USE OF THE EPIOCULAR ASSAY FOR PRECLINICAL QUALIFICATION OF FORMULAS FOR HUMAN CLINICAL STUDIES

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Cosmetic products applied around the eyes must be extremely mild because of the sensitivity of the skin in this region and the chronic use of such products. The topical application, assay using the EpiOcular tissue construct (Ghassemi et al 1997), is being extensively evaluated for the prediction of product mildness. In this study, we report the correlation between ET50 (exposure time required to reduce cell viability to 50%) responses in the EpiOcular assay and eye-area irritation in human clinical testing. Formulations were applied neat to the EpiOcular construct (MatTek) for up to 4 hours or 20 hours (depending on the expected degree of irritancy) and the ET50 of the water-treated controls were measured using tetrazolium dye (MTT) reduction. The EpiOcular assay was used as part of the preclinical qualification of products for subsequent in vivo studies. The in vivo studies were safety-in-use studies performed to evaluate eye irritation potential in individuals with self-perceived sensitive eyes or who were contact lens wearers. These studies are intended to evaluate eye-area products under “real-world use.” These studies were conducted under the supervision of an ophthalmologist. The ophthalmologic evaluation included a gross exam, slit-lamp exam, and visual acuity exam. After baseline exams, subjects were instructed to use the eye area formulation over the next several weeks. Final examinations were conducted to determine eye irritation after the use period. The eye irritation scale ranged from no irritation (0) to severe irritation (4). Ten eye area products were evaluated in the EpiOcular assay with ET50 values ranging from >240min to >1440min. Products with ET50 values >240min were evaluated clinically and showed no to minimal irritation in the clinical studies. These observations establish that the data from an EpiOcular assay lend support to the results of an in vivo assessment of the product. In addition, the lack of ocular irritation potential established, by these studies also indicate that the product is not likely to induce dermal irritation.

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