging) in Test of Bactericidal Activity, it should be appropriate.

Storage Standard of Peroxyacetic Acid preparations and Ingredients Containing it

Peroxyacetic Acid should be stored in a hermetic container in a cold dark place which is inflammable.

(10) Citric Acid Preparations

Definition Citric Acid preparations contains Citric Acid as an active ingredient. However, Diluent, stabilizers, dissolving agents, etc. can be added for dilution or stability in quality.

Compositional Specifications of Citric Acid preparations

Description Citric Acid preparations occurs as transparent liquid having a characteristic odor.

Identification An aqueous solution of Citric Acid preparations (1→10) is acidic.

Purity (1) Sulfate : When 0.5 g of Citric Acid preparations is tested for Sulfates, its content should not be more than the amount that corresponds to 0.5 ml of 0.01 N sulfuric acid.

(2) Oxalate : When 1 g of Citric Acid preparations is dissolved in 10 ml of water, where 2 ml of calcium chloride solution is added, it should not be turn turbid.

(3) Arsenic : When 0.77 g of Citric Acid preparations is dissolved in 5 ml of water, which is tested by Arsenic Limit Test, its content should not be more than 1.33 ppm.

(4)Lead : When 5.0 g of Citric Acid Preparations is tested by Atomic Absorption Spectrophotometry or Inductively Coupled Plasma Emission Spectroscopy, its content should not be more than 0.5ppm.

(5) Mercury : When Citric Acid preparations is tested by Mercury Limit Test, its content should not be more than 1.0 ppm.

(6) Calcium : 1 g of Citric Acid is dissolved in 10 ml of water, which is neutralized with ammonia solution. When 1 ml of ammonium oxalate solution is added, it should not be turn turbid.

(7) Coloring Substance by Sulfuric Acid : 5 ml of sulfuric acid is added to 0.5 g of Citric acidis, dissolved by heating at 90°C for 1 hour. When the color of the solution is observed with a white background, the color should not be deeper than that of the color standard K.

(8) Polynuclear Aromatic Hydrocarbon : 25 g of Citric Acid is dissolved in 30 ml of water by heating at about 50°C. After cooling, the solution is extracted 3 times with 20 ml each of n-hexane for UV absorption spectrophotometry grade. It is centrifuged at 2,500~3,000 rpm for about 10minutes and concentrated to 1~2 ml by evaporating n-hexane out. After cooling, n-hexane (for UV absorption spectrophotometry grade) is added to the concentrate to bring the total volume to 10 ml, Test Solution. Absorbance of test solution is measured at 260~350 nm with 1

cm cell. The difference in absorbance (compared to reference solution) should not be more than 0.05 in this range. In this case, use the reference solution obtained by following method. To 30 ml of water, extract 3 times with 20 ml of n-hexane(UV absorption spectrophotometry grade) repeatedly, and follow the same procedure as test solution.

- (9) Isocitric acid : Weigh 0.5g of Citric Acid, heat at 105°C for 3 hours, cool, and dissolve in 10 ml of acetone. Measure 0.005 ml of the test solution, and perform Paper Chromatography without using a control solution. No more than one spot is observed. For the filter paper, use a No. 2 filter paper for chromatography, and stop the development when the developing solvent rises about 25 cm. Then air-dry, and spray with bromophenol blue TS for citric acid. Allow a n-butanol-formic acid-water mixture(8:3:2) to stand, and use the upper layer obtained as the developing solvent.

Test of Bacterial Activity Citric acid preparations is tested as directed under Test of Bacterial Suspension in Test of Bacterial Activity. It should be appropriate.

Storage Standard of Citric Acid preparations and Ingredients Containing it

Citric acid preparations should be stored in a hermetic container in a cold dark place which is inflammable.

(11) Iodine Preparations

Definition Iodine preparations contains Iodine as an active ingredient. However, Potassium Iodine can be added for dilution or stability in quality.

Compositional Specifications of Iodine preparations

Description Iodine preparations occurs as reddish brown liquid having a characteristic odor.

Purity (1) Chloride and Bromide : Dissolve 1.0 g of Iodine preparations in 20 ml of water and shake it to mix and filter it. Add 1 drop of sulfurous acid water(1→5) to 10 ml of the balance solution until yellow color is clear. After adding 1 ml of ammonia solution to this solution, again add 1 ml of silver nitrate solution little by little and water to make to 20 ml. Shake it to mix and filter it. 2 ml of the first balance solution is discarded. When 10 ml of the next balance solution is taken and 2.0 ml of nitric acid and water are added to make to 20 ml, the turbidity of solution should not be darker than a reference solution. Add 5 ml of water to 0.20 ml of 0.01 mol hydrochloric acid, 2.5 ml of ammonia solution, 1 ml of silver nitrate solution, 2.0 ml of nitric acid and water to make to 20 ml, this solution is used as a reference solution.

(2) Lead : When 5.0 g of Iodine preparations is tested by Atomic Absorption Spectrophotometry or Inductively Coupled Plasma Emission Spectroscopy, its content should not be more than 10 ppm.

Test of Bacterial Activity Iodine preparations is tested as directed under Test of Bacterial Suspension in Test of Bacterial Activity. It should be appropriate.

Storage Standard of Iodine preparations and Ingredients Containing it

Iodine preparations should be stored in a hermetic container in a cold dark place which is inflammable.

(12) Chlorine Dioxide Preparations

Definition Chlorine Dioxide preparations contains 1 or more of hydrogen peroxide, chlorous acid, sodium chlorite, hydrochloric acid, chlorine, sodium chlorate, hypochlorous acid, Sodium Hypochlorite, sodium thiosulfate or sulfuric acid as an active ingredient. Chlorine Dioxide Preparations contain Chlorine Dioxide as an active ingredient. However, Diluent, stabilizers, dissolving agents, etc. can be added for dilution or stability in quality.

Compositional Specifications of Chlorine Dioxide preparations

Description Chlorine Dioxide preparations occurs as pale yellow liquid having a pungent odor.

Identification When the mixed (5 ml of acetic acid and 1 g of potassium iodine) solution is added to 5 ml of this diluted solution (10 mg/l), the color of this solution is yellow. Again when 1 ml of starch solution is added, the color of this solution is dark blue.

Test of Bacterial Activity Chlorine Dioxide preparations is tested as directed under Test of Bacterial Suspension in Test of Bacterial Activity. It should be appropriate.

Storage Standard of Chlorine Dioxide preparations and Ingredients Containing it

Chlorine Dioxide preparations should be stored in a hermetic container in a cold dark place which is inflammable.