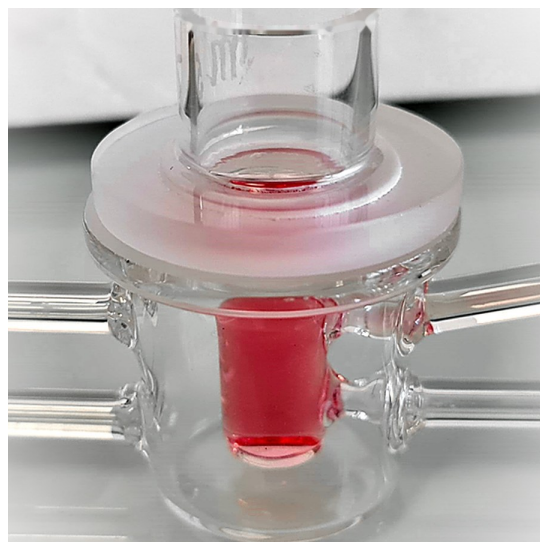


IVPT STUDY DESIGN

Skin	Ex vivo human skin, ethically sourced. Full-thickness, dermatomed, or heat-separated epidermis. Intact or barrier-impaired.
Membrane QC	Thickness measured on every disc. Barrier integrity verified before dosing (TEWL); discs outside acceptance criteria are rejected.
Diffusion cells	Static Franz-type cells, temperature-controlled to 32 °C at the skin surface, continuous stirring.
Receptor fluid	Selected and justified for each compound; sink conditions demonstrated.
Dosing	Finite or infinite dose, applied topically. Vehicle and formulation comparisons supported.
Sampling	Serial receptor sampling to 24 h, longer on request.
Mass balance	Surface wash and swabs · tape stripping (stratum corneum) · epidermis · dermis · receptor fluid · cell wash.
Quantification	LC-MS/MS at qualified partner laboratories, or liquid scintillation counting (LSC) for radiolabelled test items.
Data reported	Cumulative amount permeated, maximum flux (J_{max}), lag time, permeability coefficient (K_p), and mass balance recovery.
Design	Number of donors and replicates set according to the study objective and the regulatory route.

SPECIALITY — DAMAGED SKIN

Disruption by **tape stripping**, **abrasion**, **microneedling** or **SDS**, against the intact control from the same donor.



Human skin mounted on a Franz-type diffusion cell

REGULATORY CONTEXT

OECD TG 428	Skin Absorption: In Vitro Method
OECD GD 28	Guidance Document for the Conduct of Skin Absorption Studies
OECD No. 156	Guidance Notes on Dermal Absorption, 2nd edition (2022)
SCCS/1358/10	Basic criteria for the in vitro assessment of dermal absorption of cosmetic ingredients, with the SCCS Notes of Guidance in force
FDA (draft, 2022)	In Vitro Permeation Test Studies for Topical Drug Products Submitted in ANDAs
EFSA (2017)	Guidance on dermal absorption — plant protection products

EX VIVO SKIN EXPLANTS — ADDITIONAL ENDPOINTS

Viable human skin explants maintained in culture, treated topically or through the medium. Run alone, or alongside an IVPT study on skin from the same donors.

Barrier function TEWL · Lucifer Yellow penetration by fluorescence microscopy and image analysis	Anti-aging Extracellular matrix and dermal–epidermal junction markers	Inflammation Cytokine and inflammatory mediator release
Pigmentation Melanin content and melanogenesis markers	Wound healing Re-epithelialisation and repair kinetics	Safety Viability, irritation and tolerance endpoints

Readouts across both models: histology and immunostaining · biomarker quantification · gene expression.

WHY PKDERM

Animal-free by design. An independent French CRO built entirely on human-relevant in vitro and ex vivo models. Damaged-skin models characterised in Barthe M. et al., *Systematic characterization of the barrier function of diverse ex vivo models of damaged human skin*, Front. Med. 2024;11:1481645. Two patents held by PKDERM. Contributor of the human precision-cut lung slice work in Matralis A.N. et al., *Cell Rep. Med.* 2026;7:102778. Scientific consultancy and hands-on training available.

WHAT YOU RECEIVE

Study protocol Agreed with you before start, with acceptance criteria stated up front	Raw and processed data Full data set, calculations and quality-control records
Study report Interpretation, figures and conclusions for your regulatory or claim file	Scientific support Discussion of results and advice on the next study