
NEW ASPECTS OF THE SLUG MUCOSAL IRRITATION (SMI) ASSAY: PREDICTING OCULAR STINGING, ITCHING AND BURNING SENSATIONS

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BACKGROUND AND AIM OF THE PROJECT

The Slug Mucosal Irritation (SMI) assay was initially developed to predict the mucosal irritation potency of pharmaceuticals using the terrestrial slug *Arion lusitanicus*. In a later phase, it was also applied as an alternative for the Draize test (rabbit eye irritation test) to test chemicals and cosmetics.

Eyes are very sensitive to stinging, itching and burning (SIB) sensations. A screening method for ocular discomfort would be very helpful in the development and refinement of ocular formulations. The aim of this study was to investigate whether the SMI-test could also demonstrate a relation between an increased mucus production (MP – expressed as % of initial body weight) in slugs and an elevated incidence of SIB sensations in human eyes, using shampoos as test substance. Hence, we will be able to improve the newly developed protocol and examine its predictability with reference to non- and mildly irritating formulations in humans.

DEVELOPMENT OF THE PROJECT

Shampoos were selected to set up this pilot study since these surfactant-based rinse-off personal care formulations are generally mild to moderate eye irritants and are frequently being used by the majority of the population. Some preliminary results of the SMI-test made a clear distinction between certain surfactant-based formulations, with their composition and certain ingredients playing a very important role.

The stinging potency of an artificial tear (Art-Tear) and 5 shampoos (A-E) was evaluated with the SMI-test by placing 3 slugs per treatment 3 times on 100 μ l of the test item. After each 15-min contact period (CP), MP was measured. Evaluation of the results is based upon the total MP during the 3 repeated CPs. Experiments were repeated 3 times. Additionally, a human eye irritation test (HEIT - study approved by an independent Commission for Medical Ethics, associated with University Hospital Ghent, Belgium) was set up: 24 participants were dripped 10 μ l of a shampoo dilution in water or an artificial tear in one eye, while in the other eye 10 μ l of water was instilled as a control. Eval-

uation of the test items was performed both by participants (self evaluation: no discomfort = 0, to very severe SIB = 5) and an ophthalmologist (clinical evaluation) at several time points (30 sec up to 30 min) and total scores were calculated.

Preliminary analyses show that (1) ArtTear was best tolerated (total MP < 3% (SMI); median total score 0 (HEIT)); (2) MP and scores for shampoos were clearly higher than for ArtTear and water; (3) A was the best tolerated shampoo in both tests (total MP 3.4%; median total score 1), while B, C and D resulted in a more pronounced reaction in slugs (total MP 3.8%-5.8%), with variability in the scoring behavior of the participants (median total scores 7.5-9); (4) E induced the highest MP in slugs (8%) and received the highest scores for immediate discomfort; (5) in the HEIT, the clinical evalu-

ation of the ophthalmologists did not correlate well with the self evaluation of the participants. These results indicate that the SIB protocol of the SMI-test is a good tool to predict clinical ocular discomfort with reference to non- and mildly irritating formulations in humans.

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