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**Abstract-Title:**

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

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**Abstract-Text:**

**Purpose:** In vitro tissue models have been or are being validated 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). Regulatory agencies and other users need to be assured that models will provide consistent, high quality data over time, not just during the validation process (K. Gupta et al., Regul Toxicol Pharmacol. 2005 Dec;43(3):219-24). 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" (A. Rispin et al. Regul Toxicol Pharmacol. 2006 Jul;45(2):97-103). **Methods:** Long-term reproducibility and performance data from the past 14 years of commercial production of in vitro epidermal (EpiDerm) and ocular (EpiOcular) models is compiled. Quality control testing against benchmark chemical treatment of weekly batches of EpiDerm and EpiOcular was performed using the MTT assay. The exposure time needed to reduce viability to 50% (ET-50) for Triton X-100 was determined. **Results:** For EpiOcular, yearly average ET-50 values have ranged from 22.0 minutes to 27.3 minutes. Coefficients of variation (CV) for negative control tissues have averaged under 6% for every year since 1997. In addition, the yearly average CV for all tissues has never exceeded 6.7%. For EpiDerm, yearly average ET-50 values have ranged from 5.9 hrs to 7.5 hrs. The CV for negative control tissues have averaged under 7.5% for every year since 1996.