

〈原 著〉

皮膚刺激性試験における試験使用動物数の削減について ——2段階判定法の検討——

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Reduction of Group Size in Animal Experiments for Skin Irritation Tests — Proposal of a two-step method —

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Abstract

Recently, the 3R principle of replacement, reduction, and refinement has been prompted by the animal rights movement. This paper investigated the possibility of reducing the number of animals used in skin irritation tests (Single topical application: Guinea pigs), by proposing a two-step method to realize the reduction without decreasing the precision of judgment. The proposed method uses, in the first step, three animals in an experiment instead of the conventional five-animal experiment to evaluate the irritancy of test chemicals, and replicates, as the second step, the experiment only when the observed mean irritation score is near the predetermined critical value or the variability in scores among the animals is greater than a certain constant. The effectiveness of the proposed method was evaluated from two aspects, *i.e.*, the empirical and the theoretical aspects. In the former, the application of the proposed method to historical data accumulated in a laboratory revealed that about a 30% reduction in the number of animals was possible by the proposed method compared with the conventional procedure. A similar conclusion was induced from a theoretical model based on a prior distribution on the irritancy of test chemicals.

Key words: skin irritation, reduction in numbers, animal alternative study, statistical analyses.