



EDANA Guidelines for Testing Feminine Hygiene Products

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1. Introduction

These guidelines were developed by a group of leading manufacturers of feminine hygiene products, their suppliers, and leading test institutes with expertise in testing femcare products. They are designed as a best practice tool for third-parties to consider to ensure scientifically sound testing of femcare products and meaningful results.

Femcare products include those worn externally (pads, liners) and those worn internally (tampons).¹ These products are collectively referred to as femcare products, and are assessed for performance, assurance of safety for consumer use, for comparison, and to support informed purchase decisions by consumers.

Product tests are aimed at assessing key properties such as absorption capacity and comfort. Performance can be tested in a laboratory and/or through user trials. User trials are crucial to evaluate overall product performance, whereas laboratory tests should be used to complement the results of user trials and to evaluate specific product properties.

These guidelines include all steps of a test on femcare products, including sampling, test design, scientific method, analysis, interpretation and publication of results. Statistical methodology and technical parameters impacting test results are taken into consideration for the development of the guidelines. In very specific situations the purpose of the test might warrant some deviations to this guideline. Experts in consumer product testing can provide further guidance.

Third party tests intended to serve as the basis for consumer information must include a user trial. To ensure that the products are tested in an accurate manner and are assessed in alignment with the recommendations in these guidelines, and that the results reflect the actual experience of consumers, it is recommended to consult manufacturers and to conduct tests in a laboratory experienced in testing femcare products.

For convenience contact details for the main manufacturers that are members of EDANA are included in the annexes, along with suggested laboratories that are EDANA members, standard method references, and questions for user trials. Any feedback and input to the guidelines is welcome and will be taken into consideration in future versions.

For comments and questions, please e-mail info@edana.org

¹ Products like incontinence products and menstrual cups are outside the scope of these guidelines



2. Project Manager Check List

The list below is intended to provide a high-level overview of considerations to be taken into account when planning and conducting tests on femcare products.

The list outlines a number of suggestions which can be used in their entirety or not, and may be completed with further criteria.

General aspects

1. The organisation is financially independent from manufacturers of femcare products
2. The test compares products of equivalent size, similar construction and intended use
3. The sampling is representative of products available on the market
4. Experts in femcare products were consulted prior to the choice of characteristics to be tested to ensure their relevance
5. Manufacturers of all femcare products tested have been informed which of their products, including batch number, will be tested and which test methods will be used
6. Subjective evaluation of the products is based on a user panel or consumer surveys
7. Test results were checked by experts and communicated to manufacturers ahead of publication
8. The publication includes the price of each product
9. Clear guidelines were given to manufacturers and retailers on how they can use the results
10. The highest weighting is given to overall satisfaction, leakage protection and skin comfort
11. Detailed information on each product and their manufacturer is recorded and supported with pictures
12. At least one sealed pack is stored by the laboratory for six months after the test

Aspects related to laboratories

13. A laboratory qualified in testing of femcare products was commissioned
14. Technical lab tests were carried out on at least 8 randomized samples for each product
15. All test methods are relevant for femcare products, reproducible and scientifically rigorous

16. For tests related to substances, results are indicated together with applicable legal standards and regulations

Aspects related to user trials

17. Sampling, test design, user panel recruitment and analysis of test results comply with the latest version of ASTM E1958, AFNOR (ISO/DIS 11136) and/or ESOMAR guidelines

18. Performance tests were carried out during at least one menstrual period by a representative panel of users reflecting e.g. age, weight distribution, market distribution of brands/types of product

19. Users filled in detailed questionnaires

20. If the test/user panel was conducted in a country other than where the test result is published, comparability of the two countries was assessed and this is clearly indicated

3. List of abbreviations

| | |
|---------|--|
| AFNOR | French Normalization Association |
| AHP | Absorbent Hygiene Product |
| ASTM | American Standard Test Method |
| ESOMAR | European Society for Opinion and Market Research |
| Femcare | Feminine Care |
| ISO | International Organization for Standardization |
| NWSP | Nonwoven Standard Procedures |
| Syngina | Synthetic vagina (EDANA Test Method) |

4. General principles and recommendations

Sampling, test design, panel recruitment and the analysis of test results for user trials must comply with the latest versions of ASTM E1958, AFNOR (ISO 11136) “Sensory analysis -- Methodology -- General guidance for conducting hedonic tests with consumers in a controlled area” and/or ESOMAR² guidelines, as applicable.

Communications with manufacturers and distributors before and throughout the testing process is recommended (see section 6). Producers of femcare products can provide helpful insights for a product test, e.g. which products are comparable and/or which markets are similar, whether new technologies have been introduced into the market or if planned product changes will be made before the publication of the test results.

1. Sample selection

1. The test must compare products of equivalent size, similar construction, intended use and quality level (value/performer/premium) if not full assortment.
2. For performance based comparative tests, if only one size or product type is tested, tests should be conducted on the main product designs and/or the main type and size.
3. The products that are included in the test must be representative of the products available on the market (brands, types, price etc.). These guidelines refer to fully commercially available products (see point 2 in the introduction above).
4. Particular care must be taken regarding product condition before testing to reduce risks of deviations due to exposure to insufficient or excessive heat and/or humidity. Testing organisations must ensure that products are stored in the appropriate conditions before any laboratory tests or user trials are carried out.
5. It is recommended to keep products in their original packaging due to the risk of contamination or altering the performance of products and/or packaging. If samples are used during a user panel, essential information on the use of the product should still be visible to consumers.
6. Test products must be purchased in the country of the user trial. Products or product lines marketed under the same brand may be manufactured by different companies, to different specifications or in different plants, but to the same quality requirements. In order to avoid discrepancies between products tested and products effectively put on the market, tests covering several countries/regions must ensure that samples are collected from relevant plants/manufacturers. Manufacturers/distributors can advise on this (see Annex I).

² <http://www.esomar.org>

II. Characteristics and parameters tested

1. Unless a test is conducted with a specific purpose (e.g. for carrying out an assessment for product absorption only), the test protocol should cover all characteristics of the product relevant to the use of the product by the consumer.
2. It is recommended that the final choice of characteristics to be tested is made after consulting experts in the product category e.g. specialised test laboratories, manufacturers or other independent experts. This will ensure that the tests match the actual use of the products and the expectations of consumers.
3. When the characteristics tested reflect a subjective evaluation of the product, they must be based either on assessments by a consumer panel or on surveys conducted among representative consumers. Consumer surveys must be conducted and analysed according to standard statistical practices (i.e. latest version of ASTM E1958).
4. If a test or survey is subject to limitations or reservations, these must be clearly communicated when the results are published. For example, if only eco-labelled products were tested this should be clearly stated when the results are published.
5. Qualitative criteria and sustainability-related parameters may be included in the publication of the results provided this does not unreasonably impact the ranking based on quantitative tests and panel results.

5. Test methods

The test methods used must be validated and based on product-relevant reproducible and repeatable methods. If not possible, the reasons why other methods were selected should be given to the interested parties, on the initiative of the organisation responsible for the consumer tests.

Tests must be carried out in laboratories that are accredited based on ISO/IEC 17025. Information on the test methods used should be available to all relevant stakeholders.

A list with recommended test methods is available in Annex III. In the next section, the different types of tests and their purpose, will be described in a qualitative way.

I. Various types of tests

In general, testing of femcare products can take place in two ways: primarily through user trials and user panels or secondarily through tests carried out in a laboratory. User trials provide insights into the perceptions of consumers, laboratory tests provide indications about the performance and the presence of specific substances in a product.

Reason: there is no guideline for the laboratories how to declare a product as safe!

1. User trials are crucial to evaluate overall product performance. They are needed to weigh the objective results obtained according to consumer expectations by laboratory testing. For consumer tests, user trials should be the predominant tool in terms of product ranking based on product performance.
1. Laboratory tests should be used to complement the results of user trials and to evaluate specific quantifiable product properties. Objective laboratory performance tests should be linked with the subjective evaluation of the product. Parameters listed in section III are examples of commonly used measures. The final decision of which parameters are to be measured should be determined collaboratively between the sponsor and the test laboratory.

II. User trials and user panels

The following should be considered when designing the test set up:

1. The panels should be a good representation of the population relevant to the test market. In case various products are being tested for comparison, the panels should be similar in terms of age profile and they should use products similar in size, brand and type. The users should be healthy females of menstruating age (panellists are typically between 18 and 49 years old).
2. The participants in the panel should represent consumers that normally purchase a range of the main brands available in the market (e.g. to include the market leader, other brands and retailer brands).

3. For test design, it is recommended to use a monadic or sequential monadic test design and ensure that the same product is continuously tested during one menstrual period for tampons and sanitary napkins. It is important to consult an expert in consumer testing of femcare products.
4. To ensure viable statistics, it is important to have a sufficiently large test panel and allow enough time. Our recommendation is a minimum of 100 users per product for a home use panel. Input from an expert on statistics is required to design the panel test in a way that the data obtained can lead to results with the expected accuracy and confidence intervals. Comparative testing should be conducted in accordance with relevant standards e.g. ISO/IEC Guide 46:2017 (Comparative testing of consumer products and related services -- General principles) and ASTM E1958 - 16a (Standard Guide for Sensory Claim Substantiation).

The duration for the user trial should take typical habits and practices into account along with other relevant parameters, such as country, size/dimension, absorption and type of product (for example day/night use).

The recommended duration of a trial is 3 - 7 days. It is recommended that users test only one type of product at a time during the menstrual period. The number of products tested should reflect the user habits on the market in scope of the test. The minimum number of products tested should be as follows:

- For panty-liners - a minimum of 8
 - For pads - a minimum of 12 (test to be discontinued at the end of menstrual period)
 - For tampons - a minimum of 15 (test to be discontinued at the end of menstrual period)
5. It is important that questions in the questionnaires are balanced and phrased neutrally. It is recommended to assess the following criteria as part of a user trial (see also ANNEX IV):
 - Overall satisfaction
 - Leakage protection
 - Dry feeling
 - Skin comfort (how the product feels in contact with the skin)
 - Ease of application / removal of the product
 - Does the product stay in place?
 - Discretion
 - Overall fit
 - Softness
 - Optional comments (positive/neutral/negative)
 6. Questionnaires used should be based on a mix of statements that will not create any bias for the consumer, with a consistent scale for responses. In addition to the questionnaire, it is recommended that each participant keep a diary.
 7. All participants should be current users of the femcare product type or category of product being tested. A record of relevant characteristics, such as participants' use of contraception should be kept.

8. The product should be used in the same way and conditions as the product participants normally use. In addition, clear usage instructions should be provided and consistent with instructions provided by the manufacturer on the pack or information leaflet. For pads and liners, this may include suggestions like “use as you would normally use your usual pad or liner”. For tampons, usage instructions must be provided that are consistent with the guidance of the EDANA Tampons Code of Practice³
9. If the test is conducted in a different country than the target market, the comparability of the two countries in relation to habits and usage should be confirmed and the name of the country where the test was conducted should be clearly stated.
10. Women with a menstrual condition, those with a chronic skin condition in the vaginal area, those who become ill during the course of the user trial, as well as pregnant and lactating women should not participate in the test.

III. Laboratory tests

To balance statistical accuracy and workload/duration of study, a minimum of 8 samples should be tested, and results should be reported with the average and standard deviation from those 8 samples from the same batch. Ideally the batch evaluated by the laboratory should be identical to the one evaluated in the user trial.

It is good practice to include a description of the construction of the product, together with the dry weight and dimensions.

In section A the most common laboratory tests are briefly described.

The methods related to liquid management do require a test liquid, which can be artificial menstrual fluid, PIF (Paper Industry Fluid⁴) or a saline solution. The test method needs to specify which is selected and the laboratory conducting the test needs to carefully record the specification of the liquid they used.

³ Available on www.edana.org

⁴ See section 7 of AFNOR Q34-018:1994

A. Performance tests

For performance based comparative tests, if only one size or product type is tested, tests should be conducted on the main product designs and/or the most common size.

Performance properties are, in general, properties that are noticeable by the consumer. They have an impact on user satisfaction, however, the results of performance tests are not linear to user satisfaction. In most cases, a potential consumer is not aware of these properties, unless the property does not support the normal use of the product. Different performance tests exist to evaluate internal and external femcare products as outlined below.

1. Strike through / penetration (pads/liners)

Strike through / penetration time is a measure for the speed at which liquid is absorbed by the product.

2. Wetback (pads/liners)

Wetback (or rewet) is a measure for the amount of liquid that is released by the product to the skin after absorption when pressure is applied to the product.

3. Absorbency test (pads/liners)

For sanitary pads and panty liners various methods are in use to measure the absorption capacity of the products. Various methods have been developed to assess the retention capacity (absorption before leakage). These methods range from simple designs (dunk, fluid acquisition) to those that take the shape and the features to prevent leakages into consideration.

4. Adhesion/stay in place (pads/liners)

The last performance test deals with the adhesive system that is applied to keep the product in place during use. Part of the evaluation is also the removal of the product from the garment after use.

5. Syngina (tampons)

The word 'Syngina' is constructed from the words 'synthetic' and 'vagina'. the Syngina test (NWSP 350.1.R1(15)) measures the absorption of the tampon in a device that mimics regular usage conditions in terms of pressure and temperature. This test determines the number of droplets on the packaging to demonstrate the absorbency of the tampon, as outlined in the EDANA Tampon Code of Practice.

6. Strength of the string (tampons)

The strength of the string of the tampon and the connection with the absorbing part is a standard quality control test carried out by manufacturers. The consumer's expectation is that the string is strong enough to withstand to the pressure exerted during removal.

7. Linting /fibre fluff-off (tampons)

Fibre fluff off is the retention of loose fibres in the vagina after use. Medical and scientific evidence demonstrates that the occasional retention of a few fibres in the vagina is not correlated to health implications and that these fibres are readily shed from the vagina.

B. Tests unrelated to product performance

Legislation

Occasionally, third party organizations may consider assessing feminine hygiene products for aspects not related to performance, such as presence of substances.

Testing of Femcare products and the interpretation of results must be conducted and put in perspective with applicable regulations. In Europe, the main regulations for femcare products are:

- The General Product Safety Directive 2001/95 (GPSD)
- Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Further information on regulatory requirements and voluntary guidelines in the EU can be found in EDANA's "Supply Chain Information for Absorbent Hygiene Products"⁵. EDANA supports the use of Exposure Based Risk Assessment (EBRA) as a methodology for the assurance of safety of feminine hygiene products. The testing organisation should enquire with manufacturers as to what type of product safety assessment processes are in place.

Testing

When testing for the presence of substances, it is firstly important to carefully select a suitable method. Using an inappropriate solvent/extraction may result in detectable levels of a chemical which are not extracted under realistic exposure conditions. Choosing a method without using it in an appropriate context, easily leads to poor results: one may not identify a chemical compound which is present, or vice versa, one identifies a compound that is actually not present, but has been created during the analytical test.

When assessing products for the presence of substances, the test must represent real-life usage conditions, and as such, it is recommended to use test liquids that reflect the actual use by consumers⁶ (see section III) rather than strong solvents for extraction purposes.

When reporting detected levels, the levels should be put into context vs e.g. regulatory thresholds established as safe for consumers by authorities or trace levels found in the environment.

Some testing organisations have carried out tests on feminine hygiene for microbial contamination. It is first of all important to remember that the products are not intended to be sterile and, due to the dry nature of the products and their raw materials, femcare products have low water activity. Microbial growth and proliferation requires the presence of water in a product. The low water activity value of these products and their raw materials will therefore mitigate the risk of microbial

⁵ <http://www.edana.org/industry-initiatives/product-stewardship/download-supply-chain-information-form>

⁶ <http://www.edana.org/discover-nonwovens/products-applications/absorbent-hygiene-products/traces-in-ahp>

growth and survival. In addition, manufacturers' adherence to Good Manufacturing Practices (GMP), use of high quality materials and the highly-automated manufacturing process under which these products are produced minimise the possibility of microbial contamination during production. They also comply with any local regulatory requirements where relevant when evaluating the potential presence of any microbial growth in femcare products and their raw materials.

6. Interpretation of results

Test results and conclusions should be thoroughly checked to assure scientific plausibility, consistency, reproducibility, and statistical or biological relevance. Test laboratories and producers of femcare products can provide valuable inputs, e.g. by spotting factual errors or inconsistencies.

The significance of any differences that are observed between products should be taken into consideration when evaluating results. If the differences are not statistically significant no conclusions can be drawn regarding the property at hand. Results should always be communicated in plain language.

Testing equipment has become very advanced and the detection levels for identifying residues of substances have become more precise. Ever lower levels of traces of unwanted substances may be detected, also in absorbent hygiene products (AHPs), even if they are produced according to state of the art sourcing and manufacturing practices. These traces can originate from a variety of sources, as some substances are ubiquitous in the environment.

The presence of such substances must be put in context of exposure scenarios based on the intended use of the product as per Exposure Based Risk Assessment (EBRA) methodology.

It is important to recognise that the identification of a substance above the detection limit does not necessarily pose a risk to consumers. Any test results must therefore be put in their right context to allow for fair interpretation.

Where applicable, quantitative results related to substances must be put in context of regulatory limits and requirements, to allow the consumer to know whether the substance is present in quantities that exceed legal thresholds or not.

Testing organisations are encouraged to consult recognised experts (e.g. toxicologists) to interpret and/or verify the results from testing laboratories or testing institutes.

7. Evaluation criteria and weighting

The evaluation should be based on the consumer experience results from the user trial, and can be complemented with lab tests. The highest weighting should be given to overall satisfaction, leakage protection and comfort. The other criteria can be given a lesser weight. The evaluation should be based on consumer expectations derived from panel tests. All consumer expectations for performances should be considered in this weighting.

Other parameters should be mentioned separately and ranked in addition if desired. In all cases, weighting should be indicated as part of the final publication to ensure that the results can be correctly interpreted.

8. Communication of test results to manufacturers

1. Information on the scope of the test must be included in the first communication with manufacturers.
2. The test results, including the list of characteristics tested, the methods used and product references (batch number or other product coding), should be forwarded to the manufacturer before publication.
3. Testing organisations must give the manufacturers a reasonable amount of time to respond and communicate their comments in time to be considered before publication of results.
4. Comments from manufacturers should be taken into account by the testing organisation.
5. The testing organisation may also communicate the name of the laboratory conducting the test and the determination of the method used, provided the laboratory agrees to this.

9. Publication and reporting of results

1. The results must be presented in language, units and symbols that are understandable to the consumer.
2. The presentation of the test results must be clearly explained. It must include the criteria used to select the products tested, the representativeness and the sampling of the products, the characteristics selected and the test methods used, including their limitations if any.
3. The presentation of the results should include any complementary information on the relative importance given to the different tests conducted and/or to the characteristics of the product, including the reasons for their relative weighting.
4. Applicable legal standards and regulations must be referred to when communicating test results.
5. Factors that may have an impact on the perceived performance of the products should be taken into consideration. Amongst the information provided to the consumer, the price of the product is essential to the appreciation of the value of the product.
6. If one or more products are identified as best or better than others, the criteria used to reach this conclusion should be listed.
7. Testing organisations must provide clear guidelines on the use of test results by manufacturers and retailers to ensure that the publication of the test results by third-parties does not alter their meaning and objectivity. For example, it should be required to indicate the date and source of the test result.
8. Illustrations should feature products that are effectively available in the target market.

10. Miscellaneous

The below outlines a number of factors which should be taken into account in the testing of femcare products.

I. Inventory - General Data

The following information from the packaging of the sampled products should be recorded in the test report:

- Brand name and product name and size
- Absorbency level (when applicable)
- Manufacturer and / or distributor (e.g. retailer brand)
- Promotional information and advertising claims, illustrations
- The type of packaging (bag or box)
- Quantity of contents
- Application, disposal and recycling information
- Batch number or other product coding



II. Photo Documentation

The testing organisation is to produce test sample and packaging photos for the test publication to enable the clear identification of the product tested.

III. Reserve Test Samples (from the same batch)

Reserve test samples (at least one sealed bag) are to be kept under suitable conditions (see page 8) and stored for the testing organisation for six months for potential re-evaluation.

ANNEX I – List of contacts from EDANA member companies producing femcare products

Note: Testing organisations are welcome to contact EDANA should they have any doubts as to whom they should contact within a given company or to ensure that they are contacting all relevant market players. Contact information for EDANA member companies is available here: <http://www.edana.org/industry-support/membership>

Abena Produktion

<http://www.abena.com>

Albaad Massuot Yitzhak

<http://www.albaad.com>

Corman

<http://www.corman.it>

Drylock Technologies

<http://www.drylocktechnologies.com>

Essity

www.essity.com/

Hygiene Oederan

<http://www.hygiene-oederan.com>

Johnson & Johnson

<http://www.jnj.com>

Kimberly-Clark

<http://www.kimberly-clark.com>

Laboratorios Indas

<http://www.indas.es>

Lil-Lets UK

<http://www.lil-lets.com>

Mega Disposables

<http://www.megadis.gr>

Ontex

<http://www.ontexglobal.com>

Procter & Gamble

<http://www.pg.com>

Tosama

<http://www.tosama.si>

ANNEX II – List of relevant test laboratories that are members of EDANA

Centexbel

www.centexbel.com

EUROFINS

www.eurofins.com

Hy-Tec Hygiene Technologie

www.hytec-group.de

SGS Courtray

www.sgs.com/tissuehygiene

Swerea

www.swerea.se

Centre Technique du Papier (CTP)

www.webCTP.com

Galab Laboratories

www.galab.de

ipi Institut für Produktforschung

www.ipi.de

SGS Institut Fresenius

www.institut-fresenius.de

ANNEX III – Selected test methods or standards

| Test | Reference | Description |
|-------------------------------------|---|---|
| Absorption rate/time of penetration | NWSP 070.7.R0(15) <i>Repeated Liquid Strike-Through Time (Simulated Urine)</i> | |
| Leakage simulation test | | Various customised methods, no standard |
| Wetback / rewet | NWSP 070.8.R0(15) <i>Wetback After Repeated Strike-Through Time (Simulated Urine)</i> NWSP 080.10.R0(15) <i>Nonwovens Coverstock Wetback</i> | |
| Syngina | NWSP 350.1.R1(15) <i>Menstrual Tampons Absorbency- Syngina Method</i> | Tampon test |
| Linting | NWSP 160.1-4.R0(15) <i>Resistance to Linting of Nonwoven Fabrics (Dry)</i> | Coverstock test |
| Strength of string | Australian standard 2869/2008 | Use unster or tensile tester |
| Evaluation of adhesion systems | | Various setups with tensile tester |

ANNEX IV – Sample of questions to consider for questionnaires

Questionnaire Example (after usage)

General Information

- Name (to be kept confidential)
or
- Panellist-Identification
- Weight in kg
- Height in meters
- Age
- Product usage
- Brand use
- Contraception
- Flow intensity
- Tested product:

Product questions

Strongly recommended:

1. How would you rate the product overall (excellent-very good-good-fair-poor)?
2. Comments: What did you like about this product? (open question)
3. Comments: What did you not like about this product? (open question)
4. How would you rate the leakage protection of this product (excellent-very good-good-fair-poor)? EXTERNAL
5. How would you rate the absorbency of this product (excellent-very good-good-fair-poor)? INTERNAL
6. How would you rate the product in contact with your skin (excellent-very good-good-fair-poor)?
7. How would you rate overall comfort (excellent-very good-good-fair-poor)?
8. How would you rate the product's ability to help control odours (excellent-very good-good-fair-poor)?
9. Do you have any additional comments about the product?

Other parameters that could be rated, e.g. through follow-up questions, may include:

- Appearance
- Dry feeling
- Softness
- 'Bunching'
- Flexibility
- Information about use
- Day vs night use
- Ability to stay in place
- Ease of application
- Ease of removal
- Size / dimension
- Shape
- Does the adhesive strip leave any residues in garments?
- Packaging
- Disposal