Cosmetic studies

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The trend in cosmetics goes towards highly effective active agents. Since the Cosmetic Directive demands for safe cosmetic preparations that are free of adverse effects, there is need for comprehensive quality control and validation of the products. A selection of quality control procedures is described in the following.

Depending on the particular requirements, different types of studies and validations are carried out. They test the product safety or in other words they verify that the product is free of adverse effects at a reasonably foreseeable use, but they also examine the promised efficacy of the product as for instance an improved skin hydration, skin elasticity. The results are documented in a written cosmetic safety report which is required by law. Also a description of the efficacy of the product is required which has to be truthful and verifiable.

Cosmetic studies cannot be compared with pharmaceutical product studies that have to comply with more sophisticated requirements. Frequently it is reverted to the studies of raw material manufacturers or technical literature. Just to mention an example: if a cream is to be developed to increase skin hydration by using the active agent panthenol (provitamin B_5), it is allowed and also state of the art to refer to the efficacy description of the raw material manufacturer respectively to technical literature. It informs that panthenol improves the skin hydration, supports cell formation, has anti-inflammatory effects, impedes itching, and the manufacturer now also makes use of these statements for the newly developed cream. The specific nature and frequency of application also are included in the efficacy description. It needs to be said that this kind of evaluation takes insufficient account of potential interactions with the cream base.

In the case that the manufacturers run their own test series, they can either opt for tests with study participants (test persons) or with cell cultures respectively skin models. In the first case we speak of “in-vivo”-studies and in the second case we are dealing with “in-vitro”-studies. These studies can provide the manufacturer with valuable information on the safety respectively efficacy of the product. In this context a statistically relevant number of test persons is required with skin conditions that are suitable for the respective tests. A comparison of the results of several studies frequently is difficult as there is a large variety of test methods and test conditions often are not really comparable. External influences also can have an impact on the test result.

In studies with test persons, the preparations usually are applied onto the skin following the recommendations of the manufacturer and then it is examined how the previously defined parameters are modifying. Examples for parameters for instance are skin hydration, lipid content, elasticity, pH value or wrinkle depth. Modifications are recorded in an objective validation system however attention should be paid to the fact that the measured results also are subject to considerable natural variations. Hence it is absolutely necessary to implement the tests under standardized surrounding conditions. Blind studies also are imperative.

In comparison with the studies of the pharmaceutical industry, the number of test persons generally is considerably lower. An essential aspect is that pharmaceutical products can have adverse effects which have to be detected in qualitative as well as quantitative studies. In order to obtain a sufficient basis for the evaluation of less frequently occurring adverse effects, the number of test persons has to be adequately high. Cosmetic products are not supposed to have adverse effects. This already is considered when selecting the raw materials and appropriately examined in the safety report.

Biochemical processes that are difficult to implement with human test persons can be studied with the help of cell cultures. The influence of a product on the collagen synthesis can be tested in this way. In this connection the accuracy and applicability of the particular model plays a decisive role. Not every model can be transferred one-to-one to the human body. Furthermore the question rises whether the active agent also can permeate to the desired area in real life conditions or eventually is not able to penetrate deeply enough.

Non-human specimen allow to test physical-chemical features of the products as for instance the spreadability of different combinations of oils or in other words how well a product can be spread on the skin. This helps to draw conclusions on the penetrability of the products into the skin.

Subjective consumer tests also provide information on the effects of cosmetic products. The test persons here use the finished product according to specific instructions for a certain period of time. They are provided with a questionnaire to record their personal observations regarding tolerance, sensorial properties or efficacy. Also in this case the responsibility of the test supervisor is vital for the study results. As valuable as the results can be for an internal use as for instance in product development as easy the tests can be influenced in this kind of study by targeted selection of the test persons and additional influence on the test environment as for instance by free cosmetic treatments in order to control the outcome of the results.

A frequent term in this context is “dermatologically tested”. This means that a skin tolerance test has been carried out. It goes without saying however that this kind of test is part of product safety validation. Legislation basically requires this kind of test for all cosmetic products.

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