Phototoxicity 3D SKIN model

Photo3D assay

"Phototoxicity is defined as a toxic response from a substance applied to the body which is either elicited or increased (apparent at lower dose levels) after subsequent exposure to light, or that is induced by skin irradiation after systemic administration of a substance" (OECD TG 432, 2004).

The interaction of an exogenous substance in the skin (systemic drug or topically applied substance) with ultraviolet radiation can result in a phototoxic reaction that typically resembles sunburn. "Acute phototoxic reactions are

The aim of this assay is to predict the cutaneous phototoxic potential of any chemical, raw materials or drug substances in direct contact with reconstructed human epidermis,

In Vitro Toxicity

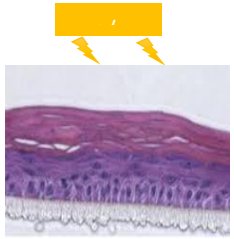
Principle of the assay:

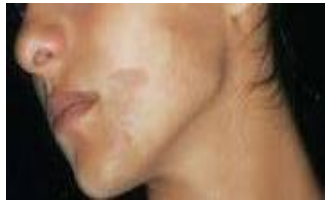
The **Photo3D assay** evaluate the dermal phototoxicity effect of a wide range of substance types by topical UVA exposure of reconstructed Human epidermis.

The basis of the in vitro RHE phototoxicity test is a comparison of the cytotoxicity effect of a test item on Reconstructed Human Epidermises when tested in presence and in absence of exposure to a non-cytotoxic dose of UVA light.

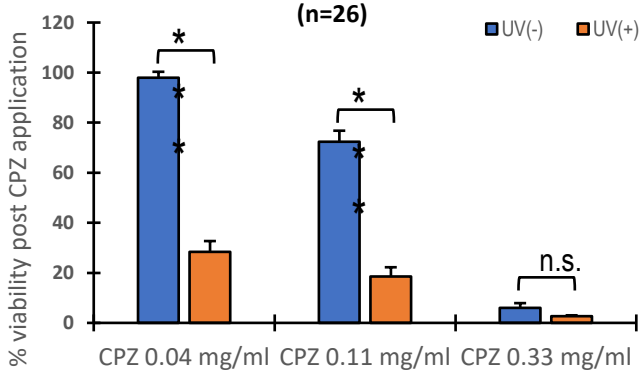
The percentage of viability of the treated tissues is calculated with respect to a negative control. The difference of viability between the two conditions (exposed and non-exposed) allows to classify the test item: if this difference is >30%, this test item is considered as phototoxic.

The performance of the in vitro RHE phototoxicity test instead or in addition to the standard 3T3 NRU assay is required by the sponsor based on the intrinsic characteristics of the test substance. This assay is adapted to both raw materials and final product testing and is particularly adapted to the testing of substance difficult to solubilize in aqueous solvent.





Historical data:
RHE viability (%) after Chlorpromazine application (n=26)



Delivrables

- Classification of the test substance: non-Phototoxic or Phototoxic

- EC50 (+/-UVA): concentration of test material that causes a 50% decrease in viability, relative to the solvent control; in the presence and in the absence of UVA exposure.

Answers to FAQ

- Formats available : screening and "in the spirit of GLP"

- Test system : 3D reconstructed Human Epidermis : RHE (Skinethic) or Epiderm (Mattek)

- **Test conditions :**
- **Appropriate solvent search for susbtance application**
- **Test concentration to be defined with the Sponsor exposed and non-exposed to UV-A**

- Controls : Air, Background, Vehicle Chlorpromazine (Positive control)

- Results : 10 days after study acceptance

- Report (for GLP studies): 1 month after study acceptance

- Test substance requirements:

- 1g or 1 ml for GLP studies