

# Bio-waiver option for Class I and III

Bio-waiver study conducted at **Raptim Research PVT. LTD.** using CaCo2 cell line for **Buspiron HCL** is approved by **USFDA** in **May 2018**.



RAPTIM RESEARCH PVT. LTD.

A CONTRACT RESEARCH ORGANIZATION

## THE MAIN FACTORS:

### DISSOLUTION + SOLUBILITY + INTESTINAL PERMEABILITY

To measure the rate and extent of absorption of a drug that is stable in the GI tract

## BCS- I METHODOLOGY

### 1 Feasibility:

- Evaluation of bidirectional permeability of test drug at two concentrations

### 2 Development and Pre-study Assessment

- Optimization of Assay method for permeability assessment
- Tolerance of the test drug (at 100% drug concentration) by the cell monolayer
- Bidirectional Permeability to evaluate drug transport
- Nonspecific binding of the test drug
- Quantity of drug and maximum time required to reach equilibrium to evaluate solubility class
- Analytical method development on HPLC and LCMS

### 3 Pivotal Studies

- Unidirectional permeability without permeability markers
- Bidirectional permeability at three concentrations of test drug (1%, 10% and 100% of the highest strength of test drug) with permeability markers
- Solubility study (USP buffers, range 1.2 to 6.8) at  $37 \pm 1^\circ\text{C}$
- Gastro-intestinal stability of test drug
- Analytical method validation

## RAPTIM EXPERIENCE

### A Bio-waiver studies using Caco2 cell Lines [ Completed studies ]:

- Buspiron
- Doxepin
- Levorphanol Tartrate
- Dexamphetamine
- Varenicline Tartrate
- Ramelteon
- Valbenazine and its Metabolite
- Pimavanserin Tartrate
- Cyclophosphamide
- Imatinib
- Hydroxychloroquine Sulfate
- Brivaracetam
- Amitriptyline
- Guanfacin
- Cevimeline
- Dicyclomine
- Capacetabine
- Propranolol
- Lormetazepam
- Migalastat

### B Bio-waiver studies using Caco2 cell Lines [ Ongoing ]:

- Solriamfetol
- Lofexidine

### 1 USFDA approved studies (11 studies):

- Buspiron (2)
- Levorphanol (1)
- Ramelteon (2)
- Valbenazine (1)
- Pimavanserin (1)
- Brivaracetam (1)
- Amitriptyline (1)
- Cevimeline (1)
- Doxepin (1)

### 2 EU approved studies (1 study):

- Varenicline

### 3 Health Canada (1 study):

- Buspiron

## SERVICES OFFERED:

Bioequivalence Study, Analytical Service, BCS Bio-waiver Study, IVRT/IVPT, Binding studies (Equilibrium and Kinetic), Clinical Study, Patient-PK Study, Data Management, Dermatology, Medical & Scientific Writing, Complex & long duration study

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350+  
BIOANALYTICAL METHODS

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