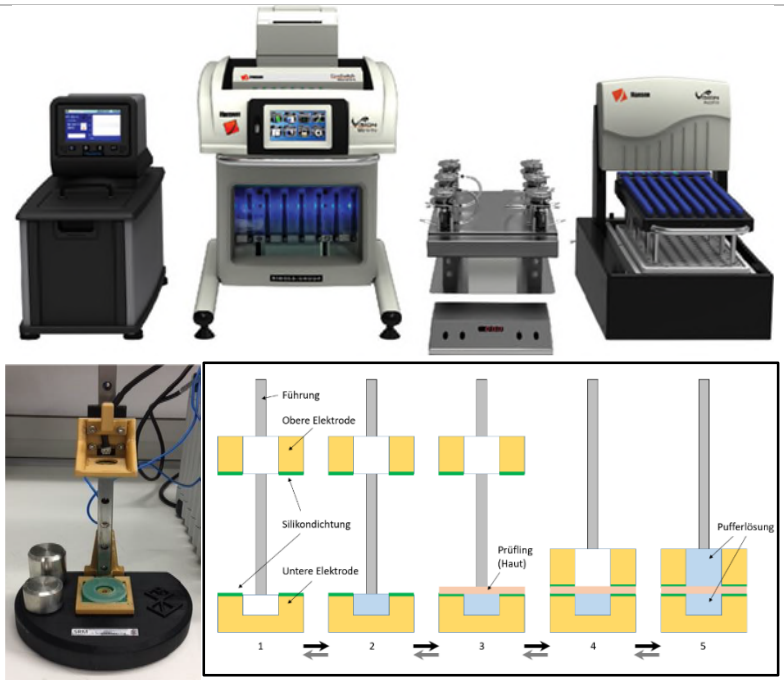
Permeation through excised human skin

Method name	Permeation through human skin for the development and quality control of topical applied drug products
Organ system	Skin
Subject area	Transport study skin
Area of application	Dermal drug testing & development
Relation of the method to the 3Rs	Replacement & Reduction, Prediction of permeability and bioequivalence
Figure	
Brief description	The fully automated Hanson Vision® Microette™ system (upper figure) allows to easily replicate permeation through excised human skin or membranes. Sampling, temperature in the system and stirring speed can be individually adjusted to the project requirements. For quality control of the barrier, the in-house developed SkinTER instrument (lower figure) is used. This allows a simple and non-destructive assessment of the skin quality based on transepithelial resistance (TER) before starting the experiments.
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Publications	European Medicines Agency. (2014). Guideline on quality of transdermal patches Guideline on quality of transdermal patches Table of contents. *European Medicines Agency*, *44*(August), 1–28. Retrieved from http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/12/WC500179071.pdf. Food and Drug Administration. (1997). Guidance for Industry, Nonsterile Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation, (May). OECD. (2011). Guidance notes on dermal absorption series on testing and assessment. *OECD Environment, Health and Safety Publications*, *36*(156). Knoth, Katharina et al. 2021. “Development and Evaluation of a Quality Control System Based on Transdermal Electrical Resistance for Skin Barrier Function in Vitro.” *Skin Research and Technology* 27(5): 668–75.

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