Establishment of new in vitro eye irritation test method using the reconstructed human corneal epithelium, LabCyte CORNEA-MODEL

Masakazu KATOH, Fumiyasu HAMAJIMA, Takahiro OGASAWARA, Ken-ichiro HATA
Japan Tissue Engineering Co., Ltd., Japan

In vitro eye irritation testing, which is alternative to animal testing such as Draize eye test using rabbits, is required from an animal welfare. We have developed the reconstructed human corneal epithelium model, LabCyte CORNEA-MODEL, and investigated a test method to evaluate eye irritation effect using this model. In this presentation, we report about an optimization of eye irritation test method using LabCyte CORNEA-MODEL and about the prediction potency of an optimized LabCyte CORNEA-MODEL eye irritation test. In evaluating the cell viability and the barrier function of LabCyte CORNEA-MODEL among inter- or intra-lots, there was little difference in each lot and showed good reproducibility. From the results of several optimization experiments of eye irritation test using LabCyte CORNEA-MODEL, the application periods of chemicals were set to 1 minute for liquid chemicals and 24 hours for solid chemicals, and the post-incubation periods were set to 24 hours for liquids and nothing for solids, respectively. If the viability was less than 50%, the chemical was judged as eye irritant. Sixty one chemical substances were applied to the optimized protocol using LabCyte CORNEA-MODEL and the correlation with in vivo class was evaluated. The prediction of the new eye irritation test methods using this model was highly correlated with in vivo eye irritation (sensitivity 100%, specificity 80.0%, and accuracy 91.8%). From these results, it was suggested that the eye irritation test using LabCyte CORNEA-MODEL could be a useful alternative method to Draize eye test for variety of chemicals with irritant potency.