STATE SANITARY AND EPIDEMIOLOGICAL SERVICE OF UKRAINE

MANUAL
Use of Biomoj for Pre-sterilisation Cleansing of Medical Devices

Kyiv – 2013

Developed by Central Sanitary and Epidemiological Station at the Ministry of Health of Ukraine, a state institution, with participation of SPC Farmacos Limited Liability Company (Ukraine).

This Manual is intended for healthcare institutions and other organisations using pre-sterilisation cleansing of medical devices.

Healthcare organisations and institutions may reproduce this Manual in such quantity as may be necessary.

Manual on Use of Biomoj for Pre-sterilisation Cleansing of Medical Devices dd. February 05, 2009 shall be deemed invalid.

APPROVED
By Chief Sanitary Officer of Ukraine
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MANUAL
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1. GENERAL PROVISIONS

1.1 Product name: Biomoj as per Technical Specifications TU U 22902465.005-96 as amended.

1.2 Manufacturer: SPC Farmacos LLC (Ukraine).

1.3 Composition, contents of active ingredients and excipients, % wt: sodium alkyl benzene sulfonate (sulfonol) 5.0 to 8.0; alkaline protease 1.0 to 1.1 (active ingredients); sodium carbonate; dispersant; filler.

1.4 Pharmaceutical form, physical and chemical properties: White to light yellow loose powder. May contain lumps crushable when pressed and stained enzyme inclusions. Has characteristic odour of the raw materials used. Concentration of hydrogen ions (pH) in 1% solution (by mass fraction) is 9.0 to 11.5. Readily soluble in water. Aqueous solutions of Biomoj are transparent, colourless, and non-corrodible for medical items made of metal, glass, polymer, rubber and composite materials. The product is incompatible with cationic surfactants.

1.5 Intended use: Pre-sterilisation cleansing of medical devices made of metal, glass, rubber and polymer materials (including rigid and flexible endoscopes, medical tools for flexible endoscopes, dental and surgical instruments). Cleansing of surfaces in rooms, floor, patient care items, interior items and the like.

Washing of facilities at educational institutions, communal and household facilities, facilities at companies operating in perfume and cosmetic product manufacturing, microbiology, food processing and pharmaceutical industries, restaurants and trading facilities, facilities at hairdressing and beauty salons, pharmacies, temporary accommodations, and transport facilities.

1.6 Specific properties of the product: Biomoj has wetting, washing, emulsifying properties, removes protein or fat contamination, traces of blood, medicines and disinfectants from external surfaces and surfaces of internal channels of medical devices, is easily removed from items after use and leaves no stain.

1.7 Product toxicity and safety: Biomoj belongs to moderately hazardous substances in case of ingestion (hazard category 3 substance per GOST 12.1.007) and to low-hazardous substances in case of contact with the skin (hazard category 4 substance per GOST 12.1.007). Shows no skin-resorptive or irritant action and sensitizing properties. In its native form (powder), the product causes ocular irritation and irritation of the upper respiratory tract. When used in the recommended concentrations, the product does not cause ocular irritation or irritation of the upper respiratory tract. The product has no mutagenic, carcinogenic or embryotoxic action (based on the active ingredient). Since the product is free from any volatile component, there is no risk that product components may get into the air of the working area when Biomoj is used for manual or mechanised pre-sterilisation cleansing of medical devices.

2. PREPARATION OF WORKING SOLUTIONS

2.1 Methods and conditions for preparation of working solutions: Prepare Biomoj working solutions in a labelled container made of any material by dissolving the product in water. To prepare working solutions, use drinking water in accordance with State Sanitary Standard & Regulation 2.2.4-171.

2.2 Calculations for preparation of working solutions: To prepare Biomoj working solution in the concentration required (based on the product), follow calculations presented in Table 1 below.

Table 1: Calculations for preparation of Biomoj working solutions

Concentration, % (based on the product)	1 dm^3 of solution (1 L)		10 dm^3 of solution (10 L)	
	Biomoj, g	Volume of water, cm^3	Biomoj, g	Volume of water, cm^3
0.15	1.5	998.5	15.0	9985.0
0.3	3.0	997.0	30.0	9970.0
0.5	5.0	995.0	50.0	9950.0

2.3 Shelf life and storage conditions for the working solution: Use Biomoj working solution for 24 h after preparation provided the colour has not been changed. Any unused working solution may be stored for 14 days in a container tightly closed with a lid. Biomoj working solutions with shelf life longer than 14 days are suitable for cleansing surfaces in rooms, floor, patient care items, interior and other items.

3. METHODS OF USE

3.1 Where to use: Medical devices made of metal, glass, rubber, polymer and composite materials, including rigid and flexible endoscopes, medical instruments for flexible endoscopes, dental and surgical instruments (pre-sterilisation cleansing) and surfaces in rooms, floor, patient care items sick and interior items (washing)

3.2 Methods of pre-sterilisation cleansing of some items with the product working solution

3.2.1 Use Biomoj working solution for pre-sterilisation cleansing of medical devices made of metal, glass, rubber, polymer and composite materials after disinfection. Use manual or mechanised pre-sterilisation cleansing of medical devices. Clean detachable items disassembled.

3.2.2 For manual pre-sterilisation cleansing of medical devices with Biomoj working solution, follow the steps below:

Rinse devices with running water for (0.5±0.1) min.

Soak devices in 0.5% Biomoj solution at (40±5) °C for (15.0± 1.0) min. Do not maintain the temperature of Biomoj solution during soaking and washing of medical devices.

Wash each item in Biomoj working solution using a bottle brush, brush or cotton-gauze swab for (0.5±0.1) min.

Rinse medical devices with running water for 3 min.

Rinse medical devices with distilled water for (0.5±0.1) min.

Dry medical devices with hot air at (85±5) °C until moisture is completely removed.

3.2.3 Perform mechanised cleansing of medical devices with Biomoj working solutions by jet, rotary, or brushing (except for rubber items) method or combine with ultrasound cleansing method.

For mechanised cleansing of specific medical devices with Biomoj working solution, follow requirements of manuals for your equipment.

3.2.4 For mechanised pre-sterilisation cleansing of medical devices with Biomoj working solution, follow the steps below:

Rinse devices with running water for (0.5±0.1) min.

Mechanically clean using Biomoj working solution (by rotary method with 0.15% Biomoj solution; by jet and brushing method or in combination with ultrasound cleansing with 0.3% Biomoj solution).

Rinse devices with running water for (0.5±0.1) min.

Rinse with running water for 3 min.

Rinse with distilled water for (0.5±0.1) min.

Dry with hot air at (85±5) °C until moisture is completely removed.

3.2.5 For pre-sterilisation cleansing of flexible and rigid endoscopes, use Biomoj working solution in regimens described in Tables 2 and 3.

3.2.5.1 Rigid endoscopes should be subject to pre-sterilisation cleansing unassembled. After soaking in Biomoj working solution, wash every part separately and clean thoroughly any hard-to-reach parts (such as internal channels, side valves, etc.)

Once rigid endoscopes are washed with distilled water, put them onto a clean sheet to remove moisture from outer surfaces. Remove moisture from internal channels with a continuous-action syringe or an electric suction machine.

3.2.5.2 Once flexible endoscopes are soaked in Biomoj working solution, start cleansing with an instrumental channel: inject the working solution into the channel using an electric suction machine or a continuous-action syringe, wash a channel with a brush to cleanse an instrumental channel. After washing, remove water from flexible endoscope channels using an electric suction machine or a continuous-action syringe. Then air-dry channels and wipe the outer surface with a clean woven cloth.

3.2.5.3 For pre-sterilisation cleansing of medical instruments for flexible endoscopes, follow regimens described in Table 4.

3.2.5.4 Immerse instruments with open internal channels fully in Biomoj working solution and fill in channels with the working solution using a continuous-action syringe or a water-jet pump through a nozzle attached to the distal end of the instrument. Remove the nozzle for the soaking period. After soaking, wash the outer surface of instruments with the working solution using a brush or a bottle brush; then reattach the nozzle and wash a channel with Biomoj working solution using a continuous-action syringe or a water-jet pump.

Soak instruments without open channels in Biomoj working solution and clean using a brush or a bottle brush.

3.2.5.5 For combined cleansing with ultrasound facilities, immerse instruments fully in Biomoj working solution. Fill in internal channels with Biomoj working solution using a continuous-action syringe or a water-jet pump before immersion.

3.2.5.6 Rinse instruments with running drinking water and distilled water when they are fully immersed into water. Rinse instrument channels using a continuous-action syringe or a water-jet pump.

3.2.5.7 When rinsed with distilled water, place instruments onto clean sheet to remove moisture from outer surfaces. Use vacuum (water-jet pump) to remove moisture from open internal channels of instruments through a nozzle attached to a distal end of the instrument.

3.2.5.8 Sterilise flexible and rigid endoscopes and medical instruments thereto after pre-sterilisation cleansing.

3.3 To clean surfaces in rooms, floor, patient care items and interior items, use 0.15 to 0.5% Biomoj solutions. After washing with Biomoj working solution, rinse patients care items and interior items with running drinking water for (0.5±0.1) min.

4. PRODUCT WARNINGS AND PRECAUTIONS

4.1 Necessary personal equipment for protection of skin, respiratory system and eyes when the product is used: special clothing (a coat, a hat, and a rubberised apron) as required by DSTU 7239, rubber gloves to protect against chemicals and micro-organisms as required by DSTU EN 374-1 or GOST 20010, goggles type ПО-2 or single screen as required by DSTU EN 166.

4.2 General warnings and precautions when the product is used:

To ensure labour safety, prevent poisoning and occupational diseases, adhere to the following health and safety rules whenever the product is used:

Before pre-sterilisation cleansing, disinfect medical devices (except for new medical devices that have never been used before).

Persons under the age of 18 years, pregnant or breast-feeding women or those with hypersensitivity to the product or any of its components may not use the product for pre-sterilisation cleansing of medical devices.

Persons with skin lesions such as scratches, wounds and irritation on open parts of the body which may be exposed to the product or its working solutions may not handle the product for a while.

Do not wear special clothing unless the product is handled.

Before you begin to handle the product, check the special clothing and personal protective equipment for usability. Do not use defective personal protective equipment for pre-sterilisation cleansing of medical devices.

Do not leave the product and its working solutions unattended. Hand over any product and its working solutions remained unused at the end of a working day to a person responsible for storing products intended for pre-sterilisation cleansing of medical devices.

Do not eat or smoke during pre-sterilisation cleansing of medical devices. Once the operations are over, wash your face and hands with soap and water.

4.3 Warnings and precautions for preparation of working solutions: Any staff preparing Biomoj working solutions should be provided with personal equipment to protect skin, upper respiratory tract and eyes: special clothing (such as a coat, a hat, and a rubberised apron) as required by DSTU 7239, rubber gloves as required by DSTU EN 374-1 or GOST 20010, goggles type РО-2 or single screen as required by DSTU EN 166, and a particulate respirator ШБ-1 “Pelustok” as required by GOST 12.4.028.

4.4 Warnings and precautions when the product is used for cleansing of certain items:

Soak medical devices in 0.15 to 0.5% Biomoj working solution in a container closed with a lid. Since the product is free from any volatile component, there is no risk that product components may get into breathing air for medical staff or patients at healthcare institutions when Biomoj working solution is used for pre-sterilisation cleansing of medical devices by soaking in a container closed with a lid.

During pre-sterilisation cleansing of medical devices, medical staff should be provided with personal protective equipment: special clothing (such as a coat, a hat, and a rubberised apron) as required by DSTU 7239, rubber gloves as required by DSTU EN 374-1 or GOST 20010, and goggles type ПО-2 or single screen as required by DSTU EN 166.

4.5 Product disposal: Dilute spent working solutions 1:2 (product to water) and discard into the sewerage system.

Return batches of Biomoj which are expired or found defective due to violation of storage conditions to the manufacturer for further processing.

5. SIGNS OF ACUTE POISONING AND FIRST AID FOR POISONING

5.1 Signs of acute poisoning: Signs of ocular irritation include lacrimation, conjunctival oedema and hyperaemia. Accidental inhalation of the native product (powder) may cause irritation of mucous membrane of the upper respiratory tract such as throat tickle and cough.

5.2 First aid for acute (respiratory) poisoning: In the event of inhalation, make sure a suffered has access to fresh air or is in a well-ventilated room, keep the suffered at rest and warm, and loosen tight clothing. Rinse oral and nasal cavities with drinking water. Warm milk is recommended.

5.3 First aid for contact with eyes: Rinse eyes with running water for 10 to 15 min. After rinsing, seek medical advice. In case of ocular and cornea irritation, drop 30% sulfacyl sodium solution into eyes.

5.4 First aid for contact with skin: Rinse the exposed skin with running water. In case of contact with working clothing, take off the clothing and rinse the exposed skin under the clothing with running cold water.

5.5 First aid for ingestion: Drink several glasses of drinking water at room temperature and induce vomiting. Warm milk is recommended.

5.6 Specific antidotes (if any): No specific antidote is recommended.

6. PACKAGING, TRANSPORTATION AND STORAGE

6.1 Product packaging: Biomoj (net weight: 5 kg to 20 kg) is packed in three-layer paper bags ПМ or ВМ with polyethylene inserts, convolute drums БКН-1-10-50 with polyethylene inserts, and plywood drums with polyethylene inserts. The product (net weight: 0.25 to 2.0 kg) is packed in polymer packaging; net weight of 0.01 to 0.25 kg is packaged in packs made of composite materials, in food-grade PE laminated paper bags. The product may also be packaged in food-grade PE laminated paper sachets or sachets made of composite materials (such as foil-polyethylene or paper-foil-polyethylene) and sachets made of packaging materials with illustrations and text information imprinted on film, foil or composite material.

6.2 Product transportation conditions: Biomoj may be transported by any covered vehicle provided the applicable cargo transportation rules are met. When transported by rail, covered cars should be used with single wagon load or the product may be transported by smaller shipments in cargo containers.

6.3 Shelf life and storage conditions: Store in the original packing in covered, dry, well-ventilated area with restricted access at 5°C to 30°C at least 1 m from heating devices. Avoid direct sunlight.

Guaranteed shelf life is 2 years upon the date of manufacture.

7. PRODUCT QUALITY CONTROLS

7.1 List of parameters to be defined:

7.1.1 Water content by mass fraction.

7.1.2 Concentration of hydrogen ions (pH) in 1% solution (by mass fraction).

7.1.3 Surfactant (active ingredient) content (by mass fraction).

7.2 Methods of determination

7.2.1 Determination of concentration of hydrogen ions (pH) in 1% solution (by mass fraction)

Define concentration of hydrogen ions (pH) in 1% solution (by mass fraction) in accordance with DSTU 2207.1 (GOST 22567.5).

7.2.2 Determination of surfactant (sodium alkyl benzene sulfonate) content (by mass fraction)

7.2.2.1 Measurement tools, reagents and solutions

General-purpose laboratory balance, accuracy grade 2 as required by GOST 24104 with the highest weight limit of 200 g.

Set of weights as required by DSTU OIML R 111-1.

A set of standard weights ГО-11-1110 No. 37 second-order, class F1.

Mechanical stopwatch as required by applicable regulations.

Glass thermometer as required by GOST 28498 with measurement interval from 0 to 100 °C and 0.5 °C unit value.

Closed-type electric heater as required by GOST 14919.

Laboratory autotransformer ЛАТР-1 or ЛАТР-2 as required by applicable regulations.

Water bath.

Laboratory metal stand.

Device to determine mass fraction of substances dissolved in petroleum ether or n-hexane as required by GOST 22567.6.

Muffle furnace as required by applicable regulations.

Mortar 4 as required by GOST 9147.

Desiccator 2-250 as required by GOST 25336.

Refrigerator ХПТ-1-200/14/23 ХС, ХШ1-300-29/32 ХС as required by GOST 25336.

Nozzle Н1-29/32-14/23 ТС as required by GOST 25336.

Extension АКП-14/23-29/32 ТС as required by GOST 25336.

Flasks Кн-2-100-34 ТХС, Кн-2-250-34 ТХС, Кн-1-250-29/32 ТХС as required by GOST 25336.

Flasks 1-200(1000) -2 as required by GOST 1770.

Burettes 2-2-10-0.05, 2-2-25-0.05 as required by GOST 29251.

Glass В-56-80 ХС as required by GOST 25336.

Funnels ВД-1-250 ХС or ВД-3-250 ХС as required by GOST 25336.

Evaporation cup 3 as required by GOST 9147.

Cylinders 2-25 (100) (250) as required by GOST 1770.

Pipettes 1-2-2 (5) (25) (50) as required by GOST 29169.

Ethyl alcohol as required by GOST 18300.

Sodium hydroxide as required by GOST 4328, alcoholic solution, c (NaOH) = 0.1 mole/dm³.

Potassium hydroxide as required by GOST 24363 (C.P.), alcoholic solution, c (KOH) = 0.1 mole/dm³.

Phenolphthalein as required by applicable regulations, 1% phenolphthalein alcoholic solution (by mass fraction).

Petroleum ether as required by applicable regulations (P) or n-hexane as required by applicable regulations (P).

Sodium sulphate as required by GOST 4166 (C.P.), freshly calcined at 400-450 °C. Silver nitrate as required by GOST 1277 (C.P.), concentration of solution c($AgNO_3$) = 0.1 mole/dm³ or fixanal.

Ammonium rhodanate as required by GOST 27067(C.P.), concentration of solution c (NH_4SCN) = 0.1 mole / dm³ or fixanal.

Nitric acid as required by GOST 4461(C.P.) and concentrated aqueous solution of 1: 1.

Iron alum as required by GOST 4205 (C.P.).

Chloroform as required by GOST 20015.

Sodium chloride as required by GOST 4233 (C.P.) calcined to constant weight at 500 to 600 °C and solution c(NaCl) = 0.1 mole / dm³ or fixanal.

Potassium chromate as required by GOST 4459(C.P.), aqueous solution containing 5% of potassium chromate (by mass fraction).

Filter paper as required by GOST 12026 or ashless filter paper (“white ribbon”, “red ribbon”).

Asbestos cardboard as required by applicable regulations.

Distilled water as required by GOST 6709.

Other equipment, laboratory ware and reagents with similar properties and metrological characteristics may also be used.

7.2.2.2 Preparation to testing

7.2.2.2.1 Preparation of weights to define mass fraction of substances insoluble in alcohol

Ground a sample of Biomoj taken for testing in a mortar. Weigh (2.0 ± 0.5) g of grounded Biomoj into a 250 cm^3 conical flask, add 8 cm^3 of water heated to boil and allow to dissolve.

7.2.2.2.2 Preparation of iron alum solution

Weigh (50.0±0.1) g of grounded iron alum. Dissolve the weighed quantity in 100 cm^3 of water heated to boil. Allow to cool. Iron alum crystallises in part. Remove precipitated crystals of iron alum by filtering. To reduce hydrolysis, add 5 cm^3 of concentrated nitric acid using a cylinder.

7.2.2.2.3 Preparation of potassium chromate solution

Weigh (5.0±0.1) g of potassium chromate. Add 95 cm^3 of water to the weighed sample. Mix the solution thoroughly.

7.2.2.2.4 Preparation of silver nitrate solution, c($AgNO_3$) = 0.1 mole/dm^3

Weigh (16.980±0.003) g of silver nitrate. Dissolve in water and transfer into a 1,000 cm^3 volumetric flask, make up the volume and mix thoroughly. Store silver nitrate solution in dark glassware or in glassware covered with dark paper.

7.2.2.2.5 Preparation of sodium chloride, c(NaCl) = 0.1 mole/dm^3

Weigh (5.8443±0.0005) g of sodium chloride. Dissolve in water and transfer into a 1,000 cm^3 volumetric flask, make up the volume and mix thoroughly.

7.2.2.2.6 Preparation of ammonium rhodanate solution, c(NH_4SCN) = 0.1 mole/dm^3

Weigh (7.612±0.003) g of ammonium rhodanate. Dissolve in water and transfer into a 1,000 cm^3 volumetric flask, make up the volume and mix thoroughly.

7.2.2.2.7 Determination of the correcting factor for silver nitrate solution, c($AgNO_3$) = 0.1 mole/dm^3 based on sodium chloride as required by GOST 25794.3.

7.2.2.2.8 Determination of the correcting factor for ammonium rhodanate solution, c(NH_4SCN) = 0.1 mole/dm^3 based on silver nitrate as required by GOST 25794.3.

7.2.2.3 Testing procedure

7.2.2.3.1 Determination of mass fraction of substances soluble in ethyl alcohol

While mixing vigorously, add 130 cm^3 of 96% ethyl alcohol to a 250 cm^3 conical flask with weighed sample of Biomoj by small portions using a cylinder and ground the precipitate thoroughly with a sticker.

Attach a flask to a back flow condenser and boil on water bath for 30 min. Decant alcoholic solution into a 200 cm^3 volumetric flask using a filter to avoid precipitate on a filter. Allow to decant for at least 5 minutes.

Repeat the extraction procedure using 20 cm^3 of 96% ethyl alcohol and heat the contents of a flask for 5 to 10 min. Filter the solution with precipitate into the same volumetric flask. Rinse precipitate three times in a flask and filter with hot 96% ethyl alcohol by 20 cm^3 portions. Make up with alcohol and mix. Pipette 50 cm^3 of the resulting alcoholic extract into a porcelain cup brought to constant weight and vapour alcohol completely on an electric heater covered with asbestos cardboard at (90±5) ºC or on a boiling water bath.

Dry residue left in a cup in a baker at 100-105 ºC.

Test weight 30 min after drying for the first time, then 15 min thereafter. Stop drying when mass changes do not exceed 0.002 g between two successive measurements.

7.2.2.3.2 Determination of mass fraction of sodium chloride

Pipette 20 cm³ of ethyl extract produced as per Section 7.2.2.3.1 into a conical flask; add 25 to 30 cm³ of water and 5 cm³ of nitric acid solution (1:1). Add 5 cm³ of silver nitrate solution from a drop-meter; add 2 cm^3 of iron alum solution and 3 cm^3 of chloroform. Titrate excess of silver nitrate with ammonium rhodanate solution until brown-pink staining (does not disappear in 30 sec).

7.2.2.3.3 Determination of mass fraction of substances soluble in petroleum ether or n-hexane

Weigh (30.0±10) g of Biomoj. Transfer the weighed sample into a 250 cm^3 flask, dissolve in 48 cm^3 water, and, while mixing vigorously, add 52 cm^3 of 96% ethyl alcohol by small portions. Heat the solution on water bath to 30 to 35ºC, cool to room temperature and transfer in to a ground-glass stoppered measuring flask. Rinse the flask with 15 cm^3 of 50% ethyl alcohol drained into a cylinder and rinse the flask with a small quantity of petroleum ether. Drain ether into the cylinder too. Add ether into a 50 cm^3 cylinder, closer with a stopper, mix and allow to stay until the ether layer becomes transparent. Open a stopper, rinse with small quantity of ether and close the cylinder with a stopper with a siphon tube inserted. Place an end of the siphon tube inside the cylinder 1 to 2 mm above the phase distribution line. Drain ether layer into a separation funnel to form pressure in the cylinder with a rubber bulb. When ether layer is drained, take the stopper with a siphon tube. Make sure residues of liquid drain into the cylinder and separation funnel and place the latter on a ring of the stand.

Repeat the extraction procedure three times more (by 25 cm^3 portions of ether). Rinse ether extracts in a separation funnel with 50% alcohol three times by 20 cm^3 portions and filter using a double paper filter with 4 to 5 g of calcined sodium sulphate in a 250 cm^3 flask brought to constant weight.

Rinse precipitate on a funnel with ether distilled on water bath at (80±5) ºC. Dry precipitate in the flask in a baker at (60±5) ºC. Test weight 1 h after drying for the first time, then 30 min thereafter. Stop drying when mass changes do not exceed 0.002 g between two successive measurements.

7.2.2.4 Interpretation of results

7.2.2.4.1 Calculate mass fraction of surfactant (X) as a percentage using a formula below:

$$X = X_1 - X_2 - X_3, \text{ where} \qquad [2]$$

X_1 – mass fraction of substances soluble in ethyl alcohol, %;

X_2 – mass fraction of sodium chloride, %;

X_3 – mass fraction of substances soluble in petroleum ether or n-hexane, %.

Take the arithmetic mean of the results of two parallel tests as the test result provided the allowable differences between tests do not exceed 0.5%.

Limit of acceptable total error for test results is ± 0.74% at a confidence level of P = 0.95.

Calculate mass fraction of substances soluble in ethyl alcohol (X_1) as a percentage using a formula below:

$$X_1 = \frac{(m_1 - m_2) \cdot 200 \cdot 100}{(m_3 - m_4) \cdot 50}, \qquad [3]$$

where m_1 – mass of a cup with residue after drying until constant mass is defined, g;

m_2 – mass of a cup after drying until constant mass is defined, g;

m_3 – mass of a flask with the weighed quantity of Biomoj, g;

m_4 – mass of a flask, g;

200 – volume of alcoholic extract in a flask, cm³;

50 – volume of alcoholic extract taken to remove alcohol, cm^3.

Take the arithmetic mean of the results of two parallel tests as the test result provided the allowable differences between tests do not exceed 0.5%.

Limit of acceptable total error for test results is ± 0.5% at a confidence level of P = 0.95.

Calculate mass fraction of sodium chloride (X_2) as a percentage using a formula below:

$$X_2 = \frac{(V_1 \cdot K_1 - V_2 \cdot K_2) \cdot 0{,}1 \cdot 58{,}444 \cdot 200 \cdot 100}{20\ (m3-m4) \cdot 1000}, \qquad [\ 4\ ]$$

where V_1 – volume of silver nitrate solution taken for titration, cm^3;
V_2 – volume of aluminium rhodanate solution used to titrate a sample, cm^3;
K_1 – correcting coefficient for silver nitrate solution;
K_2 – correcting coefficient for aluminium rhodanate solution;
58,444 – molecular weight of sodium chloride, g;
m_3 – mass of a flask with the weighed quantity of Biomoj, g;
m_4 – mass of a flask, g;

Take the arithmetic mean of the results of two parallel tests as the test result provided the allowable differences between tests do not exceed 0.1%.

Limit of acceptable total error for test results is ± 0.19% at a confidence level of P = 0.95.

Calculate mass fraction of substances soluble in petroleum ether or n-hexane (X_3) as a percentage using a formula below:

$$X_3 = \frac{(m_5 - m_6) \cdot 100}{m_7 - m_8}, \qquad [\ 5\ ]$$

where m_5 – mass of a flask with residue after drying to constant mass, g;
m_6 – mass of a flask after drying to constant mass, g;
m_7 – mass of a flask with the weighed quantity of Biomoj, g;
m_8 – mass of a flask, g;

Take the arithmetic mean of the results of two parallel tests as the test result provided the allowable differences between tests do not exceed 0.2%.

Limit of acceptable total error for test results is ± 0.18% at a confidence level of P = 0.95.

Table 2: Regimes for pre-sterilisation cleansing of flexible endoscopes (manual cleansing)

Steps of pre-sterilisation cleansing	Concentration, % (based on product)	Exposure time, min	Initial temperature of the working solution, °C	Equipment, auxiliary materials used
Pre-rinse with drinking water: - outer surfaces (combine with cleansing with gauze pad) - internal channel with a brush	-	 1.0±0.5 2.0±1.0		Wash-basin, bowl, (special bath) electric suction machine, syringe
Fill in channels with Biomoj working solution and soak in Biomoj working solution	0.5	15.0±1.0	40.0±5.0	Bowl, syringe
Wash in Biomoj working solution: - an instrumental channel using a brush to cleanse the channel - rinse internal channels one by one using electric suction machine or a continuous-action syringe - wash outer surfaces using gauze pad	0.5	 2.0±1.0 3.0±1.0 1.0±0.5		Bowl, electric suction machine, syringe
Rinse with drinking water	-	3.0±1.0		Bowl, wash-basin, electric suction machine, syringe
Rinse with distilled water	-	1.0±0.5		Bowl, electric suction machine, syringe
Air-dry channels	-	Until moisture is completely removed		Electric suction machine

Table 3: Regimes for pre-sterilisation cleansing of rigid endoscopes (manual cleansing)

Steps of pre-sterilisation cleansing	Concentration, % (based on product)	Exposure time, min	Initial temperature of the working solution, °C	Equipment, auxiliary materials used
1	2	3	4	5
Pre-rinse with drinking water, cleanse with a bottle brush or gauze pad. Rinse channels using a continuous-action syringe.		2.0±1.0 2.0±1.0		Wash-basin, bowl, (special bath), syringe
Soak in Biomoj working solution Fill in internal openings in endoscope parts with Biomoj working solution	0.5	15.0±1.0	40.0±5.0	Bowl, syringe
Wash every part of an endoscope using a bottle brush or gauze swab and rinse channels using a continuous-action syringe.		2.0±1.0		Bowl, tank, syringe
Rinse with drinking water		3.0±1.0		Bowl, wash-basin, syringe
Rinse with distilled water	-	1.0±0.5		Bowl, tank, syringe
Dry	-	Until moisture is completely removed	85 ±5	Clean sheet

Table 4: Regimes for pre-sterilisation cleansing of medical instruments to flexible endoscopes (manual cleansing)

Steps of pre-sterilisation cleansing	Concentration, % (based on product)	Exposure time, min	Initial temperature of the working solution, °C	Equipment, auxiliary materials used
Pre-rinse with running drinking water	-	3.0±1.0		Bowl, tank, (special bath), wash-basin
Immerse into in Biomoj working solution Fill in internal open channels with Biomoj working solution Soak in Biomoj working solution in accordance with exposure time	0.5	15.0±1.0	40.0±5.0	Bowl, tank, (special bath), syringe
Wash every item in Biomoj working solution using - a brush (outer surface) - a syringe (internal channels)	0.5	 2.0±0.5 1.5±0.5		Bowl, tank, (special bath), syringe
Rinse with running drinking water		3.0±1.0		Bowl, tank, special bath, wash-basin, syringe
Rinse with distilled water		1.0±0.5		Bowl, tank, (special bath)
Vacuum dry		Until moisture is completely removed	85 ±5	Water-jet pump