



JRF GLOBAL

IN VITRO DERMAL ABSORPTION





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A significant step in dermal exposure risk evaluation

The skin is a living membrane. It is the largest organ in the body, with a surface area of approximately 1.8 m² and a total weight estimated, for a typical human adult (70 kg), to be 4 kg. The primary function of the skin is protection, regulation of body temperature and controlling water loss. This large surface area on the other hand is susceptible for deliberate or inadvertent exposure for chemicals, during handling. Therefore, regulators are increasingly demanding risk assessment by determination to the extent of dermal absorption of a given product.

Dermal (Percutaneous, skin) absorption is a global term that describes the transport of chemicals from the outer surface of the skin both into the skin and into the systemic circulation. Several factors can affect the dermal absorption of chemicals, such as exposure period, product formulation, dose and the fate of the chemical in the skin. The permeability properties of the stratum corneum, for the most part, remain unchanged, even after its separation from the body. As a consequence, a good correlation exists between measurements derived from both *In vivo* and *In vitro* skin diffusion experiments when exposed to the chemicals. *In vitro* experiments are an appropriate surrogate for *In vivo* studies offering significant advantages over whole animal or human volunteer experiments.

An *In vitro* dermal absorption study, thus, offers a significant and valid alternative for evaluation of dermal absorption. The test thus, provides a quick and practical alternative for screening large numbers of topical formulations, while supporting the noble cause of 'three Rs' viz, Refinement, Reduction and Replacement in the animal experimentation. The experimental procedures however, are very precise, and calls for extreme precautions to undertake critical steps, intricate skills, scientific expertise and close attention for generating reliable and reproducible data.

JRF has undertaken painstaking efforts to develop the skills and expertise, which led to successful validation in compliance with the OECD principles of GLP for the *In vitro* Dermal Absorption study. We use the automated flow-through diffusion system at regulated temperature with both human and rat skin. We could conduct this study using carbon/hydrogen labeled compounds (¹⁴C / ³H) estimating the penetrated/absorbed Rad counts of the test product by Liquid Scintillation Analyser (LSA). The option using cold compounds with HPLC-MS/MS based analysis is also a reasonable alternative to the use of "hot" compounds.



JRF offers these studies complying with the critical acceptance criteria including skin integrity check, radiochemical purity check (for radiolabelled compounds), several layers of tape stripping and their extractive analysis and recovery of the input activity as per the guideline defined $\geq 95\%$. The absorption of a test chemical at different dose levels is measured over a period of time (typically 0 to 24 hours) by kinetic analysis of the receptor fluid samples, skin washings, tape strips and the treated skin. Our study protocol fully complies with the OECD Test Guideline 428 in conjunction with the accompanying the OECD Guidance Document No. 28. We have also taken into consideration the other relevant industry documents listed herewith. (e.g., SANCO/222/2000 rev.7, 2004, SCCP/1358/10 adopted 22 June 2010, EPA 40 CFR 799.5115, 2004 and EFSA, 2017).



JRF is well equipped to design studies, which can be tailor-made to demonstrate the efficiency of a product in a specific layer of the skin and support client in risk evaluation of agrochemical product/drug or cosmetic candidate. JRF offers integrated project which covers; i) *In vitro* study with Rat skin, ii) *In vitro* study with Human skin, or iii) *In vitro* study with Human and Rat skin in a single report and for Triple pack approach iv) *In vivo* study with Rat to develop a correlative risk analysis model between the *In vivo* and *In vitro* studies.

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