

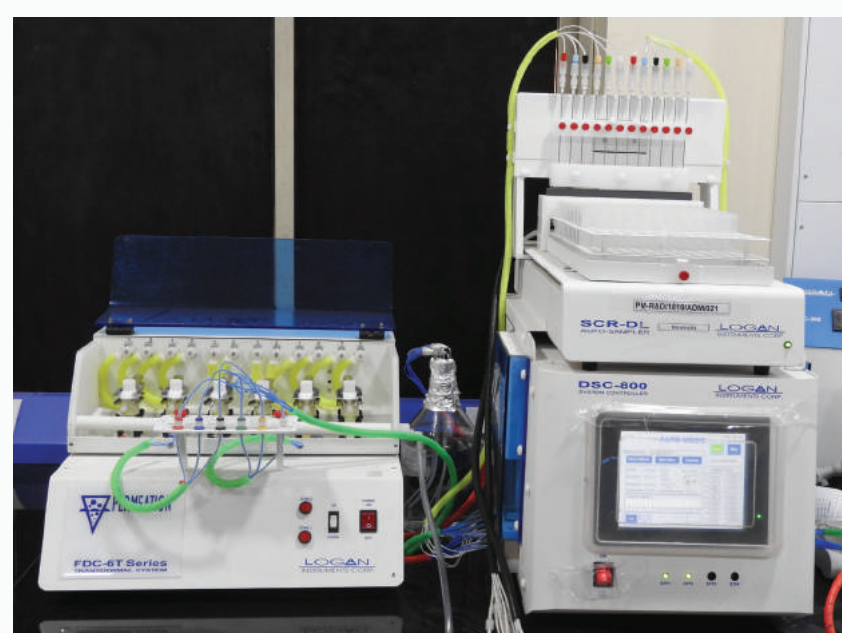
## IVRT & IVPT: Assessment Tool for Bioequivalence of Topical Products

Raptim Research Ltd. is one of the most advanced and an independent CRO providing end to end clinical research services and in-vitro services to pharmaceutical, biotechnology and medical devices companies.

Bioequivalence assessment of the topical products can be accomplished through the use of appropriately selected in-vitro techniques. For most of the dermal products; IVRT & IVPT testing would be essential to establish BE along with Q1/Q2 studies.

Raptim Research Ltd., is a leader in ***In-vitro studies*** and has developed a basket of surrogate techniques like *In-vitro Release Test (IVRT)*, *In-vitro Permeation Test (IVPT)*, *Tape stripping* and *Dermal Microdialysis* to establish bioequivalence of topical products.

- **2 (two) IVPT** studies conducted at Raptim has been submitted by sponsor to USFDA and **5 (five) IVPT** studies are in progress from global sponsors.
- **7 (seven) IVRT** studies are submitted to USFDA and **2 (two) IVRT** studies are approved by the agency.
- To meet the growing from the dermatology market, Raptim has increased expanded the infrastructure as follows:
  - **11 Franz diffusion cell** consoles of Logan with auto-sampler. The Franz Diffusion Cell is the industry standard for in-vitro percutaneous absorption kinetics of topical and transdermal products using ex vivo human skin. This model and associated methodologies support drug development in the preclinical, clinical, and post-approval phases, including the in-vitro rate-of-release assay (IVRT) based on the FDA SUPAC-SS and USP Guidance.



- Audited by **US-FDA for in-vitro studies** and the **inspection was concluded with no observations.**

### RAPTIM EXPERIENCE

IVRT Studies	IVPT Studies
Acyclovir Ointment	Acyclovir Cream
Diclofenac Gel	Doxepin Cream
Lidocaine Gel	Diclofenac Gel
Nystatin & Triamcinolone Ointment	Dapsone gel
Nystatin Cream	Tacrolimus
Nystatin Ointment	Rivastigmine Patch
Dapsone Gel 5% and 7.5%	Penciclovir Cream

### WHY PARTNER WITH US?

- Superior scientific knowledge for method development and validation of *in-vitro* studies for topical formulations.
- In-depth expertise in operating Franz Cell instruments with synthetic and tissue membranes including human skin.
- Meet the challenges of complex *In-vitro* Release Testing.
- Data interpretation and regulatory submission for approval of SUPAC-related changes.
- Meet timelines in a cost-effective manner without compromising on quality.

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