

〈原 著〉

## 安全性を重視した化粧品の開発

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### Studies Relating to the Development of Cosmetics with Emphasis on Product Safety

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This report concerns processes of development and results of safety evaluations on cosmetic products such as cleansing cream, skin lotion, milky lotion, emollient cream and emollient oil, from the aspect of safety of application.

#### 1. Processes

##### (1) Choice of raw materials

The positive materials (table 5) which were used in the formulation studies, were selected by several safety testings (tables 1-4 and figs. 1-3).

##### (2) Determination of formulae

Each cosmetic preparation was determined from the viewpoints of safety, stability and availability (table 6).

#### 2. Experimental methods

(1) Skin irritation test in rabbits. (2) Maximization test in guinea pigs and humans. (3) Mucous membrane irritation test in eyes of rabbits. (4) Closed patch test in humans. (5) Repeated insult patch test in men. (6) Practical application test (usage test).

#### 3. Results

The final five samples were selected through comparative studies with the corresponding commercial cosmetics using irritation tests in laboratory animals and humans. Furthermore, the safety of these samples was confirmed by the following:

(1) In the closed patch test on patients with skin diseases, the positive frequency of test samples was lower than those of the corresponding commercial products as controls (figs. 4 and 5).

(2) The accumulative irritation and sensitization were not detected in any sample by repeated insult patch test and maximization test in humans (table 7).

(3) Two months practical application of five test samples applied on 172 healthy volunteers produced mild reactions in only three cases.

(4) In practical application tests performed on 211 patients with skin diseases, about 90 percent of all subjects could use each sample with safety. (table 8).