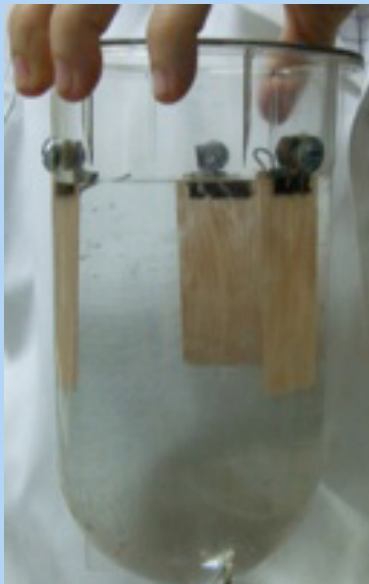




STEPS



Water Resistance In vitro Qualitative

A good indicator of likely performance when tested in vivo

Sample Preparation

Moulded PMMA plates, 50mm x 50mm, with 6µm roughness are used. The weight of each test plate is recorded before any test product is applied. 1.3 mg/sq. cm + 0.1 mg/sq. cm of test product is applied using light finger pressure to obtain an even film. The plates with applied products are allowed to dry in the dark at room temperature for 15 minutes. A known water resistant product, COLIPA P2 High SPF Reference Product, is used as a comparator.

is then filled with water until the plates are completely immersed. The apparatus temperature is set at 34°C, with the motor speed set to 15 rpm and allowed to stir for the nominated duration of the test, equivalent to intended in-vivo water resistance.

Post Immersion Analysis

At the completion of the test, the dissolution pot is removed from the apparatus and emptied. The test plates are then carefully removed to avoid disturbing the product film and allowed to dry at 35°C for two hours. The plates are then tested as per the pre immersion analysis.

Test Results

The percentage change of SPF and Curve Area (Abs) is determined by: (Pre immersion result – Post immersion result) x 100.

Pre immersion result

If the % change in the test product result is less than that of the water resistant comparator, the test product is likely to be water resistant *in-vivo*. A greater % change means the test product is less likely to be water resistant *in-vivo*. This should always be confirmed via *in-vivo* testing.

References

1. COLIPA Method for the in-vitro Determination of UVA Protection Provided by Sunscreen Products Guideline 2007.
2. DESOP - 093 Qualitative Evaluation of in-vitro Water Resistance of Sunscreens.

Pre Immersion Analysis

The test plates are then analysed using the Labsphere 2000 Spectrophotometer. Four scans are performed on each plate. One edge of the plate is marked to ensure the plate is aligned in the same direction in the post immersion analysis. This ensures

the same spots will be analysed. When the "Assay" results have been obtained, the values obtained for product SPF and Curve Area (Abs) are recorded.

Product Immersion

The test plates are then clipped into a modified dissolution pot, which is then immersed in a Sotax dissolution apparatus. Each pot, which can hold up to three samples,



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