



Regulatory Requirements for In Vitro Systems to Meet Performance Standards Over Time as well as During Validation

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ABSTRACT

In vitro models are being proposed as alternatives to animal testing for safety evaluation of cosmetics, pharmaceuticals and consumer products. Currently available organotypic human models include dermal (EpiDerm, EpiDerm-FT), ocular (EpiOcular), ectocervical (EpiVaginal) and airway (EpiAirway). Some of these models have been, or are in the process of being, formally validated for testing of corrosivity, irritation or toxicity. However, regulatory agencies and other users also need to be reassured that the models will provide consistent, good quality data over time, not just during the validation process (1). Recommended guidelines include "full characterization of cells or tissues, sampling of each lot ... for performance, and regular use of controls and benchmark chemicals to provide assurance of consistency of assay performance" (2). The current poster summarizes the long-term reproducibility and performance of in vitro epidermal (EpiDerm) and ocular (EpiOcular) models against benchmark chemical treatment. Quality control of weekly batches of EpiDerm and EpiOcular was performed using the MTT assay. The exposure time needed to reduce the viability to 50% (ET-50) for Triton X-100 was determined. For EpiOcular, the yearly average ET-50 values have ranged from 20.6 minutes to 25.0 minutes. The coefficients of variation (CV) for the negative control tissue (exposed to ultrapure H₂O) have averaged under 6% for every year since 1997. In addition, the yearly average CV for all tissues has never exceeded 6.5%. For EpiDerm, the yearly average ET-50 values have ranged from 6.0 hrs to 7.5 hrs. The coefficients of variation (CV) for the negative control tissue (exposed to ultrapure H₂O) have averaged under 7.5% for every year since 1996. These results over the past 10 years of commercial production are designed to address regulatory concerns regarding performance standards over time.

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