



Human Vaginal-Ectocervical Tissue Model for Testing the Irritation Potential of Vaginal-Care Products

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ABSTRACT/ INTRODUCTION

The utility of organotypic vaginal-ectocervical (VEC) tissue models to test the irritation potential of vaginally applied chemicals and their formulations were examined. To achieve this goal, in vitro VEC tissues were reconstructed using normal human VEC epithelial cells. The MTT assay was used to determine the exposure time necessary to decrease the tissue viability to 50% (ET50) for the controls and 20 commercially available test articles. In MTT assay, Triton X-100 (1%) and ultrapure water were used as positive and the X negative controls, respectively. The MTT % viability, histology, RT-PCR, and cytokine release patterns were used as endpoints. The results showed that the VEC tissue models have basal, parabasal, glycogenated intermediate, and the superficial cell layers. QC testing showed the tissues to be highly reproducible; the average intra-lot coefficient of variation (CV) was less than 10% and ET-50s averaged 1.40 hr \pm 0.26 (n=55 lots). Upon exposure to test articles, the tissue model was able to discriminate between the mildness of test articles. The ET50 values ranged between 3.5-7.0 hr for contraceptives, between 6.9->18 hr for anti-itch creams, and between 1.7-2.7 hr for feminine washes. Released cytokines and Gene expression levels showed that IL-1 α , IL-1 β , IL-6, and IL-8 were associated with toxicity of test materials. In conclusion, the VEC tissue models will serve as useful, highly reproducible, non-animal tools to assess the irritation potential of vaginally applied chemical and their formulations. Development of such in vitro test models are in line with the new European Union chemicals policy known as REACH. The skin and the mucosal environment are continuously exposed to a broad variety of chemicals in the form of medicaments, metals, fabrics, cosmetics, topically applied ointments, food preservatives, perfumes, vehicle emulsifiers, and day-to-day use household products, all of which are potential contact allergens. Currently, more than 100,000 chemicals are in commercial use and another 2,000 new chemicals are produced every year. Therefore, evaluation of allergenicity is important to minimize the hazards of occupational and public exposure to chemicals and products.

To be presented at EUROTOX 2007, October 7-10, 2007, in Amsterdam, The Netherlands