RAPTIM RESEARCH PVT. LTD.
A CONTRACT RESEARCH ORGANIZATION

WEB: www.raptimresearch.com
E-MAIL: contact@raptimresearch.com

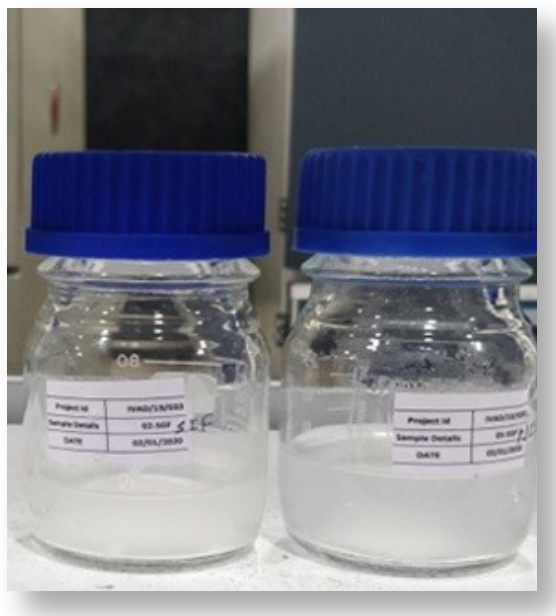
In Vitro Binding studies

The BE approach is not applicable for Locally Acting Gastro Intestinal Drugs since they are not intended to be absorbed into the systemic circulation and thus, drug concentration needs to be estimated at the local GI tract site

These drugs dissociate in the acid environment of the upper GI tract to release ionic drug species that bind to dietary phosphate or bile acids to form an insoluble complex that is eliminated via faeces

USFDA has developed product specific guidelines for In Vitro BE studies i.e

- To compare the extent and rate of binding affinity between Test and Reference formulations where Assay to be performed with minimum 12 replicates at various pH conditions
- It also includes equilibrium binding study with or without acid pretreatment and measurements of pH at different time points



Calculations and Bioequivalence

In Vitro Equilibrium Binding study

The Langmuir binding constants k1 (adsorption coefficient) and k2 (capacity constant)
The calculation of:

- Test/Reference ratio for k1
- 90% confidence interval for k2 with the acceptance criterion of 80% to 120%

In Vitro Kinetic Binding study

- The comparison of Test/Reference bound ratios at the various times

Representative data of binding study: Confidence interval acceptance criteria 80-120%

Raptim Experience on In Vitro Binding Studies:

- Colesevelam Tablets and Colesevelam Suspension
- Sevelamer Tablet and Sevelamer Suspension
- Sucralfate suspension

RAPTIM RESEARCH PVT. LTD. (INDIA):
A-226 / A-242, TTC Industrial Area,
Mahape MIDC, Navi Mumbai 400 710
Phone: +91-22-2778 1887/1889

CITUS RESEARCH LLP (INDIA):
401, 406 to 408, Super Mall - 2,
Infocity Campus, Near Gh. Zero Circle,
Gandhinagar, Gujarat 382 009
Phone +91-79-2321-3211 / 3212

RAPTIM RESEARCH PVT. LTD. (USA):
1378 Rt. 206, STE 6/280,
Skillman, NJ 08558
Phone: +1 609-333-9660