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Microbiological User Requirement Specifications for pre-moistened disposable washcloths for hospitalised patients

Hospitalised patients are often unable to perform conventional personal hygiene, and single use wet wipes are in many cases an attractive alternative for patients as well as healthcare workers. However, many of these patients are also susceptible to infections by opportunistic microorganisms, including waterborne bacteria and fungi.

Regulatory issues

Single use wet wipes for hospitalised patients are intended for cleaning skin and hair, replacing tap water and single use or reusable washcloths. In this User Requirement Specification (URS) the following considerations are taken into account regarding regulatory issues:

- Compliance with the definitions and requirements for cosmetic products in Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.
- Single use washcloths do not usually have a medical application as defined in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR). See Guidance document on the demarcation between the cosmetic products Directive 76/768 and the medicinal products Directive 2001/83 as agreed between the commission services and the competent authorities of Member States. Therefore, compliance with the MDR is not required. However, manufacturers who choose to declare a washcloth as a medical device must in addition show compliance with the requirements specified in this URS that originate from other regulations or directives.
- The European Pharmacopoeia chapter 5.1.4 describes microbiological quality criteria for non-sterile dosage forms (applied to skin), Ph. Eur. 2.6.12 describes methods for microbiological enumeration of non-sterile products, and Ph. Eur. 2.6.13 outlines microbiological tests for specified microorganisms.
- Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption.

The URS incorporates elements from all of these references. Due to the increased susceptibility of many inpatients to infections, some of the requirement regarding

manufacturing and product safety are stricter than for ordinary cosmetic products.

The current URS does not include specifications for wipes containing biocides as defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. However, information is required regarding compatibility of the wipes with some biocidal products.

European standards and other reference documents relevant for this URS are listed in Annex 1.

Microbiological limits and testing

The microbiological limits for washcloths for patients in this URS and relevant test methods are listed below. They are based on:

- EN ISO 17516:2014: Cosmetics – Microbiology - Microbiological limits
- European Pharmacopoeia chapter 5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use.
- Directive (EU) 2020/2184 on the quality of water intended for human consumption.

Microbiological limits and related test methods for washcloths (see also Table 3-9)

Types of organisms	Limit	Test method
Total aerobic mesophilic microorganisms (TAMC)	≤ 100/ml or ≤ 100/g	EN ISO 18415:2017 EN ISO 21149:2017 EN ISO 21322:2020 Ph. Eur. 2.6.12
Total yeast and mould count (TYMC)	≤ 10/ml or ≤ 10/g	EN ISO 18415:2017 EN ISO 16212:2017 EN ISO 21322:2020 Ph. Eur. 2.6.12
Escherichia coli	Absence in 250 ml or 250 g	EN ISO 18415:2017 EN ISO 21150:2015 EN ISO 21322:2020 Ph. Eur. 2.6.13
Pseudomonas aeruginosa	Absence in 250 ml or 250 g	EN ISO 18415:2017 EN ISO 22717:2015 EN ISO 21322:2020 Ph. Eur. 2.6.13
Staphylococcus aureus	Absence in 250 ml or 250 g	EN ISO 18415:2017 EN ISO 22718:2015 EN ISO 21322:2020 Ph. Eur. 2.6.13
Candida albicans	Absence in 250 ml or 250 g	EN ISO 18415:2017 EN ISO 18416:2015 EN ISO 21322:2020 Ph. Eur. 2.6.13

Compatibility with skin antiseptics

The cloths must be compatible with chlorhexidine. Results of tests for compliance shall be presented.

Tolerance to heat

The cloths must tolerate heating to 35 °C – 37 °C for at least 48 hours without deterioration of

the packaging materials or the sealing, the cloth material or the fluid. Any preservatives must retain their efficacy after heating at 37 °C for 48 hours.

Documentation of antimicrobial preservative efficacy

Efficacy of antimicrobial preservatives in the product shall be verified according to either EN ISO 11930:2019 or Ph. Eur. 5.1.3. See Table 7.

Raw materials

Test methods and testing frequency for bioburden and microbiological acceptance criteria shall be specified for all relevant raw materials.

Water supply and water quality

A description of the design and materials used for water supply and water treatment must be presented, including test methods and test frequencies for water quality. Information should be given on the standards applied, see Table 7.

Sanitation of water system

Method(s) for sanitation of the water system must be described. Any chemical disinfectants used for sanitation must be tested according to relevant European standards for chemical disinfectants. See Table 7 and 9. Testing of the disinfectant(s) should be done under both clean and dirty conditions.

Cleaning procedures, housekeeping

A description of cleaning procedures and housekeeping of the premises must be presented. See Table 1 and Table 8.

Disinfectants

Describe disinfectants used for disinfection of surfaces and production machinery including: CAS number, concentration, duration of activity and EN standards used for demonstration of efficacy. Compliance should be tested under both clean and dirty conditions. See Table 9.

Environmental monitoring

Describe the methods used for control of cleanliness in the production area according to relevant standards in the EN ISO 14664 series, EN 14141:2020 or other standards. See Table 8.

Packaging patency

A risk analysis of packaging patency should be presented as well as test methods and test frequency.

Quality control of finished products

Describe the procedure and standards used for selection of finished products for quality control and release procedures.

Quality system

GMP audit, latest date of recertification should be presented.

Declaration of conformity and third party conformity assessment

A third party conformity assessment and/or a declaration of conformity shall be provided when applicable.

Traceability and recall system

A description of product labelling and traceability system shall be provided, including traceability to distributor and end user. A recall preparedness system shall be described.

Annex 1

This annex contains a list of standards mentioned in the URS, categorised in tables according user requirements. The list is not exhaustive and manufactures can choose to use other references, including in-house manufacturing procedures, provided they are precisely described and suitable for third party control. Manufacturers are requested to indicate which standards apply to their product by marking with "X" (where applicable) in the left-hand column of the tables.

Table 1. Quality systems and Good manufacturing practice. Risk assessment.

	EN ISO 22716:2007 *Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices*
	EN ISO 13485:2016+AC *Medical devices- Quality management systems – Requirements for regulatory purposes*
	EN ISO 29621:2017 *Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products*

Table 2. Standards for sampling procedures

	ISO 2589-1:1999/A1:2011 *Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by quality limit (AQL) for lot-by-lot inspection*
	ISO 2589-2:2020 *Sampling procedures for inspection by attributes – Part 2: Sampling schemes indexed by limiting quality (LQ) for isolated lot inspection*
	ISO 2589-4:2020 *Sampling procedures for inspection by attributes – Part 4: Procedures for assessment of declared quality levels*
	ISO 3951-1:2022 *Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*
	ISO 3951-2:2013 *Sampling procedures for inspection by variables – Part 2: General specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection of independent quality characteristics.*
	ISO 3951-3:2007 *Sampling procedures for inspection by variables – Part 3: Double sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.*
	ISO 3951-4:2011 *Sampling procedures for inspection by variables – Part 4: Procedures for assessment of declared quality levels.*
	ISO 3951-5:2006 *Sampling procedures for inspection by variables – Part 5: Sequential sampling plans indexed by acceptance quality limit (AQL) for inspection by variables (known standard deviation)*
	ISO 3951-6 *Sampling procedures for inspection by variables – Part 6: Specification for single sampling plans for isolated lot inspection indexed by limiting quality (LQ)*

Table 3. Standards for cosmetics – microbiology

	EN ISO 16212:2017 *Cosmetics – Microbiology - Enumeration of yeast and mould*
	EN ISO 17516:2014 *Cosmetics – Microbiology - Microbiological limits*
	EN ISO 18415:2017 *Cosmetics – Microbiology - Detection of specified and non-specified microorganisms*
	EN ISO 18416:2015 *Cosmetics – Microbiology - Detection of Candida albicans*
	EN ISO 21148:2017 *Cosmetics - Microbiology – General instructions for microbiological examination*
	EN ISO 21149:2017 *Cosmetics - Microbiology – Enumeration and detection of aerobic mesophilic bacteria*
	EN ISO 21150:2015 *Cosmetics - Microbiology – Detection of Escherichia coli*
	EN ISO 21322:2020 *Cosmetics – Microbiology - Testing of impregnated or coated wipes and masks*
	EN ISO 22717:2015 *Cosmetics - Microbiology – Detection of Pseudomonas aeruginosa*
	EN ISO 22718:2015 *Cosmetics - Microbiology – Detection of Staphylococcus aureus*
	Ph. Eur. 5.13 *Efficacy of antimicrobial preservation*
	Parenteral Drug Association *PDA Technical Report No. 67, (TR 67) Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics*

Table 4. Standards for medical devices – microbiology

	EN ISO 11737-1:2018 *Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products*
	EN ISO 11737-1:2018/A1:2021 *Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products Amendment 1*

Table 5. Microbiological test methods described in European Pharmacopeia

	Ph. Eur. 2.6.12 *Microbiological examination of non-sterile products: Microbial enumeration tests*
	Ph. Eur. 2.6.13 *Microbiological examination of non-sterile products: Tests for specified micro-organisms*

Table 6. Tests for antimicrobial preservation

	EN ISO 11930:2019 *Cosmetics – Microbiology - Evaluation of the antimicrobial protection of a cosmetic product*
	Ph. Eur. 5.1.3 *Efficacy of antimicrobial preservation*

Table 7. Standards for water quality and water sampling

	ISO 19458:2006 *Water quality – Sampling for microbiological analysis*
	EN ISO 5667-1:2023 *Water quality – Sampling - Part 1: Guidance on the design of sampling programmes and sampling techniques.*
	EN ISO 5667-3:2018 *Water quality - Sampling - Part 3: Preservation and handling of water samples*
	EN ISO 5667-5:2006 *Water quality - Sampling - Part 5: Guidance on sampling of drinking water from treatment works and piped distribution systems*
	EN ISO 5667-16:2017 *Water quality - Sampling - Part 16: Guidance on biotesting of samples*

Table 8. Standards for cleanrooms

	EN ISO 14644-1:2015 *Cleanrooms and associated controlled environments- Part 1: Classification of air cleanliness by particle concentration.*
	EN ISO 14644-2:2015 *Cleanrooms and associated controlled environments- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*
	EN ISO 14644-3:2019 *Cleanrooms and associated controlled environments- Part 3: Test methods*
	EN ISO 14644-4:2022 *Cleanrooms and associated controlled environments- Part 4: Design, construction and start-up*
	EN ISO 14644-5:2004 *Cleanrooms and associated controlled environments- Part 5: Operations*
	EN ISO 14644-7:2004 *Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*
	EN ISO 14644-8:2022 *Cleanrooms and associated controlled environments - Part 8: Assessment of air cleanliness by chemical concentration (ACC)*
	EN ISO 14644-9:2022 *Cleanrooms and associated controlled environments - Part 9: Assessment of surface cleanliness for particle concentration*
	EN ISO 14644-10:2022 *Cleanrooms and associated controlled environments - Part 10: Assessment of surface cleanliness for chemical contamination*
	EN ISO 14644-13:2017 *Cleanrooms and associated controlled environments - Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications*
	EN ISO 17141:2020 *Cleanrooms and associated controlled environments – Biocontamination control*

Table 9. Standards for chemical disinfectants

	EN 14885:2022 *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*
	EN 1276:2019 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*
	EN 1650:2019 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*
	EN 13624:2021 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)*
	EN 13727:2012 + A2:2015 *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area — Test method and requirements (phase 2, step 1)*
	EN 13624:2021 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)*
	EN 14347:2005 *Chemical disinfectants and antiseptics — Basic sporicidal activity — Test method and requirements (phase 1)*
	EN 14348:2005 *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants — Test methods and requirements (phase 2, step 1)*
	EN 14476:2013 + A2:2019 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)*
	EN 16615:2015 *Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2)*
	EN 16777:2018 *Chemical disinfectants and antiseptics — Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area — Test method and requirements (phase 2/step 2)*
	EN 17126:2018 *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area — Test method and requirements (phase 2, step 1)*
	EN 17272:2020 *Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities*