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Hygienic Requirements for Disposable Sanitary Products

一次性使用卫生用品卫生要求

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Hygienic Requirements for Disposable Sanitary Products

1 Scope

This document specifies the hygienic requirements for raw materials, production process and products, as well as the requirements for packaging, transportation, storage and marking of disposable sanitary products, and describes the corresponding test methods.

This document is applicable to disposable sanitary products sold and used.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 191 Packaging - Pictorial Marking for Handling of Goods

GB 5749 Standards for Drinking Water Quality

GB/T 8939 Sanitary Absorbent Pads (panty liner)

GB/T 15981 Evaluating Method for the Efficacy of Sterilization for Disinfection Equipment

GB/T 26367 Hygienic Requirements for Biguanides Disinfectants

GB/T 26369 Hygienic Requirement for Quaternary Ammonium Disinfectant

GB/T 27741 Paper and Board - Determination of Migratable Fluorescent Whitening Agents

GB/T 27947 Hygienic Requirements for Phenol Disinfectant

GB/T 28004.1 Disposable Diapers - Part 1: Disposable Diapers for Baby

GB/T 28004.2 Disposable Diapers - Part 1: Disposable Diapers for Adult

GB/T 38496 Toxicological Procedures and Methods of Safety Evaluation for Disinfectant

GB 38598 General Requirement for Label and Instruction Book of Disinfection Products

GB 50073 Code for Design of Clean Room

WS/T 10009 Test Methods of Disinfection Products

Pharmacopoeia of the People's Republic of China (National Medical Products Administration,

3.5 production workshop

A place where disposable sanitary products are produced and processed.

NOTE: including weighing room (area), production and processing room (area), sub-packaging (filling) room (area), inner packaging room (area), etc. Among them, the production workshop of sub-packaging enterprises includes sub-packaging (filling) room (area) and inner packaging room (area), etc.

[source: *Hygienic Standard for Disinfection Product Production Enterprises* (Version 2009), Article 12, modified]

3.6 super absorbent materials

An absorber that can absorb several to hundreds of times its own mass of liquid water and has the capabilities of retaining and storing water after absorption.

NOTE: the absorber is composed of polymer compounds, pulp and non-woven fabrics, etc.

4 Hygienic Requirements for Raw Materials

4.1 Raw materials shall comply with the requirements of relevant specifications and standards for disinfection products and shall be non-toxic and harmless. The packaging of raw materials shall clearly indicate the name of the contents, production organization, production date or production batch No.; raw materials with special requirements shall indicate storage conditions and shelf life.

4.2 Discarded or used disposable sanitary products shall not be used as raw materials or semi-finished products.

4.3 The following prohibited substances must not be added to the raw materials.

a) Drugs listed in *Pharmacopoeia of the People's Republic of China* and their raw materials with the same name shall not be added to antibacterial (bacteriostatic) agents (disinfectants and antiseptics, traditional Chinese medicines and bacteriostatic agents are excluded, as well as pharmaceutical excipients and purified water); preparations used to generate active or passive immunity, such as: vaccines, serum or toxins and their products, and preparations used to diagnose immune status, protein and peptide preparations (except lysozyme and lysostaphin); prohibited chemical substances (except iodine) listed in *Safety Technical Specifications for Cosmetics*; other prohibited substances stipulated by the national health administrative department and other substances with a definite hazard to human health.

b) Hygiene wet wipes and other disposable sanitary products with antibacterial (bacteriostatic) functions shall not contain antibacterial drugs, antifungal drugs, antiviral drugs, hormone drugs and their raw materials of the same name, etc., and

other prohibited substances stipulated by the national health administrative department and other substances with a definite hazard to human health.

c) Non-woven fabrics, fabrics or other raw materials shall not contain prohibited ingredients, for example, migratory fluorescent whitening agents.

4.4 In accordance with the product process regulations, select production water that complies with the corresponding product quality standards. The production water for wet wipes, hygiene wet wipes and antibacterial (bacteriostatic) agents shall comply with the requirements for purified water in *Pharmacopoeia of the People's Republic of China*. The production water for other disposable sanitary products shall comply with the requirements of GB 5749 and relevant enterprise specifications and ensure the safety and effectiveness of product use.

5 Hygienic Requirements for Production Process

5.1 The purchase, storage, distribution and use of raw and auxiliary materials shall satisfy the product quality control requirements and comply with management system regulations.

5.2 The production environment hygiene indicator requirements are as follows.

a) The air in the antibacterial (bacteriostatic) agent production workshop shall comply with the requirements of *Hygienic Standard for Disinfection Product Production Enterprises*, and the purification workshop shall comply with the requirements of GB 50073; the total number of colonies in the air of other disposable sanitary products production workshops shall be less than or equal to 2,500 CFU/m^3 (the air sampler method) or shall be less than or equal to 16 CFU/(plate • 5 min) (the plate exposure method).

b) The total number of colonies on workbench surfaces that are in direct contact with unpackaged products shall be less than or equal to 20 CFU/cm^2.

c) The total number of colonies on the hands of workers who are in direct contact with unpackaged products shall be less than or equal to 300 CFU/hand (glove).

5.3 The initial contaminating bacteria of disinfection-grade disposable sanitary products shall be less than or equal to 10,000 CFU/g or CFU/mL.

5.4 Disinfection methods used for disinfection-grade disposable sanitary products shall be tested for disinfection effectiveness and shall comply with the following requirements:

a) Ethylene oxide disinfection: the killing log value of Bacillus subtilis black variant (ATCC 9372) spores is greater than or equal to 3.00;

b) Ionizing radiation disinfection: the killing log value of Bacillus pumilus E601 (ATCC 27142) spores is greater than or equal to 3.00;

c) Pressure steam disinfection: the killing log value of Bacillus stearothermophilus

the requirements of Appendix A.

7.1.2 The test method for initial contaminating bacteria shall comply with the requirements of Appendix B.

7.1.3 The test and evaluation method for the disinfection effect shall comply with the requirements of Appendix C.

7.2 Test Methods for Product Hygienic Requirements

7.2.1 The appearance of the product is determined through the methods of visual inspection and sniffing.

7.2.2 The pH of absorbent products, such as: sanitary napkins and sanitary pads, etc. shall be determined in accordance with the method of GB/T 8939. If there are corresponding determination standards on the pH of other products, conduct the determination in accordance with the methods in the corresponding standards. If there is no corresponding determination standard, conduct the determination in accordance with the method of WS/T 10009.

7.2.3 Migratory fluorescent whitening agent: sanitary napkins (pads) shall be determined in accordance with the method of GB/T 8939; diapers shall respectively be determined in accordance with the methods of GB/T 28004.1 and GB/T 28004.2; other sanitary products shall be determined in accordance with the method of GB/T 27741.

7.2.4 The test of lead, arsenic and mercury shall be carried out in accordance with the methods of *Safety Technical Specifications for Cosmetics*.

7.2.5 The test method for ethylene oxide residue in products shall comply with the requirements of Appendix D.

7.2.6 The test methods for bactericidal performance, bacteriostatic performance and stability of the products shall comply with the requirements of Appendix E.

7.2.7 Chlorhexidine gluconate and chlorhexidine acetate shall be determined in accordance with the methods specified in GB/T 26367 and relevant national standards; 2,4,4’-trichloro-2’-hydroxydiphenyl ether shall be determined in accordance with the methods specified in GB/T 27947 and relevant national standards; benzalkonium bromide and benzalkonium chloride shall be determined in accordance with the methods specified in GB/T 26369 and relevant national standards; the contents of other active ingredients shall be determined in accordance with the methods specified in WS/T 10009 and relevant national standards; those that cannot be determined using chemical determination methods will not be determined here.

7.2.8 The toxicological test methods for the products shall comply with the requirements of Appendix F.

7.2.9 The microbiological test methods for the products shall comply with the requirements of Appendix B.

Appendix A

(normative)

Test Methods for Production Environment Hygienic Requirements

A.1 Air Sampling and Test Methods

A.1.1 Sample collection

If the indoor area is less than or equal to 30 m^2, set up three points on the diagonal: inside, middle and outside; the inside and outside points are 1.0 m away from the wall. If the indoor area is greater than 30 m^2, set up five sampling points in the east, west, south, north and middle, and the surrounding four sampling points are 1.0 m away from the wall. The production enterprise may also increase the quantity and placement locations of culture media in accordance with the actual layout of the production lines.

Air sampler method: choose from a six-stage impactor air sampler or other proven air samplers. When sampling, place the sampler at a height of 0.8 m ~ 1.5 m in the center of the room, operate in accordance with the sampler instruction manual, and each sampling time shall not exceed 30 minutes.

Plate exposure method: when sampling, place a plate (with a diameter of 9 cm) containing nutrient agar culture medium at the sampling point (with a height of 0.8 m ~ 1.5 m), aseptically open the plate cover, place it upside down on the edge of the plate, expose the plate to the air for 5 minutes, then, cover the plate and send it for testing in time.

The air sampler method is preferred for air sampling.

A.1.2 Test of total number of bacterial colonies

Before sampling, place the prepared nutrient agar culture medium at 36 °C ± 1 °C and incubate it for 18 ~ 24 hours. Take it out and check whether there is any contamination and remove the contaminated culture medium.

Within 4 hours, send the collected petri plates to the laboratory, at 36 °C ± 1 °C, incubate them for 48 hours, observe the results, and count the number of colonies on the plates.

The plate exposure method shall be reported as the average number of colonies per plate: CFU/(plate • 5 min).

For the air sampler method, the total number of colonies shall be calculated using Formula (A.1):

$$Y = \frac{\Sigma n}{v \times t} \times 1\,000 \qquad \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots \text{(A.1)}$$

Where,

Y---the total number of bacterial colonies in the air, expressed in (CFU/m^3);

n---the number of colonies on each plate, expressed in (CFU);

v---the sampling rate, expressed in (L/min);

t---the sampling time, expressed in (min);

1,000---the conversion factor.

A.2 Sampling and Test Methods for Workbench Surface and Worker's Hand Surface

A.2.1 Sample collection

A.2.1.1 Workbench: place a sterilized specification board with an inner diameter of 5.0 cm × 5.0 cm on the surface of the object under test, use a cotton swab soaked in sterile physiological saline (or corresponding neutralizer) to respectively smear it horizontally and vertically for 5 times, then, cut off or break off the part of the cotton swab that comes into contact with hands, and aseptically put the cotton swab into a sampling tube containing 10.0 mL of physiological saline (or corresponding neutralizer) and submit it for testing.

A.2.1.2 Worker's hands (gloves): ask the examinee to put his five fingers together, use a cotton swab soaked in physiological saline (or corresponding neutralizer) on the curved surface of the right finger, rub it back and forth from the root to the tip of the finger twice, then, cut off or break off the part of the cotton swab that comes into contact with hands, and put the cotton swab into a sampling tube containing 10.0 mL of physiological saline (or corresponding neutralizer) and submit it for testing.

A.2.2 Test of total number of bacterial colonies

Within 4 hours, send the collected samples to the laboratory. After thoroughly shaking and mixing (it is advisable to use a vortex oscillator to shake) each sampling tube, take 1.0 mL of the sample solution, put into sterilized plates, pour in the nutrient agar culture medium, inoculate each sample into two plates in parallel, culture them at 36 °C ± 1 °C for 48 hours, and count the number of colonies on the plates.

The total number of colonies on the workbench surface shall be calculated using Formula (A.2):

$$Y_1 = \frac{Y_0}{S} \times 10 \qquad \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots \text{(A.2)}$$

Where,

Y_1---the total number of colonies on the workbench surface, expressed in (CFU/cm^2);

Y_0---the average number of colonies on the plates, expressed in (CFU);

Appendix B

(normative)

Microbiological Test Method

B.1 Product Collection and Sample Processing

From 3 transport packages of the same batch No., take at least 6 minimum sales packaging samples (if the quantity of samples cannot satisfy the test requirements, then, the sampling quantity shall be increased accordingly), of which, 1/3 samples are used for testing and 2/3 samples are used for retention. The minimum sales package sampled shall not be cracked and shall not be opened before the testing.

Under air cleanliness level 5 purification conditions, aseptically open at least 2 packages for testing; conduct sampling from each package, and accurately weigh-take 10.0 g ± 1.0 g of sample. Cut it into pieces and add to 200 mL of sterile physiological saline, thoroughly mix it to obtain a physiological saline sample solution (if the product is too light, weigh-take 2.5 g ± 0.2 g of sample and add to 50 mL of sterile physiological saline). For liquid products, draw-take 10.0 mL of the original solution and use it directly as the sample solution.

If the sample under test has bacteriostatic or antibacterial effects, a suitable neutralizer shall be selected for neutralization, and the dilution gradient shall not exceed 1 : 100. If there is no corresponding neutralizer, the membrane filtration method shall be adopted to remove the bacteriostatic or antibacterial components that affect the growth of microorganisms in the sample, then, prepare the sample solution in accordance with the above-mentioned method.

If the sample under test contains a large amount of water-absorbent resin material and thus sufficient sample solution cannot be sucked out, the amount of diluent can be increased by 50 mL each time, until enough sample solution for testing can be sucked out. When calculating the total bacterial colonies and the total fungal colonies, adjust the degree of dilution accordingly.

B.2 Test Methods for Initial Contaminating Bacteria and Total Number of Bacterial Colonies

B.2.1 Operation steps

After the physiological saline or neutralizer sample solution obtained in accordance with B.1 naturally settles, take the supernatant, and if necessary, perform a 10-fold serial dilution. Select the appropriate degree of dilution for colony counting. Inoculate a total of 2 plates, add 2.0 mL of the sample solution to each plate, then, pour 15 mL ~ 20 mL of melted nutrient agar medium that has cooled to about 40 °C ~ 45 °C into each plate and evenly mix them. After the agar solidifies, turn the plate over and incubate at 36 °C ± 1 °C for 48 hours, and count the number of colonies on the plates.

B.2.2 Colony counting

Plates with flake-like growth of bacterial colonies should not be used. Make sure that the two

with no or slightly metallic luster, or pink colonies with a darker center.

B.3.1.3 Staining microscopic examination and identification: take 1 ~ 2 suspected colonies for Gram staining microscopic examination, meanwhile, inoculate lactose fermentation tube, incubate at 36 °C ± 1 °C for 18 ~ 24 hours, and observe the acid and gas generation.

B.3.2 Result reporting

If the lactose bile salt fermentation tube generates acid and gas, the lactose fermentation tube generates acid and gas, and there are typical coliform colonies on the eosin methylene blue plate, then, the Gram stain is negative and contains no bacilli, and it can be reported that coliform bacteria are detected in the sample under test.

B.4 Test Method for Pseudomonas Aeruginosa

B.4.1 Operation steps

B.4.1.1 Enrichment culture: take 5.0 mL of the sample solution, add it to 50 mL of SCDLP (Soya Casein Digest Lecithin Polysorbate) culture medium, thoroughly mix it, and incubate at 36 °C ± 1 °C for 18 ~ 24 hours. If Pseudomonas aeruginosa grows, a thin bacterial film will appear on the surface of the culture solution, and the culture solution will often appear yellow-green or blue-green.

B.4.1.2 Isolated culture: pick the culture from the thin bacterial film of the culture solution, streak and inoculate Cetyltrimethyl ammonium bromide agar plate, incubate at 36 °C ± 1 °C for 18 ~ 24 hours, and observe the colony characteristics. Pseudomonas aeruginosa grows well on this culture medium; the colonies are flat and amorphous, diffusing to the periphery, or spreading; the surface is moist, the colonies are gray-white, and water-soluble pigments are often diffused in the culture medium around the colonies. In the absence of Cetyltrimethyl ammonium bromide agar, acetamide culture medium can also be used for isolation. Streak and inoculate the bacteria suspension on a flat plate, incubate at 36 °C ± 1 °C for 18 ~ 24 hours, and observe the colony characteristics. Pseudomonas aeruginosa grows well on this culture medium; the colonies are flat with uneven edges, and the medium around the colonies is slightly pink.

B.4.1.3 Staining microscopic examination: take a smear of suspicious colonies on the identification medium for Gram staining. If the microscopic examination shows Gram-negative bacteria, the following tests are also required.

B.4.1.4 Oxidase test: take a small piece of clean white filter paper and place it in a sterilized plate, use a sterile glass rod to pick out the suspicious colonies on the identification medium and apply it on the filter paper. Then, add a drop of newly prepared 1% dimethyl-p-phenylenediamine test solution on it. Within 30 seconds, if pink or purple appears, the oxidase test is positive; if the color does not change, it is negative. Commercial oxidase test strips or reagents may also be used for testing.

B.4.1.5 Pyocyanin test: take 2 ~ 3 suspicious colonies on the identification medium, respectively inoculate them on the slant of the medium for pyocyanin determination and

incubate at 36 °C ± 1 °C for 24 hours. Add 3 mL ~ 5 mL of chloroform, thoroughly oscillate it to dissolve the possible pyocyanin in the culture. When the chloroform turns blue, use a pipette to move it to another test tube and add 1 mL of 1.0 mol/L hydrochloric acid; shake and let it stand for a while. If the upper layer appears pink or purple, it is positive, indicating the presence of pyocyanin.

B.4.1.6 Nitrate reduction gas generation test: inoculate the suspicious colonies on the identification medium into the nitrate saline peptone water medium and incubate at 36 °C ± 1 °C for 24 hours. If there is air in the small, inverted tube of the culture medium, it is considered positive.

B.4.1.7 Gelatin liquefaction test: take the pure culture of the suspicious colonies on the identification medium, puncture and inoculate it into the gelatin medium, incubate at 36 °C ± 1 °C for 24 hours, take it out and place it at 4 °C ~ 10 °C. If it is still liquid, it is positive, and if it is solidified, it is negative.

B.4.1.8 42 °C growth test: take the suspicious culture on the identification medium, inoculate it on a common agar slant medium, and incubate at 42 °C for 24 ~ 48 hours. If Pseudomonas aeruginosa grows, it is positive.

B.4.1.9 Other tests: if biochemical identification reagents or biochemical identification cards are used, suspicious colonies shall be identified in accordance with the instructions of the commercial reagents.

B.4.2 Result reporting

After enrichment and isolated culture, if the sample under test is confirmed to be Gram-negative bacilli, and the oxidase and pyocyanin tests are both positive, it can be reported that Pseudomonas aeruginosa is detected in the sample under test. If the pyocyanin test is negative, but the liquefied gelatin, nitrate reduction gas generation and 42 °C growth tests are all positive, it can still be reported that Pseudomonas aeruginosa is detected in the sample under test.

B.5 Test Method for Staphylococcus Aureus

B.5.1 Operation steps

B.5.1.1 Enrichment culture: take 5.0 mL of the sample solution, add it to 50 mL of SCDLP culture solution, thoroughly mix it, and incubate it at 36 °C ± 1 °C for 18 ~ 24 hours.

B.5.1.2 Isolated culture: take 1 ~ 2 inoculation loops from the above-mentioned enrichment suspension, streak and inoculate Baird Parker medium (preferred) or blood agar medium and incubate it at 36 °C ± 1 °C for 24 ~ 48 hours. On Baird Parker medium, they are round, smooth, convex, moist, with a diameter of 2.0 mm ~ 3.0 mm, gray to black in color, surrounded by a turbid zone, and a transparent zone on the outer layer. When touched with an inoculation needle, the colonies appear to have the softness of buttery gum. Occasionally, similar non-lipolytic colonies will be encountered, but there are no turbid and transparent zones. Typical colonies on blood agar plates are golden yellow, large and protruding, round, opaque, with a smooth surface

B.6.1.4 Streptokinase test: draw-take 0.2 mL of potassium oxalate plasma (0.01 g of potassium oxalate plus 5.0 mL of rabbit plasma, mix it well, precipitate by centrifugation, and take the supernatant), add 0.8 mL of sterilized physiological saline, mix it well, then, add 0.5 mL of 24-h broth culture of the bacteria to be tested and 0.25 mL of 0.25% calcium chloride, mix it well, place it in a 36 °C ± 1 °C water bath, and observe once every 2 minutes (generally, it can coagulate within 10 minutes). After the plasma has coagulated, continue to observe and record the melting time. If it does not melt within 2 hours, continue to leave it for 24 hours for observation. If the clot is completely melted, it is positive, and if it still does not melt within 24 hours, it is negative (in accordance with the instructions of the commercial reagents).

B.6.1.5 Bacitracin sensitivity test: smear the suspension of the tested bacteria to a blood agar plate, use sterilized tweezers to take each piece of paper containing 0.04 unit of bacitracin and place it on the surface of the plate. Meanwhile, use known positive strains as the control and place them at 36 °C ± 1 °C for 24 ~ 48 hours, those with bacteriostatic zones are considered positive.

B.6.1.6 Other tests: if biochemical identification reagents or biochemical identification cards are used, suspicious colonies shall be identified in accordance with the instructions of the commercial reagents.

B.6.2 Result reporting

Conduct microscopic examination of Gram-positive chain-like arranged cocci, if hemolytic rings appear on the blood agar plate, and the streptokinase and bacitracin tests are positive, it can be reported that hemolytic streptococci are detected in the sample under test.

B.7 Test Method for Total Number of Fungal Colonies

B.7.1 Operation steps

After the physiological saline or neutralizer sample solution obtained in accordance with B.1 naturally settles, take the supernatant, and if necessary, perform a 10-fold serial dilution. Select the appropriate degree of dilution for fungal colony counting. Inoculate a total of 2 plates, add 2.0 mL of the sample solution to each plate, then, pour 15 mL ~ 20 mL of melted Sandcastle weak agar medium or modified Sandcastle weak agar medium cooled to 40 °C ~ 45 °C into each plate and evenly mix them. After the agar has solidified, turn the plates over and incubate them at 25 °C ± 1 °C (for Sandcastle weak agar medium) or 28 °C ± 1 °C (modified Sandcastle weak agar medium) for 72 hours. Respectively observe at 24 hours, 48 hours and 72 hours, and count the number of colonies on the plate. If colonies are found to spread, the previous colony count shall prevail.

B.7.2 Colony counting

Plates with flake-like growth of bacterial colonies should not be used. Make sure that the two plates comply with the counting requirements and perform bacterial colony counting. In accordance with Formula (B.2), calculate the results:

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