TEST CODE:
CT-022

In Vitro Test for the Regulation of Skin Pigmentation

MELANODERM™ METHOD

OVERVIEW

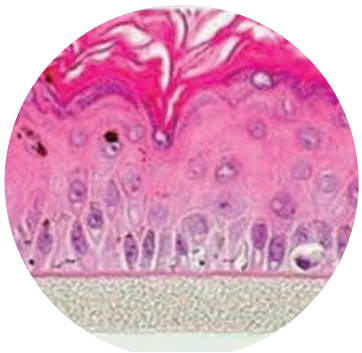
The ability to regulate human skin pigmentation has become an important characteristic of active ingredients for a variety of cosmetic products, including those designed for skin lightening, self-tanning or the correction of dark spots / blemishes.

The MelanoDerm™ human skin model provides a highly effective, animal-free means of assessing skin pigmentation, providing mechanistic and human-relevant data. It provides a quick and cost-effective pre-screen, prior to human volunteer studies, driving key decisions in formulation development. The test is used to assess novel active ingredients and formulations, providing critical insights into the mildness of the product and comparisons with leading brands.

MelanoDerm™ consists of human keratinocytes and melanocytes working together to closely model the physiology of human skin pigmentation. The test allows direct application of ingredients or formulations to the skin surface for specified dosing periods. The MelanoDerm™ models are viable for up to two weeks in culture, providing the potential to extend test protocols where relevant. Following exposure to the test item, pigmentation is recorded using photographic techniques to provide a qualitative assessment, followed by extraction of melanin from the skin models and quantitative analysis by spectrophotometry. Comparisons with untreated controls, along with benchmarks built into the study, enable an accurate evaluation of pigmentation-regulating qualities in the item being tested.

TEST SYSTEM: MELANODERM™ RECONSTRUCTED HUMAN EPIDERMIS WITH MELANOCYTES

MelanoDerm™ is a skin model composed of living human keratinocytes which have been cultured to form a multi-layered, highly differentiated epidermis. The model includes a functional skin barrier with an *in vivo*-like lipid profile. Human melanocytes are incorporated into the epidermis in an approximate ratio of 1 melanocyte to 10 keratinocytes, where they locate to the basal layer, closely simulating real-life conditions. This enables close interaction between the two cell types, which is known to be a critical factor in regulating melanin production and pigmentation. Variations of the model are available using melanocytes derived from donors of different ethnic origins, increasing the direct relevance to target groups for specific products. MelanoDerm™ is grown on special platforms at the air-liquid interface, allowing for direct application of ingredients or formulations in a way that accurately models “real life” skin exposure.



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CT-022/02-05/18

XCellR8 Redefining testing

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SUMMARY OF THE TEST METHOD

Preliminary testing:

- Prior to the skin lightening assay, a cytotoxicity assay is performed using the EpiDerm™ skin model, ensuring that the test item is not toxic to the cells for the duration of the study.
- The test item is applied to the tissue surface for 2 and 7 days. In parallel, sterile water is applied for 48 hours as the negative control. Tissue viability is then assessed using the metabolic dye "MTT".

MelanoDerm™ test:

- MelanoDerm™ skin models are exposed to ingredients or formulations applied to the tissue surface 3 times per week, up to a maximum of 14 days.
- The negative control (sterile water) and the positive control (kojic acid) are applied to parallel skin models for the same period of time.
- At the specified time points (eg 3, 7, 10 and 14 days), pigmentation is assessed qualitatively by photographing the surface of the models, and quantitatively by extraction of melanin and comparison to a standard curve.

COSMETIC CLAIMS SUPPORTED	*Self-tanning, Skin lightening, Dark spot correction*
TURNAROUND TIME	*8 – 12 weeks*
AMOUNT OF SAMPLE REQUIRED	*Minimum 10ml (liquids) / 10g (solids)*
PRICE	*Our test prices are dependent on the quantity of test items. Please enquire for a quote using the contact information shown below, or the contact form on our website.*
FURTHER DOWNLOADS	XCellR8 Good Laboratory Practice (GLP) Compliance Certificate.

QUALITY STATEMENT

XCellR8 is accredited by the UK Medicines and Healthcare Products Regulatory Authority (MHRA) for the conduct of *in vitro* safety testing in compliance with Good Laboratory Practice (GLP). This means that we are able to provide you with test results that may be used at a regulatory level to demonstrate product safety, where the test is an approved regulatory method. The test method described here is non-regulatory but is conducted in our GLP-accredited laboratory.

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