

Percutaneous Absorption

In vitro Release Test and Trasdermal Permeation of topical formulations by Franz diffusion cells



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IN VITRO RELEASE TEST

- Optimization and comparison of different formulations during formulation development phase.
- Development and validation of release rate methods for topical formulations.
- Quality control for *in vitro* release of manufacturing batches

In vitro method development in compliance with SUPAC-SS and FDA requirements. *(Guidance for Industry: SUPAC_SS: Nonsterile Semisolid Dosage Forms. FDA, 1997)*

IN VITRO PERMEATION TEST

- Determination of percutaneous absorption including flux rates and transdermal permeability of the active compounds.
- Penetration studies :
 - · Quantification of the API remaining in the skin
 - · Penetration in mucous membranes
 - · Penetration in cornea
- Applications:
 - · Optimization and comparison of formulations
 - · Selection of suitable excipients
 - · Selection of lead candidate formulations for topical products
 - · Assessment of safety of cosmetic actives

Permeation studies are performed in accordance with OECD and EMA guidelines (*Guideline for the testing of chemicals. Skin absorption: in vitro method. OECD 428, 2004; Guidance document for the conduct of skin absorption studies. OECD 28, 2004; EMA Guideline on quality of transdermal patches. EMA, 2014*)



