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Microbiology in cosmetics

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They are an integral part of everyday life, everyone knows and uses them: cosmetic products. Be it perfumes, deodorants, sunscreens, mouthwash solutions or makeup.

Their use is by no means a new phenomenon. Records from ancient Egypt dating back to 1550 B.C. already contain cosmetic formulations[1]. Since then, both the applications and the range of cosmetic products have multiplied. In 2017, sales of cosmetics in Switzerland alone amounted almost 2 billion Swiss Francs[2]. Consumption has also raised consumer expectations for product quality. The demand for organic and natural cosmetics from sustainable production remains high. The associated use of natural raw materials and the renunciation of preservatives pose new challenges for manufacturers. An essential aspect in this context is microbiological product safety, since all cosmetics come into direct contact with the skin or mucous membranes. In the event of microbial contamination, they pose a health hazard. In order to guarantee the safety of a product, a concept for monitoring and ensuring microbiological quality is therefore required on the part of the manufacturer.

Legal framework conditions and risk analysis

Microbiological tests have long been an important part of quality assurance in food and pharmaceuticals. Medicines are tested and evaluated according to international pharmacopoeias. Food is tested in accordance with ISO standards. The subsequent evaluation is largely based on guidance and warning levels from the Hygiene Regulation (HR). These limit values ensure that production was carried out under appropriate hygienic conditions and that proper raw materials were used. They are therefore a central aspect of consumer and patient protection.
According to the new Swiss Cosmetic Products Ordinance (CPO, 2017)[3] the implementation of microbiological quality controls is now also mandatory for cosmetics. A transitional period of 4 years applies to the implementation of the new regulation, which was harmonized with the EU Cosmetics Regulation 1223/2009 in force since July 2013. Cosmetic products for which no safety assessment or product information file is available and which have not been manufactured in accordance with GMP guidelines may only be marketed until 30 April 2021.
The largest and at the same time most complex innovation of the current CPO concerns the absolutely necessary product information file (PIF), which is created by the manufacturer in self-control for each cosmetic product. The product information file contains, among other things, the safety report, which has to inform about the following microbiological quality aspects:

1. **Microbiological specification of the cosmetic product**
2. **Antimicrobial effectiveness testing (AET)**

For example, the manufacturer has to use the ISO standard 2962 to evaluate on a risk basis which microorganisms could be introduced or penetrate the product to a hazardous degree. This risk analysis is mainly oriented towards the area of application of the product and the consumer group. In general, infections through the mucous membranes of the mouth, nose or eyes are more likely than through the skin, which is why products for these applications carry greater risks. With regard to the product's target group, infants and people with a weakened immune system tend to be at a higher risk of infection than healthy adults. Based on the identified risks, specifications for the microbiological contamination of the products are defined. The ISO standard 17516[4] is recommended as a basis for orientation (see 1). The analyses are also carried out according to specific ISO standards for cosmetics (see 1). Furthermore, the manufacturer has the opportunity to define specifications deviating from ISO 17516 with correspondingly documented reasons.

1 Recommended specifications according to ISO 17516 as well as the decisive ISO standards for laboratory implementation

Microorganisms	Specification A	Specification B	ISO standard
Total aerobic mesophilic microorganisms (bacteria and yeasts and molds)	Max. 200 CFU in 1 g or mL	Max. 2000 CFU in 1 g or mL	21149 and 16212
Escherichia coli	Not detectable in 1 g or mL		21150
Staphylococcus aureus	Not detectable in 1 g or mL		22718
Pseudomonas aeruginosa	Not detectable in 1 g or mL		22717
Candida albicans	Not detectable in 1 g or mL		18416

A: Products specifically designed for children under three years of age, the eye area or mucous membranes
B: Other products · CFU: colony-forming units

A good indicator of the general microbial load of a product is the total number of aerobic mesophilic microorganisms (both bacteria, yeasts and molds). Furthermore, the product should be examined on a risk basis for specific microorganisms depending on the application and target group (see 2).

If the cosmetic product cannot be classified as low-risk in terms of microbiological exposure, an antimicrobial effectiveness testing must be carried out in addition to the specifications. It is tested whether the preservatives contained in the product sufficiently inhibit the activity of potentially present germs.

Preservatives are all substances that are used in cosmetic products because of their antimicrobial properties.

The AET now has its own standard for cosmetic products, ISO 11930[5], so that it does not have to be carried out in accordance with the European Pharmacopoeia, chapter 5.1.3, as was previously the case. The cosmetic product is inoculated with a defined number of microorganisms and tested for the reduction of germs after fixed storage times. All ISO methods must be verified in principle in order to be able to carry out the analyses within ISO 17025 accreditation.

Execution of microbiological analysis

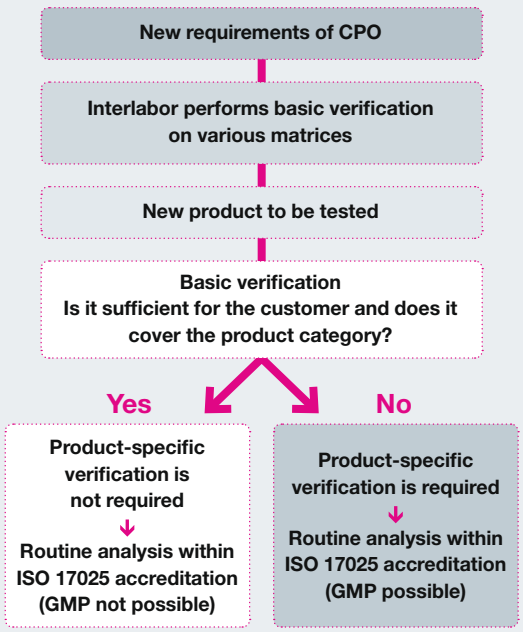
Microbiological testing of food and pharmaceuticals according to various standards and guidelines as well as corresponding verification of the procedures have been part of routine analysis at Interlabor Belp AG for years.

In response to the requirements of the new CPO, extensive basic verification was carried out. For this purpose, the ISO methods including AET were applied to various cosmetic products. Tested were a greasy sun cream for children, a water-based cleansing milk (incl. make-up remover), an alcohol-based mouthwash solution and a silicone-containing shampoo.

2 Microbiologic examination parameters for cosmetics

Test parameter	Occurrence	Test recommendation	Additional information
Total number of aerobic mesophilic microorganisms	Occurrence is germ-dependent	Every product	Indicator of the overall microbiological quality of the product
Escherichia coli	Moist environmental sources Feces	Products for oral use	Indicator for fecal impurities Possible triggering of gastrointestinal infections
Staphylococcus aureus	Natural occurrence, e.g. on the skin of healthy people	Products for application on the skin and mucous membranes	Possible causing of blood poisoning, Toxic Shock Syndrome (TSS), wound infections and pneumonia In case of multi-resistant strains (MRSA) difficult to control with antibiotics
Pseudomonas aeruginosa	Occurring in the environment (mainly in water)	Products for use as aerosols (spray cans) Products for application on the skin and mucous membranes	Possible triggering of pneumonia and secondary infections in patients with cystic fibrosis
Candida albicans	Natural occurrence in mouth/throat, vaginal area and gastrointestinal tract	Products for vaginal application	Possible triggering of candidiasis (fungal infections)

3 Scheme



By adding a defined number of microorganisms in the presence and absence of the cosmetic product, the extent to which the microorganisms can be recovered was investigated.

It was also used to test whether the preservatives can be neutralized during microbiological testing so that they do not affect microbiological growth. Through basic verification, the optimum method and suitable dilution medium were determined for each matrix. Due to the variety of available techniques and reagents, this was a time-consuming and costly preliminary work, which, however, makes it possible to reduce the planning and implementation costs of future projects. The documentation of the basic verifications is freely available to all customers as a project basis. Depending on the product and desired scope of validity, they can decide together with Interlabor Belp AG on the basis of risk whether additional product-specific verification makes sense. If a routine analysis under GMP is desired, this is absolutely necessary (see 3).

Conclusion

In order to ensure the microbiological harmlessness of cosmetics with regard to consumer health, the corresponding analytical and regulatory know-how is required in addition to detailed knowledge of the product itself, its manufacturing process and intended use. In addition, it is recommended to develop a tailor-made analytical concept for microbiological product quality within the scope of the safety report of the product information file. □

References

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