Annel

COSMETIC TESTING

STABILITY AND COMPATIBILITY TESTS

Stability and compatibilitytestsare thebasiccosmetic tests necessary for preparing a safety assessment (CPSR) and they are **mandatory**

The main purpose of a **stability test** is to assess the ability of a cosmetic product to maintain its physical, chemical and microbiological properties from the moment of manufactured to the moment of use by the customer,when stored in appropriate conditions.

Compatibility with packaging enables the demonstration that a product remains stable over time, and there are no interactions between the product and packaging.

The scope of stability tests includes:

- stability and compatibility of products
- compatibility of the product with the packaging
- PAO/shelf life
- cycle test

MICROBIOLOGICAL PURITY TESTS

Microbiology testing helpsminimize theriskofpotentialdamage.
Accredited tests for the identification of microorganisms should meet the following requirements:

- **EN ISO 16212** – total yeasts and moulds count
- **EN ISO 21149** – total aerobic count
- **EN ISO 21150** – detection of Escherichia coli
- **EN ISO 22718** – detection of Staphylococcus aureus
- **EN ISO 22717** – detection of Pseudomonas aeruginosa
- **EN ISO 18416** – detection of Candida albicans

"Microbiological purity test"- it is **always mandatory**?

No

Microbiological testing is mandatory, but it is not always mandatory for microbiologically low-risk cosmetic products.

CHALLENGE TEST

Challenge test confirms that the **preservatives** used protect the produt against the development of dangerous microorganisms and protect it from reinfection during use.
The procedure involves infection of the tested product with strains of Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, and Aspergillus brasiliensis, followed by monitoring the decrease in microorganism levels over a period of time

"Challenge Test"- it is **always mandatory**?

No

Challenge test is mandatory, but for microbiologically low-risk cosmetic products is not always mandatory

Products with specific physico-chemical characteristics that have a **low risk of microbial growth**:

- **water activity ≤ 0.75**
- **pH ≤ 3 or pH≥ 10**
- **high alcohol content (> 20%)**
- **production conditions: filing temperature > 65°C**
- **packaging: single-use products or products which cannot be opened** (e.g.airless containers)
- **raw materials that can create an environment antagonistic to microorganisms**:

Polar organic solvents
Oxidizing dyes
Propellant gases
Aluminium chlorohydrate and related salts: > 25%
Strong oxidizing agent or strong reducing agents
Other substance if supported by data

To determine whether a product is microbiologically low-risk, several factors must be taken into account, including dosage method, volume, and shelf life

PATCH TEST

Adverse reactions may arise fromboth natural andsynthetic ingredients.A patch test is a dermatological procedure conducted under the supervision of a dermatologist, and its results allow for the use of the declaration **'dermatologically tested'**. Patch testing is one of the methods used to evaluate the allergy potential of a cosmetic product.While not mandatory, it is strongly recommended

Examples of dermatological tests:

- open test
- semi-open test
- closed test
- T-shirt test
- single application test

All tests should be performed using the testing methods,
which are accepted by the EU or UK authorities.

- Regulation (EC) **No 1223/2009** Of The European Parliament And Of The Council Of 30 November 2009 on cosmetic products
- Cosmetics Europe – The Personal Care Association **Guidelines – Product test Guidelines for the Assessment of Human Skin Compatibility 1997**
- Cosmetics Europe – The Personal Care Association **Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008**

COA - “CERTIFICATE OF ANALYSIS”

Physicochemical testing of a cosmetic product involves measuring parameters confirming the quality of the composition and determining harmful substances.

✓ **organoleptic assessment**

determination of appearance, colour match, aroma

✓ **determination of viscosity**

✓ **determination of density**

✓determination of allergens

The determination of allergens is typically conducted for perfumes and perfumed cosmetic products. According to Commission Regulation (EC) 2023/1545 of 26 July 2023, amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council regarding the labeling of fragrance allergens in cosmetic products, the list of allergens has been updated. The new regulation expands this list from 26 to over 80 allergens, whose presence must be indicated in the INCI list when their concentration exceeds:

- 0.001% in leave-on products

- 0.01% in rinse-off products

The transition period for placing cosmetic products on the Union market until **31 July 2026** and until **31 July 2028** for withdrawal of products from the Union market.

- Cosmetics Europe – The Personal Care Association **Guidelines On The 'Fragrance Allergens' Requirements**

✓ **determination of water activity**

Mandatory for all cosmetic products, water is one of the most important factors controlling the rate of microorganism growth. As water activity increases, the product becomes more susceptible to microbial growth.
According to ISO 29621:2017 **water actvity ≤ 0.75** can be one of the factors for determining a product as **microbiologically low-risk**.

✓ **determination of the pH value**

For cosmetics containing water, pH measurement is mandatory, while it's impossible for water-free cosmetic products.
A **pH** range of **≥ 3.5 or ≤ 10** does not support the growth of microorganisms, and a cosmetic product falling within this range can be described as **microbiologically low-risk**, according to ISO 29621:2017

✓ **determination of heavy metals**

Mainly for color cosmetics products, a small trace of a prohibited substance (e.g., Hg, Pb, Co, As, Cd, Sb, Ni) in the final cosmetic product is permitted, provided that its presence is unavoidable under Good Manufacturing Practice (GMP) and does not pose a risk to the consumer.According to **Article 17 of Regulation (EC) No 1223/2009**:

"The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3."

✓ **determination of preservatives**

According to Article 3 of Regulation (EC) No 1223/2009:

"Preservatives' means substances which are exclusively or mainly intended to inhibit the development of microorganisms in the cosmetic product"

Annex V of of Regulation (EC) No 1223/2009 presents list of preservatives allowed in cosmetic products with their maximum concentration

✓ determination of nitrosamines

According to **Article 17 of Regulation (EC) No 1223/2009**: "The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3."

The risk to human health associated with the presence of anitrosamines in cosmetic products is presented in the **Cosmetics Directive (76/768/EEC)**

Annex II : Nitrosamines, Secondary alkyl- and alkanolamines and their salts are prohibited

Annex III: Sets the maximum concentration of nitrosamines in mono and tri-alkylamines and alkanolamines and in fatty acid dialkylamines and dialkanolamidesis is **50 µg/kg**.

In summary, trace amounts of nitrosamines are allowed for products: manufactured with GMP, not harmful to human health and containing unavoidable trace amounts of nitrosamines

- Cosmetics Europe – The Personal Care Association - **Technical Guidance document on minimising and determining nitrosamines in cosmetic 2009**

IN-USE TESTS AND EFFICACY TESTS

In-use tests or efficacytests arenecessarytoconfirmproperties of the cosmetics products are compatiblewith marketing claims.

In-use test relies on volunteers **subjectively** evaluating the product while using it in their own homes.

Efficacy tests enable an **objective** evaluation of the impact of a cosmetic product on the skin. Some of the tests are:

- measurement of TEWL
- measurement of skin moisturization
- measurement of pH of the skin
- measurement of wrinkles
- measurement of smoothing of skin surface
- measurement of hair thickness

Stability and Compatibility Tests
CoA (organoleptic assessment. determinationof viscosity. density, water activity)

→ **Always mandatory**

Microbiological Purity Test
Challenge Test

→ **Mandatory but for microbiologically low-risk products is not mandatory**

Patch test
In-use Tests and Efficacy Tests
CoA (pH, determination of allergens, nitrosamines, heavy metals, preservatives)

→ **Mandatory but depending on cosmetic formulation, ingredients, properties and marketing claims**