

## Eye Irritation : In-Vivo - 10 Subject

In-vivo eye irritation test based on the Draize Test, but using human subjects.

### Alternatives or Additions

- Half subjects who are contact lens users.
- Several colours of the same formulation can be composited.

### Experimental Design

**Subjects:** Panels of 10 subjects, male and female, randomly selected.

- Informed of the nature of the test including possible adverse reactions.
- Written informed consent documents signed by all participants prior to induction.
- Parental consent will be obtained from minors.
- Only subjects that are considered dependable and able to read, understand and follow directions will be requested to participate.
- Prior to initiation of a test, each subject will complete a medical history form. The subjects will not exhibit any physical or dermatological condition which would preclude application of the test material(s).

### Test Material Information:

A sufficient quantity of each test material should be submitted by the sponsor.

Please forward liquids - approx. 50ml ; powders, semi-solids - approx 50g

Product must be submitted with documentation indicating appropriate preservative efficacy.

### Method

- Microlitre quantities diluted or undiluted, instilled directly into the eye.
- 24 hrs following application of the product, subjects return to the facility for evaluation of test sites by trained laboratory personnel.

**Evaluation** by visual examination of :

Cornea : Opacity, area involved, degree of density. Most dense area is taken for reading.

Iris : Folds, congestion, swelling, reaction to light.

Conjunctivae : Redness: (refers to

Vessels

Chemosis: Degree of swelling.

Discharge : Degree.

### Reporting:

The final report, scored against standard scale, will include: purpose, test materials, panel selection and demographics, experimental design, results and conclusions. Results of dermal responses will be presented in tabular form.

### References

Draize J. H., Woodward, G & Calvery H.O. J. Pharmacol. Exp. Ther. 82, 377-390.

CTFA Safety Testing Guidelines CTFA Aug 1991

Internal Test Protocol.