HOHENSTEIN

Skin irritation

The test method is used to predict the irritation potential of extracts from medical devices and their components. For this purpose, the influence of the extracts on the viability of reconstructed human epidermis (RhE) is measured and the samples are classified with regard to their potential to cause irritation.

Description

Skin irritation is the property of a substance or material to cause reversible damage and destruction of the tissue after skin contact. In the in vitro test for skin irritation according to **DIN EN ISO 10993-23**, human three-dimensional skin models are used which, analogous to the human epidermis, are composed of different cell layers.

The samples / extracts are applied to the surface of the skin models and incubated overnight. Subsequently, the models are washed. The vitality of the applied skin cells is quantitatively determined in comparison to control cultures and allows an assessment of the irritant potential of the sample.

This test is particularly suitable for

- Medical devices made from all types of material
- Textiles in health care system

Customer benefit

- Product optimization
- Consumer safety
- Advertising impact
- Minimization of complaints

Marketing Instruments – Labels and Certificates

On passing the test, the product may be awarded the certificate “Biological Safety” and/or the quality label “Medically tested” (in conjunction with the cytotoxicity test according to DIN EN ISO 10993-5).

Test sample requirements

General

- If dyestuffs, auxiliaries or avivages are used in different quantities, articles which use the highest quantity must be selected (worst-case)
- For ready-made samples, send the complete product
- In the event of complaints, provide the product in question for testing, if possible (please do not provide retain samples)
- Test samples must be packed individually to avoid contamination during transport, i.e. pack them separately e.g. in plastic bags
- Provide sufficiently precise designations of the test sample (material composition, item number, etc.)

Quantity of material

- At least 40 g of the test sample or size of DIN A3, respectively

Duration of the test

- Usually 20-30 working days; date confirmation after receipt of test sample

Test criteria

- According to DIN EN ISO 10993-23, if at least one of the extracts shows a viability of less than or equal to 50% compared to the negative control the sample tested shall be considered to have irritant activity.