

## Nail Permeation Studies

Treatment of fungal infections of nails such as onychomycosis, nail psoriasis involves oral therapy with antifungals. However, there are bioavailability problems due to first pass metabolism.

Therefore, many of the pharmaceutical companies have developed transungual drug delivery system i.e. topical delivery through nails as an alternate approach. But topical delivery system also has its own challenges as nail is made up of cross-linked keratin.

There are challenges in developing formulation as well as in evaluating the efficacy and establishing the bioequivalence. For bioequivalence study, USFDA recommends BE study with clinical endpoint.

For such studies having subjects with onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes* is a difficult task.



Nail sample (thumb nail)

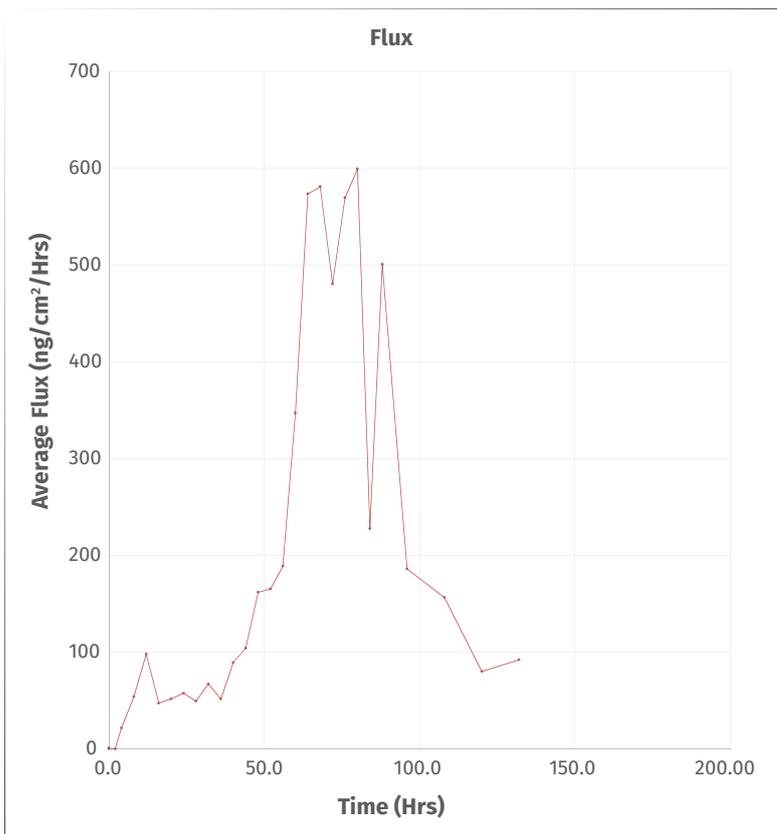


Nail cells with receptor chamber + donor Chamber and 'o' ring for identified dosing area



Nail mounted on cell with receptor chamber + donor chamber with water supply tubing to maintain temperature of receptor media throughout the fdc experiment

# The Raptim Research Pvt. Ltd. Advantage



## Solution

We at Raptim have developed in-vitro nail permeation technique which is same as in-vitro permeation studies using the Cadaver skin.

### Raptim has:

- + Access to cadaver nails
- + Capability to develop analytical method to **picogram level**

In our in-vitro lab, we have developed in-vitro nail permeation technique for Efinaconazole and planning to work on different anti-onychomycosis drugs like Amorolfine, Ciclopirox, Terbinafine and Luliconazole.

## Value Addition

With the expertise available for in-vitro studies and the capabilities to develop analytical method to **picogram level**, Raptim can be a preferred partner for companies who are working on developing products for the treatment of onychomycosis.

### Raptim will be helping in the process of:

- + Formulation development
- + Control correspondence with regulatory agencies
- + Selection of right formulation for pivotal studies and comparative in-vitro studies

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