Quality Standards for Permanent Wave Agents

1. Dual-step Cold Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients

These agents are used at room temperature. They consist of the first agent containing thioglycolic acid and/or its salt and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent is a liquid containing thioglycolic acid and/or its salt as active ingredient with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (h). A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH

Measure the pH of this agent at 25°C using a glass electrode pH meter: it is between 4.5 and 9.6.

(b) Alkali

Take exactly 10 mL of a sample in a 100-mL volumetric flask, add purified water (hereinafter referred to as “water”) conforming to the Japanese Standards of Quasi-Drug Ingredients (PFSB Notification No. 0331030, March 31, 2006; hereinafter referred to as JSQI) to make 100 mL, and use this solution as the sample solution.

Measure exactly 20 mL of the sample solution, and titrate with 0.1 mol/L hydrochloric acid VS. The amount of the volumetric solution consumed is not more than 7 mL per mL of the sample (Indicator: 2 drops of methyl red TS).

(c) Reducing substance after boiling under acidic condition

Measure exactly 20 mL of the sample solution obtained in (b), add 50 mL of water and 5 mL of 30 % sulfuric acid, and boil for 5 minutes by gentle heating. After cooling, titrate with 0.05 mol/L iodine VS, and designate the amount of 0.05 mol/L iodine VS consumed as A mL (indicator: 3 mL of starch TS).

The content (as thioglycolic acid, %) of the reducing substance after boiling under acidic conditions calculated by the following equation shall be between 2.0 % and 11.0 %.

Content (as thioglycolic acid) of the reducing substance after boiling under acidic condition=0.4606×A

However, when the content of the reducing substance after boiling under acidic conditions is more than 7.0 %, dithiodiglycolic acid or its salt shall be contained as additives in an amount of dithiodiglycolic acid equal to or more than the excess of the reducing substance after boiling under acidic conditions.

(d) Reducing substance other than the reducing substance after boiling under acidic condition

To 50 mL of water and 5 mL of 30 % sulfuric acid in a 200-mL glass-stoppered flask add exactly 25 mL of 0.05 mol/L iodine VS. To this solution add exactly 20 mL of the sample solution obtained...
in (b), stopper the flask tightly, shake, allow to stand at room temperature for 15 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as B mL (indicator: 3 mL of starch TS). Separately, take 70 mL of water and 5 mL of 30 % sulfuric acid in a 200-mL glass-stoppered flask, proceed in a similar manner and designate the amount of the volumetric solution consumed as C mL.

The amount per mL of the sample of 0.05 mol/L iodine VS consumed for the reducing substance other than the reducing substance after boiling under acidic condition, which is calculated by the following equation, is not more than 0.6 mL.

Amount (mL) per mL of the sample of 0.05 mol/L iodine VS consumed for the reducing substance other than the reducing substance after boiling under acidic condition

\[ \frac{(C - B) - A}{2} \]

(e) Reducing substance after reduction

Measure exactly 20 mL of the sample solution obtained in (b), add 30 mL of 1 mol/L hydrochloric acid and 1.5 g of zinc powder (85), stir by a stirrer for 2 minutes with careful attention not to mix air bubbles, and filter the solution under vacuum through a filter paper (4A). Wash the residue with a small amount of water three times, add washing to the filtrate and boil for 5 minutes by gentle heating. After cooling, titrate with 0.05 mol/L iodine VS, and designate the amount of 0.05 mol/L iodine VS consumed as D mL (indicator: 3 mL of starch TS).

Or, measure accurately 10 g of the sample, add 50 mL of sodium lauryl sulfate solution (1 in 10) and 20 mL of water and heat to approximately 80°C on a water bath. After cooling, make 100 mL in total, use this solution as the sample solution and proceed in a similar manner.

The content (%) of the reducing substance after reduction calculated by the following equation is not more than 4.0 %.

Content (%) of the reducing substance after reduction = \[ \frac{4.556 \times (D - A)}{W} \]

W: Amount of the sample (mL or g)

(f) Iron

To 20 mL of the sample in a 300 mL decomposition flask add 20 mL of nitric acid, and heat carefully until the reaction subsides. After cooling, add 5 mL of sulfuric acid, and heat again. To this solution add carefully 2-mL portions of nitric acid, and heat until the solution is clear and colorless or light yellow. After cooling, add 1 mL of perchloric acid, heat until the white fumes of sulfuric acid evolve, and allow to cool. Add 20 mL of a saturated solution of ammonium oxalate, and heat until white fumes evolve. After cooling, add water to make 100 mL, and use this solution as the sample solution.

Separately, prepare a solution with 20 mL of water in the same manner as the sample solution. To 50 mL of this solution add exactly 2.0 mL of Standard Iron Solution, adjust to a pH between 9.5 and 10.0 by adding carefully ammonia water (28) under cooling, and use this solution as the standard matching fluid. Transfer the two solutions to separate Nessler tubes, to each add exactly 1.0 mL of mercaptoacetic acid, and add water to make 100 mL.

Compare the colors of the two solutions: the sample solution has no more color than the standard matching fluid (not more than 2 ppm as iron).

(g) Heavy metals

Take 2.0 mL of the sample and perform the test as directed under the Method 2, the Heavy Metals Limit Test, JSQI General Tests: the limit is not more than 20 ppm. Prepare the control solution with 4.0 mL of Standard Lead Solution.

(h) Arsenic
Perform the test with 2.0 mL of the sample solution obtained in (f) as directed under the Arsenic Limit Test of the JSQI General Tests: the limit is not more than 5 ppm.

(2) Second agent

The second agent should meet the following requirements (a) or (b).

(a) Potassium bromide, sodium bromide, sodium perborate or the mixture of these substances to which a suitable osmotic agent, stabilizing agent, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added for maintaining quality or enhancing usefulness of the product.

(i) Clarity and color of solution

For preparations in powder or in tablet form, dissolve an amount of the sample per dose per person in 200 mL of cold or lukewarm water, take in a colorless flat bottomed colorimetric tube, and observe vertically against white paper: no distinct insoluble foreign matters are observable.

(ii) pH

Perform the test as directed in 1-(1)-(a) with the second agent prepared before use in accordance with Dose and Administration: the pH of this solution is between 4.0 and 10.5.

(iii) Heavy metals

To 2.0 mL of the second agent prepared before use in accordance with Dose and Administration add 10 mL of water, then add 1 mL of hydrochloric acid and evaporate on a water bath to dryness. Incinerate the residue at a temperature below 500°C, dissolve in 10 mL of water and 2 mL of dilute acetic acid, add water to make 50 mL and use this solution as the sample solution.

Perform the test with the sample solution as directed under the Method 4, the Heavy Metals Limit Test of the JSQI General Test: the limit is not more than 20 ppm. Prepare the control solution with 4.0 mL of Standard Lead Solution.

(iv) Oxidizing activity

Measure accurately about a tenth of an amount of the second agent prepared before use according to the Dose and Administration in a 200-mL volumetric flask and add water to make 200 mL. Transfer 20 mL of the solution to a glass-stoppered flask, add 10 mL of dilute sulfuric acid, stopper tightly at once, and shake once or twice gently. To this solution, add 10 mL of potassium iodide TS carefully, stopper tightly, allow to stand in a dark place for 5 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as E mL (indicator: 3 mL of starch TS).

The oxidizing activity per dose per person, calculated by the following equation, is not less than 3.5.

Oxidizing activity per dose per person=0.2783×E

(b) Hydrogen peroxide or hydrogen peroxide to which a suitable osmotic agent, stabilizing agent, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added for maintaining quality or enhancing usefulness of the product.

(i) pH

Perform the test as directed in 1-(2)-(a)-(ii): the pH of the solution obtained is between 2.5 and 4.5.

(ii) Heavy metals

Proceed as directed in 1-(2)-(a)-(iii).

(iii) Oxidizing activity

Measure exactly 1 mL of the sample in a 200-mL glass-stoppered flask, add 10 mL of water and 5 mL of 30% sulfuric acid, stopper tightly at once, and shake once or twice gently. To this
solution, add 5 mL of potassium iodide TS carefully, stopper tightly, allow to stand in a dark place for 30 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as F mL (indicator: 3 mL of starch TS).

The oxidizing activity per dose per person, calculated by the following equation, is between 0.8 and 3.0.

Oxidizing activity per dose per person = 0.001701×F×amount (mL) per dose per person

The content (%) of hydrogen peroxide, calculated by the following equation, is not more than 2.5%.

Content (%) of hydrogen peroxide = 0.1701×F

2. Dual-step Cold Permanent Wave Agents containing cysteine, its salt and/or acetylcysteine as active ingredients

These agents are used at room temperature. They consist of the first agent containing cysteine, its salt and/or acetylcysteine as an active ingredient and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent is a liquid containing cysteine, its salt and/or acetylcysteine as an active ingredient and not containing nonvolatile inorganic alkali. It should meet the following requirements (a) to (g). A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH

Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 8.0 and 9.5.

(b) Alkali

Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 12 mL per mL of the sample.

(c) Cysteine

(i) Preparation of the sample stock solution

Measure 10 mL of the sample in a suitable reflux apparatus, add 40 mL of water and 20 mL of 5 mol/L hydrochloric acid TS and heat under reflux for 2 hours. After cooling, transfer the solution into a 100-mL volumetric flask, add water to make 100 mL and use this solution as the undiluted sample stock solution.

For the sample which is known to contain no acetylcysteine, take exactly 10 mL of the sample in a 100-mL volumetric flask, add water to make 100 mL and use this solution as the undiluted sample stock solution.

(ii) Preparation of the sample solution

Pass 25 mL of the sample undiluted stock solution through a layer of a column 8 to 15 mm in inside diameter packed with 30 mL of strongly acidic ion-exchange resin (H type) at the flow rate of 2 mL/min. Wash the resin layer with water and discard the eluate and washing. Pass 60 mL of 3 mol/L ammonia water through the resin layer at the flow rate of 2 mL/min, transfer the eluate to a 100-mL volumetric flask, wash the resin layer with water, and to the combined washing and eluate add water to make 100 mL and use this solution as the sample solution.

(iii) Assay of cysteine

Measure exactly 20 mL of the sample solution, neutralized with dilute hydrochloric acid as needed (indicator: methyl orange TS), add 4 g of potassium iodide and 5 mL of dilute
hydrochloric acid and dissolve with shaking. To this solution, add exactly 10 mL of 0.05 mol/L iodine solution, stopper tightly, allow to stand in ice water in a dark place for 20 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as G mL (indicator: 3 mL of starch TS).

Perform a blank test in a similar manner and designate the amount of the volumetric solution consumed as H mL.

The content (%) of cysteine calculated by the following equation is between 3.0 % and 7.5 %.

$$\text{Content (\% of cysteine)} = 1.212 \times 2 \times (H - G)$$

For “Total reducing power” described in 2-(4)-(d) of the approval standards, “20 mL of the sample solution” in this test method shall be deemed to be replaced with “5 mL of the undiluted sample stock solution”.

(d) Reducing substance after reduction

Measure exactly 10 mL of the sample solution obtained in 2-(1)-(b), add 30 mL of 1 mol/L hydrochloric acid TS and 1.5 g of zinc powder (85), stir by a stirrer for 2 minutes with careful attention not to mix air bubbles, and filter the solution under vacuum through a filter paper (4A). Wash the residue with a small amount of water three times and combine washings and filtrate. Add 4 g of potassium iodide and dissolve with shaking. To this solution, add exactly 10 mL of 0.05 mol/L iodine solution, stopper tightly, allow to stand in ice water in a dark place for 20 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as I mL (indicator: 3 mL of starch TS). Perform a blank test in a similar manner and designate the amount of the volumetric solution consumed as J mL.

Separately, measure exactly 10 mL of the sample solution, neutralized with dilute hydrochloric acid as needed (indicator: methyl orange TS), add 4 g of potassium iodide and 5 mL of dilute hydrochloric acid and dissolve with shaking. To this solution, add exactly 10 mL of 0.05 mol/L iodine solution, stopper tightly, allow to stand in ice water in a dark place for 20 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as K mL (indicator: 3 mL of starch TS). Perform a blank test in a similar manner and designate the amount of the volumetric solution consumed as L mL.

The content (%) of the reducing substance (as cystine) after reduction, calculated by the following equation, is not more than 0.65 %.

$$\text{Content (\% of the reducing substance (as cystine) after reduction)} = 1.202 \times \frac{(J - I) - (L - K)}{2}$$

(e) Iron

Proceed as directed in 1-(1)-(f).

(f) Heavy metals

Proceed as directed in 1-(1)-(g).

(g) Arsenic

Proceed as directed in 1-(1)-(h).

(2) Second agent

Proceed as directed in 1-(2).

3. Dual-step Tepid Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients

These agents are warmed to a temperature lower than about 60°C before use. They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient and the second agent
containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent
The first agent is a liquid containing thioglycolic acid and/or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid.

It should meet the following requirements (a) to (h). A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
Perform the test as directed in 1·(1)·(a): the pH of the solution obtained is between 4.5 and 9.3.

(b) Alkali
Perform the test as directed in 1·(1)·(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 5 mL per mL of the sample.

(c) Reducing substance after boiling under acidic condition
Perform the test as directed in 1·(1)·(c): the content (as thioglycolic acid, %) of the reducing substance after boiling under acidic conditions is between 1.0 % and 5.0 %.

(d) Reducing substance other than the reducing substance after boiling under acidic condition
Proceed as directed in 1·(1)·(d).

(e) Reducing substance after reduction
Proceed as directed in 1·(1)·(e).

(f) Iron
Proceed as directed in 1·(1)·(f).

(g) Heavy metals
Proceed as directed in 1·(1)·(g).

(h) Arsenic
Proceed as directed in 1·(1)·(h).

(2) Second agent
Proceed as directed in 1·(2)

4. Dual-step Tepid Permanent Wave Agents containing cysteine, its salt and/or acetylcysteine as active ingredients
These agents are warmed to a temperature lower than about 60°C before use. They consist of the first agent containing cysteine, its salt and/or acetylcysteine as an active ingredient and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent
The first agent is a liquid containing cysteine, its salt and/or acetylcysteine as an active
ingredient and not containing nonvolatile inorganic alkali. It should meet the following requirements (a) to (g).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
   Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 4.0 and 9.5.

(b) Alkali
   Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 9 mL per mL of the sample.

(c) Cysteine
   Perform the test as directed in 2-(1)-(c): the content (%) of cysteine is between 1.5 and 5.5 %.

(d) Reducing substance after reduction
   Proceed as directed in 2-(1)-(d).

(e) Iron
   Proceed as directed in 1-(1)-(f).

(f) Heavy metals
   Proceed as directed in 1-(1)-(g).

(g) Arsenic
   Proceed as directed in 1-(1)-(h).

(2) Second agent
   Proceed as directed in 1-(2)

5. Single-step Cold Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients

These agents are used at room temperature. They contain thioglycolic acid and/or its salt as an active ingredient with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. They should meet the following requirements (1) to (8).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(1) pH
   Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 9.4 and 9.6.

(2) Alkali
   Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is between 3.5 and 4.6 mL per mL of the sample.

(3) Reducing substance after boiling under acidic condition
   Perform the test as directed in 1-(1)-(c): the content (as thioglycolic acid, %) of the reducing


substance after boiling under acidic condition is between 3.0 % and 3.3 %.

(4) Reducing substance other than the reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(d).

(5) Reducing substance after reduction
Perform the test as directed in 1-(1)-(e): the content (%) of the reducing substance after reduction
is not more than 0.5 %.

(6) Iron
Proceed as directed in 1-(1)-(f).

(7) Heavy metals
Proceed as directed in 1-(1)-(g).

(8) Arsenic
Proceed as directed in 1-(1)-(h).

6. Dual-Step Permanent Wave Agents with the first agent containing thioglycolic acid and/or its
   salt as active ingredients (consisting of components to be mixed at use, generating exothermal
   reaction)
   These agents consist of the first agent-(1) containing thioglycolic acid and/or its salt as active
   ingredient, the first agent-(2) containing a amount of hydrogen peroxide smaller than the
   equivalent amount of thioglycolic acid and/or its salt contained in the first agent-(1) and the second
   agent containing oxidizing agent. The first agent-(1) and the first agent-(2) are mixed to raise its
   temperature to about 40°C with an exothermic reaction before use. The quality standards for these
   agents are as follows.

(1) First agent-(1)
This agent is a liquid containing thioglycolic acid and/or its salt as active ingredient. It should
meet the following requirements (a) to (h).
A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent,
perfume and other substances may be added to this agent in order to maintain quality and to
enhance usefulness.

(a) pH
Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 4.5 and 9.5.

(b) Alkali
Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed
is not more than 10 mL per mL of the sample.

(c) Reducing substance after boiling under acidic condition
Perform the test as directed in 1-(1)-(c): the content (as thioglycolic acid, %) of the reducing
substance after boiling under acidic condition is between 8.0 % and 19.0 %.

(d) Reducing substance other than the reducing substance after boiling under acidic condition
Perform the test as directed in 1-(1)-(d): the amount of 0.05 mol/L iodine VS consumed for the
reducing substance other than the reducing substance after boiling under acidic condition per mL
of the sample is not more than 0.8 mL. In this test add 50 mL of 0.05 mol/L iodine VS.

(e) Reducing substance after reduction
   Perform the test as directed in 1·(1)·(e): the content (%) of the reducing substance after reduction is not more than 0.5 %.

(f) Iron
   Proceed as directed in 1·(1)·(f).

(g) Heavy metals
   Proceed as directed in 1·(1)·(g).

(h) Arsenic
   Proceed as directed in 1·(1)·(h).

(2) First agent·(2)
   This agent is a liquid containing an amount of hydrogen peroxide smaller than the equivalent amount of thioglycolic acid and/or its salt contained in the first agent·(1). It should meet the following requirements (a) to (c).
   A suitable penetrant, pH adjusting agent, stabilizing agent, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
   Perform the test as directed in 1·(1)·(a): the pH of the solution obtained is between 2.5 and 4.5.

(b) Heavy metals
   Take 2.0 mL of the sample and proceed as directed in 1·(2)·(a)·(iii).

(c) Hydrogen peroxide
   Take exactly 1 mL of the sample in a 200 mL glass-stoppered flask, add 10 mL of water and 5 mL of 30% sulfuric acid, stopper tightly at once, and shake once or twice gently. To this solution, add 5 mL of potassium iodide TS carefully, stopper tightly, allow to stand in a dark place for 30 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as M mL (indicator: 3 mL of starch TS). The content (%) of hydrogen peroxide calculated by the following equation is between 2.7 % and 3.0 %.
   \[
   \text{Content(%) of hydrogen peroxide} = 0.1701 \times M
   \]

(3) Mixture of the First Agent·(1) and (2)
   This product is a 3:1 mixture (in volume) of the first agent·(1) and (2). It contains thioglycolic acid or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (f). It generates heat on mixing and is warmed to about 40°C before using. In the test, mix one dose per person of the first agent·(1) with one dose per person of the first agent·(2), allow to stand at room temperature for 10 minutes, cool to room temperature and use the solution as the sample solution.

(a) pH
   Perform the test as directed in 1·(1)·(a): the pH of the solution obtained is between 4.5 and 9.4.
(b) Alkali
    Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 7 mL per mL of the sample.

(c) Reducing substance after boiling under acidic condition
    Perform the test as directed in 1-(1)-(c): the content (as thioglycolic acid, %) of the reducing substance after boiling under acidic condition is between 2.0 % and 11.0 %.

(d) Reducing substance other than the reducing substance after boiling under acidic condition
    Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction
    Perform the test as directed in 1-(1)-(e): the content (%) of the reducing substance after reduction is between 3.2 % and 4.0 %.

(f) Temperature rise
    Place one dose per person of the first agent-1 and one dose per person of the first agent-2 in a thermostat maintained at 25°C, and allow to stand until the temperature of the agents rises to 25°C. Transfer the first agent-1 to a 100-mL beaker and record temperature (T0) of the solution. To this add the first agent-2, measure temperature immediately with shaking, and record the highest temperature (T1).
    Calculate the temperature rise by deducting T0 from T1: it is between 14°C and 20°C.

(4) Second agent
    Proceed as directed in 1-(2)

7. Dual-step Cold Hair Straightening Agents containing thioglycolic acid or its salt as active ingredients
    These agents are used at room temperature. They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent
    The first agent contains thioglycolic acid and/or its salt as active ingredients, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (i).
    A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, viscous agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
    Proceed as directed in 1-(1)-(a).

(b) Alkali
    Proceed as directed in 1-(1)-(b).

(c) Reducing substance after boiling under acidic condition
    Proceed as directed in 1-(1)-(c).
(d) Reducing substance other than the reducing substance after boiling under acidic condition
   Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction
   Proceed as directed in 1-(1)-(e).

(f) Viscosity
   Perform the test according to Method 2 under the Viscosity of the JSQI General Tests; the limit is not more than 40,000 mPa·s.

(g) Iron
   Proceed as directed in 1-(1)-(f).

(h) Heavy metals
   Proceed as directed in 1-(1)-(g).

(i) Arsenic
   Proceed as directed in 1-(1)-(h).

(2) Second agent
   Proceed as directed in 1-(2)

8. Dual-step Tepid Hair Straightening Agents containing thioglycolic acid and/or its salt as active ingredients
   These agents are warmed to a temperature lower than about 60°C before use. They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent
   The first agent contains thioglycolic acid and/or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (i).
   A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, viscous agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
   Proceed as directed in 3-(1)-(a).

(b) Alkali
   Proceed as directed in 3-(1)-(b).

(c) Reducing substance after boiling under acidic condition
   Proceed as directed in 3-(1)-(c).

(d) Reducing substance other than the reducing substance after boiling under acidic condition
   Proceed as directed in 1-(1)-(d).
Reducing substance after reduction
Proceed as directed in 1-(1)-(e).

Viscosity
Proceed as directed in 7-(1)-(f).

Iron
Proceed as directed in 1-(1)-(f).

Heavy metals
Proceed as directed in 1-(1)-(g).

Arsenic
Proceed as directed in 1-(1)-(h).

Second agent
Proceed as directed in 1-(2)

9. Dual-Step Cold, Hair Straightening Agents containing thioglycolic acid or its salt as active ingredients using a high temperature hair iron
For these agents, after treatment with the first agent at room temperature, the first agent is washed with water sufficiently and the moisture is wiped off. The procedure includes the use of a high temperature hair iron (not more than 180°C). They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient, and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent
The first agent contains thioglycolic acid and/or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (i).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, viscous agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
Proceed as directed in 1-(1)-(a).

(b) Alkali
Proceed as directed in 1-(1)-(b).

(c) Reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(c).

(d) Reducing substance other than the reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction
Proceed as directed in 1-(1)-(e).
(f) Viscosity
   Proceed as directed in 7-(1)-(f).

(g) Iron
   Proceed as directed in 1-(1)-(f).

(h) Heavy metals
   Proceed as directed in 1-(1)-(g).

(i) Arsenic
   Proceed as directed in 1-(1)-(h).

(2) Second agent
   Proceed as directed in 1-(2)

10. Dual-Step Tepid, Hair Straightening Agents containing thioglycolic acid or its salt as active
    ingredients using high temperature hair-iron
    These agents are warmed to a temperature lower than about 60°C before use and after treatment
    with the first agent, the first agent is washed with water sufficiently and the moisture is wiped off.
    The procedure includes the use of high temperature hair-iron (not more than 180°C). They consist
    of the first agent containing thioglycolic acid and/or its salt as active ingredient, and the second
    agent containing an oxidizing agent. The quality standards for the first and the second agents are
    as follows.

(1) First agent
    The first agent contains thioglycolic acid and/or its salt as active ingredient, with a total amount
    of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should
    meet the following requirements (a) to (i).
    A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent,
    viscous agent, perfume and other substances may be added to this agent in order to maintain
    quality and to enhance usefulness.

(a) pH
   Proceed as directed in 3-(1)-(a).

(b) Alkali
   Proceed as directed in 3-(1)-(b).

(c) Reducing substance after boiling under acidic condition
   Proceed as directed in 3-(1)-(c).

(d) Reducing substance other than the reducing substance after boiling under acidic condition
    Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction
    Proceed as directed in 1-(1)-(e).

(f) Viscosity
Proceed as directed in 7-(1)-(f).

(g) Iron
Proceed as directed in 1-(1)-(f).

(h) Heavy metals
Proceed as directed in 1-(1)-(g).

(i) Arsenic
Proceed as directed in 1-(1)-(h).

(2) Second agent
Proceed as directed in 1-(2)

11. Reagents, Test Solutions and Standard Solutions
The reagents, test solutions and standard solutions used in the tests in 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 above are shown as follows unless otherwise specified.

(1) Reagents and Test solutions
(a) Zinc powder (85), ammonia solution (28), 1 mol/L hydrochloric acid TS, 5 mol/L hydrochloric acid TS, hydrochloric acid, dilute hydrochloric acid, perchloric acid, dilute acetic acid, ammonium oxalate, nitric acid, starch TS, methyl orange TS, methyl red TS, mercaptoacetic acid, potassium iodide, potassium iodide TS, sodium lauryl sulfate, sulfuric acid and dilute sulfuric acid
As specified in the Reagents and Test Solutions of the JSQI General Tests.

(b) 3 mol/L ammonia solution
To 61 mL of strong ammonia solution (JSQI reagent) add water to make 300 mL.

(c) 30 % Sulfuric acid
Cautiously add 17.1 mL of sulfuric acid (JSQI reagent) to 30 mL of water, cool and dilute with water to make 100 mL.

(2) Standard solution
(a) 0.1 mol/L hydrochloric acid, 0.1 mol/L sodium thiosulfate and 0.05 mol/L iodine solution
As specified in the Standard Solutions for Volumetric Analysis of the JSQI General Tests.

(b) Standard lead solution
As specified in the Standard Solutions of JSQI General Tests.

(c) Standard Iron solution
Dissolve 0.7021 g of ammonium iron (II) sulfate hexahydrate (JSQI reagent), accurately weighed, in 50 mL of water, add 20 mL of sulfuric acid, then add dropwise 0.6% potassium permanganate solution (prepared by dissolving 0.6 g of potassium permanganate (JSQI reagent) in water to make 100 mL) with warming until the pale red color of the solutions persists, cool and add water to make exactly 1000 mL. Take 10 mL of this solution in a 100-mL volumetric flask and add water to make 100 mL.

12. Remarks
“%” and “ppm” used in the standards are defined as follows. In the case of a liquid preparation, “%” and “ppm” denote percent weight in volume and parts per million weight in volume. In the case of a powder or tablet preparation, “%” and “ppm” denote percent weight in weight and parts per million weight in weight. In the case of viscous sample which cannot be measured exactly in a directed volume, it may be measured in equivalent weight. In such case, 1 g is deemed equivalent to 1 mL.

An alternative method for the test method specified in the standards, of which the correctness and accuracy are equal to or greater than that specified, may be used. However, when a questionable result is obtained, the specified method shall be used for the final determination.