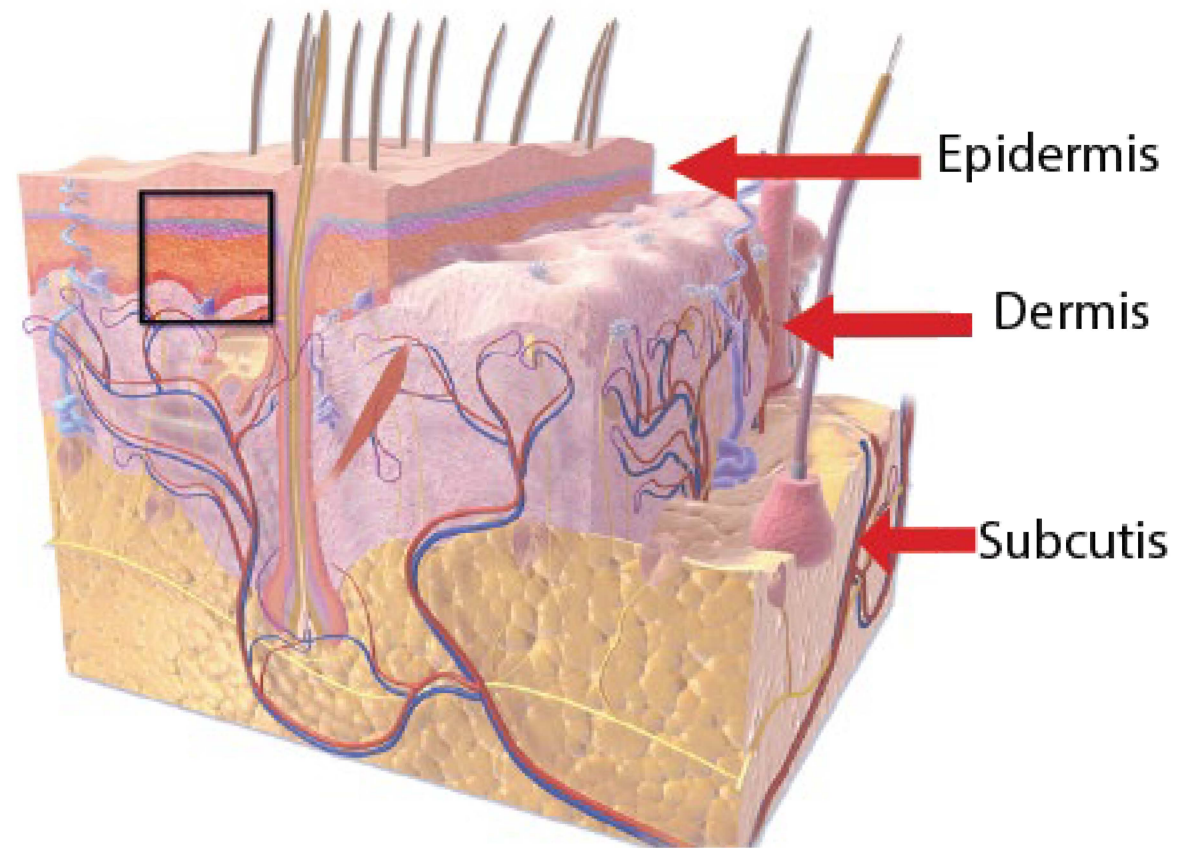


In Vitro Permeation Testing (IVPT)

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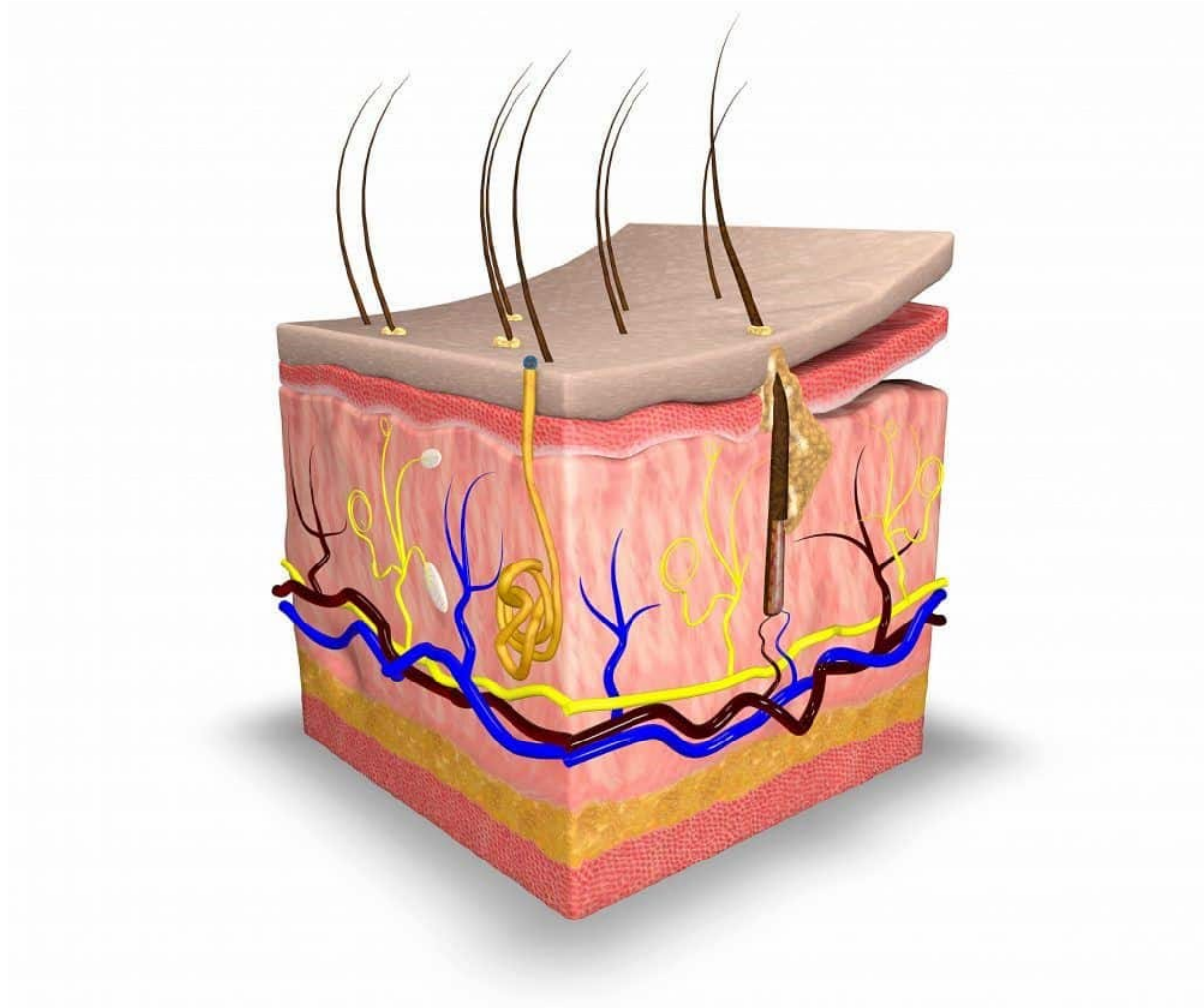


What is IVPT?

- A laboratory test used to measure the permeation of active pharmaceutical ingredients through the skin, attempting to simulate real-world conditions.
- May be used comparatively with different products to demonstrate bioequivalence between some generic and reference topical drug products.



Human Skin



Q1 Q2 Q3 Sameness

- Q1 – Quantitative
- Q2 - Qualitative
- Q3 – Physicochemical structure
- Sameness – as defined by measurement standards, measurement error, allowable batch variability



The importance of Q3

- Q3 is the basis for the "look and feel" of a product.
- Greater degrees of freedom with emulsion/mixed phase formulations
- Includes particulate and globule considerations, viscosity, metamorphosis (absorption, drying), drug-emulsion compartment



Why is IVPT important clinically?



- Evaluates comparatively the permeation of the active ingredient across a sample of human skin – a bioequivalence assay.
- Important for non-Q1 same, non-Q2 same formulations, provides bioequivalence parameter that considers skin permeation especially important for multiphase topical that has site of action in the skin.
- Ensures that generic products provide the same therapeutic effect as branded products, especially in terms of absorption and drug delivery.



Workshop Goals

- IVPT Method Procedures: Challenges and Solutions
 - What are common challenges
 - Step-by-Step Process of an IVPT study including practical demonstrations
- Critical Considerations and Best Practices
 - Considerations for method development and validation
 - Best practices for handling issues with IVPT studies
 - Skin sample variability
 - Challenges in handling formulations
 - Apparatus inconsistencies