

Bio-waiver option for Class I and III

Bio-waiver study conducted at **Raptim Research PVT. LTD.** using CaCo2 cell line for **Buspirone 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 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]:

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

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

- Lormetazepam
- Docusate Sodium
- Azacitidine

SERVICES OFFERED:

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

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250+
BIOANALYTICAL METHODS

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