

## **MVA Scientific Consultants**

### **Report of Results: MVA6158 Patch Permeability**

Two LifeWave “patch” products, one brown patch and one white patch, were hand delivered to MVA Scientific Consultants on 8 November 2004. MVA Scientific Consultants was asked to examine the patch product to determine whether or not the adhesive-backed polyethylene film allowed the water soluble compounds contained in the patch products to migrate out of the patch product where they could potentially be absorbed into the skin of a person wearing a patch product. Additional patches were hand delivered to MVA Scientific Consultants on 19 November 2004. The work was performed from 12 November 2004 to 22 November 2004.

The patches were examined utilizing a combination of reflected brightfield microscopy, reflected darkfield microscopy, transmitted brightfield microscopy, scanning electron microscopy (SEM) and Fourier transform infrared microspectroscopy (FTIR). A reagent was chosen, based on information provided by the manufacturer, that would react with substances present in the brown (glucose) patch and in the white (glycerin) patch. The reagent chosen reacts with glycerin and with glucose to form a white precipitate. Sample patches at room temperature, sample patches heated to 40 degrees Centigrade for one hour and sample patches exposed to approximately 500 millitor of vacuum were tested by applying reagent to the adhesive side of the patch after removal of the release paper. The presence of a white precipitate would indicate that water soluble components contained in the blister area of the patch had migrated across the polyethylene-adhesive film and were available for absorption by the skin of a person wearing the patch.

Based on my examinations and testing of the construction of the white and brown patch products, I would not expect the water soluble components that reside within the patch products to migrate across the polyethylene film and be available for absorption through the skin of a person wearing the white or brown patch product.