



Long Term Reproducibility of In Vitro Reconstructed Skin Models for Regulatory Testing Purposes – Evidence of Good Tissue Culture Practice

Helena Kandarova, Mitchell Klausner, Joseph Kubilus, Paul Kearney, Patrick Hayden, Yulia Kaluzhny and John Sheasgreen
MatTek Corporation, Ashland, MA.

Validated *in vitro* methods are urgently needed as alternatives to animal testing for compliance with REACH and EU Cosmetics Directive legislation. Some of the *in vitro* assays/tissue models have been, or are being, formally validated for use in testing for corrosivity, irritation or toxicity. However, regulatory agencies and other users require assurance that models will provide consistent, quality data over time, not just during validation (Gupta et al., 2005). Recommended guidelines for good cell/tissue culture practice include e.g. full characterization of cells or tissues, sampling of each lot for performance, and regular use of controls and benchmark chemicals to provide assurance of the consistency in performance of the models and assays (Cooper-Hannan et al. 1999, Coecke et al., 2005, Rispin et al., 2006).

One demonstration of good cell/tissue culture practice for commercially manufactured skin models is their long-term reproducibility and consistence performance in validated test assays. In compliance with GMP and ISO standards, MatTek Corporation evaluates the quality of each lot of commercially manufactured product. The release criteria include: viability determination, proof of product sterility, screening of histology and evaluation of the barrier properties of the model using the MTT ET-50 assay with the benchmark chemical Triton X-100. Acceptance and rejection criteria have been established for each *in vitro* product and are strictly adhered to.

The presented poster summarizes data showing long-term reproducibility of EpiDerm and EpiOcular reconstructed tissue models. Quality controls for each tissue lot of EpiDerm and EpiOcular were performed and the yearly averages have been calculated. Since 1997, EpiOcular's yearly average ET-50 values ranged from 20.6 minutes to 25.0 minutes. Coefficients of variation for negative control tissue have averaged under 6% for the entire historical data set. The yearly average CV for all tissues never exceeded 6.5%. For EpiDerm, the yearly average ET-50 ranged from 6.0 to 7.5 hrs. The CV for the negative control tissue averaged under 7.5% for every year since 1996. Results of quality control data for commercially available products, manufactured over the past 10 years have address regulatory concerns regarding long-term reproducibility and have fulfilled of the standards for good cell/tissue practice.

Keywords: REACH, EpiDerm, EpiOcular, long-term reproducibility, good cell/tissue culture practice

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