

## **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*)



