



Skin Photoallergy Test

皮肤光变态反应试验方法

China Food and Drug Administration

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Skin Photoallergy Test

1 Scope

This method specifies the basic principles and test requirements for the animal skin photoallergy test.

This method applies to the skin photoallergy detection of cosmetic ingredients and products.

2. Test Purpose

This test is an attempt to assess and predict the possibility of skin photoallergy caused by exposure to sunlight after the humans are repeatedly exposed to the cosmetic ingredients and their products.

3. Definition

3.1 Skin photoallergy

The skin is exposed to the test substance and irradiated under ultraviolet rays to induce a photosensitization state by acting on the immune system of body. After a certain rest period, the skin is exposed to the same test substance again and irradiated under ultraviolet rays to cause a specific skin reaction, in the forms of erythema, edema, and the like.

4. Principle

Photosensitivity in the broad sense includes phototoxicity (also known as photoirritation) and photoallergy.

Skin photoallergy is an immunologically cell-mediated cutaneous reaction activated by light, which is a special type of IV-type allergic reaction. It is such an adverse reaction that happens in the skin cell layer after the photosensitive substance are transdermally absorbed or reach the skin through circulation and then react with the light absorbed. At present, the more accepted principle is that the photosensitive substance absorbs light energy and becomes activated, and combines with the protein in the skin in the form of hapten to form hapten-protein conjugate, which is transmitted to the immunocompetent cells via the epidermal Langerhans' cells, thus causing lymphocyte sensitization and other immunoreactions. The sensitized lymphocytes release lymphokines when they are exposed to the same antigen again, which result in a series of harmful reactions.

5. Basic Principle of Test

5.1 The test animals are removed of hairs from neck, and are then applied with an induction dose of cosmetic ingredients or products on skin for several times (adjuvant and skin injury treatment may be given in advance to enhance sensitivity) and are further exposed to a certain dose of ultraviolet light for several times, which induce specific immunity system (induction phase); after a certain rest period, the test animals are given a challenge dose of test substance on the back hairless skin and are then exposed to a certain dose of ultraviolet light. The test animals are observed and compared with the control animals about the degree of skin reaction to the challenge exposure to the test substance.

5.2 Test animals and breeding environment

Male or female adult white guinea pigs (weighed 350 g-500 g) that meet the requirements of national standards are used. Female animals shall be nulliparous and non-pregnant.

Animals, experimental environment, feeds and drinking water shall comply with the corresponding national standards. It is essential that guinea pigs receive an adequate amount of Vc in a suitable manner.

5.3 Preparation before animal testing

Animals are acclimatized to the experimental environment for 3-5 days prior to the test. The animals are randomized and assigned to the test group, the negative (solvent) control group, and the positive control group. The animals are subject to skin preparation (hair removal) on their neck 24 h before the start of the induction exposure to avoid abrading the skin. The animals are weighed before the test commences and at the end of the test.

5.4 A full observation (including systemic and local reactions) shall be given to the animals at the induction or challenge stage.

6. Test Method

Adjuvant and strip methods are used in this test. Before the test, pre-experiment shall be made to rule out the possibility of cutaneous primary irritation reaction and phototoxicity caused by the test substance.

6.1 Animals and grouping

Animals are assigned to the test group, positive control group and negative control group (at least 5 animals in each group). If the test is also an attempt to obtain the sensitization intensity value of the test substance and grade the photosensitization intensity thereof, at least 10 animals are required for each group.

In the negative control group (at the induction phase), the solvents are applied to the skin preparation central region at the neck and 30 minutes later, ultraviolet irradiation is undergone. In the negative control group (at the challenge phase), the solvents are applied to the skin preparation area 3, 4 on the back and 30 minutes later, ultraviolet irradiation is undergone.

At the challenge phase, the back region 1 of guinea pig is undergone no solvent application and no irradiation; the region 2 is undergone no solvent application but only irradiation; the region 3 is undergone solvent application but no irradiation; the region 4 is undergone solvent application and irradiation (see Fig. 2A).

6.2 Dose level

The concentration of test substance used for each induction exposure shall be the highest concentration to cause mild skin irritation. The concentration of test substance used for challenge exposure shall be the highest non-irritant dose. The test concentration level can be obtained from a pilot study using two or three animals.

Induction and challenge concentration selection of test substance, positive control, and negative control: the appropriate concentration after cutaneous primary irritation and phototoxicity are excluded by

pre-test. The allergization rate of the selected positive control at the selected concentration shall be mild or moderate.

6.3 Positive controls

The positive control adopts the 6-methylcoumarin or tetracholosalicylanilide (TCSA). The commonly used solvents for the positive controls are acetone, ethanol or a mixture of the above two in a certain ratio.

A positive control group is required for each test.

6.4 Preparation of sensitizer

In this test, a 1:1 mixture (v/v) of FCA and physiological saline is used as a sensitizer in the induction phase.

6.5 UV light source

6.5.1 Light source selection

UVA at the wavelength of 320nm-400nm is selected in both the induction phase and the challenge phase. If UVB is contained, the dose shall not exceed 0.1 J/cm². The light source can be selected from the black light lamp, the ultra-high pressure mercury lamp plus a filter or other UVA light source that meets the above conditions.

6.5.2 Irradiation dose

The irradiation doses in the induction phase and the challenge phase are set to 10.2 J/cm².

6.5.3 Determination of intensity

The light intensities (mW/cm²) are measured by the radiation meter at several points in the irradiation areas of shoulder (induction phase) and back (challenge phase) of the experimental animals, and calculated as the average value.

6.5.4 Calculation of irradiation time: take the irradiation dose of 10.2 J/cm² as an example, and calculate the irradiation time according to the following Formula.

$$\text{Irradiation time (min)} = \frac{\text{Irradiation dose (10200mJ/cm}^2\text{)}}{\text{Light intensity[mJ/(cm}^2 \cdot \text{s)]} \times 60}$$

Note: 1mW/cm²=1mJ/cm²/sec

6.6 Test procedures

6.6.1 Skin preparation

18h-24h before the formal test, the animals are removed of hairs from skin at the neck with a hair

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