PREVALIDATION OF A HEMI-CORNEAL MODEL FOR CORNEAL SAFETY AND PERMEABILITY TESTING

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Made possible by financial support granted by the Centre for Documentation and Evaluation of Alternatives to Animal Experiments (ZEBET), we have developed a hemi-cornea model to provide a tool for corneal safety- and transcorneal drug permeability testing, in order to replace animal experimentation. The hemi-corneal model is exclusively based on human corneal cell lines cultured under serum-free conditions, which have been optimized for the maintenance of functional and structural characteristics of the tissue.

The use of this hemi-cornea for corneal safety testing involves topical application of test materials to the surface of the epithelium and the subsequent assessment of their effects on cell viability using the MTT assay. For determination of the transcorneal drug permeation the permeation coefficients of aqueous solutions of test compounds are calculated.

Recently, the hemi-cornea project entered the prevalidation phase to prove collaboratively with industry partners the applicability of hemi-cornea models in eye irritation testing and transcorneal drug permeation studies.

This includes:

- inter-laboratory method transfer for the hemi-cornea construction,
- assessment of the reproducibility of the hemi-cornea construction (intra- and inter laboratory variability) in all participating laboratories,
- definition of a preliminary prediction model for eye irritation and transcorneal permeation,
- transfer for the test protocols.

Keywords: hemi-cornea, corneal irritation, transcorneal permeation, prevalidation