

NICEATM Poster Presentation

Society of Toxicology 44th Annual Meeting

March 6 - 10, 2005

New Orleans, LA

Validation Status of the Bovine Corneal Opacity and Permeability (BCOP) Test Method

C. Inhof^{1,2}; N. Choksi^{1,2}; D. Allen^{1,2}; J. Truax^{1,2}; R. Tice^{1,2}; W. Stokes¹

1. NICEATM, NIEHS, Research Triangle Park, NC, USA.

2. ILS, Inc., Research Triangle Park, NC, USA.

Concerns about animal welfare and an interest in higher throughput testing have led researchers to develop alternative *in vitro* test methods for the current rabbit eye test. NICEATM evaluated four *in vitro* ocular test methods for their ability to identify substances that cause irreversible or severe irritation or corrosion. One of these test methods, BCOP, is an organotypic model that provides short-term maintenance of normal physiological and biochemical function of the cornea in an isolated system. The ability of BCOP to correctly identify ocular corrosives and severe irritants using available BCOP and corresponding *in vivo* eye irritation data was evaluated according to current hazard classification schemes for the U.S. EPA (n=101), the European Union (n=141), and the UN Globally Harmonized System (n=104). Depending on the classification scheme used, BCOP had a false positive rate of 20-26%, and a false negative rate of 22-26%. In terms of reliability, the assay was determined to have acceptable intra- and inter-laboratory reproducibility. A proposed standardized test method protocol and a proposed recommended list of reference substances have been developed for future validation and testing studies to further assess the accuracy, reliability, and the applicability domain of BCOP for the detection of ocular corrosives/severe irritants. Investigators should consider using BCOP prior to eye irritation testing in animals. BCOP may be useful in a tiered testing strategy where positive results can be used to classify and label a substance, while substances with negative results would undergo additional testing to identify false negative ocular corrosives/severe irritants and to identify those chemicals with reversible ocular effects. This approach would reduce the number of animals used for eye irritation testing and reduce the number of animals experiencing pain and distress. ILS staff supported by NIEHS contract N01-ES 35504.

SOT Itinerary Information:

ID# 2005
Location: Ballrooms A & B
Date/Time: March 10, 2005 / 8:30 - 11:30 AM
Category: Alternatives to Mammalian Models