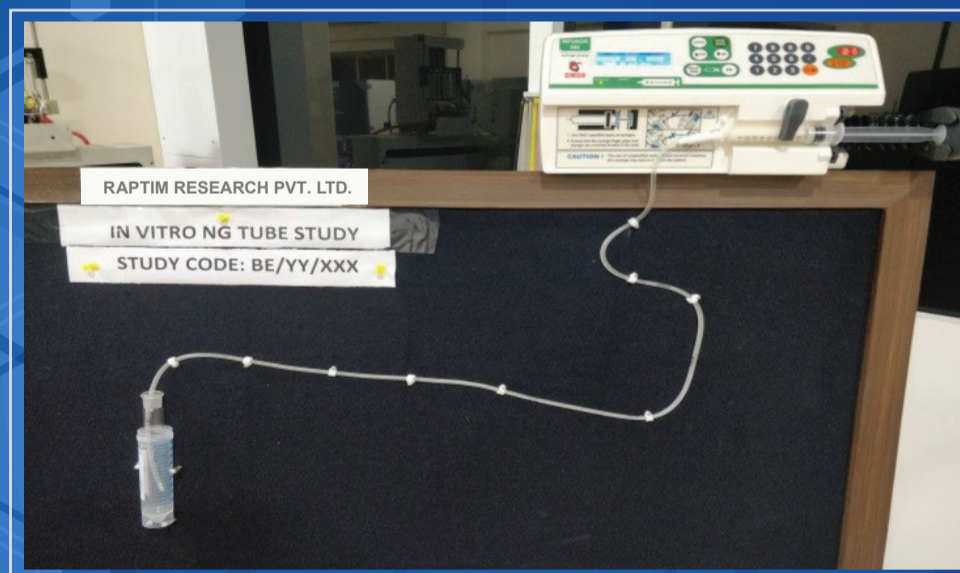


IN-VITRO FEEDING TUBE STUDIES

IN-VITRO FEEDING TUBE STUDIES

- + Individual product specific bioequivalence guidance recommends in-vitro feeding tube studies for products such as **oral suspension** and **capsules containing pellets, granules or beads**
- + Administration of products through feeding tube studies is recommended in patients having underlying disease that makes it difficult to swallow or for intensive care patients.
- + At Raptim, we have developed and established in-vitro feeding tube studies which include:
 - ✓ Comparative recovery testing
 - ✓ Particle size distribution study
 - ✓ Comparative acid resistance stability testing
 - ✓ Sedimentation volume testing
- + In-Vitro feeding tube methods - Optimization of parameters
 - ✓ Different sizes (8 FR to 20 FR) and materials of tubes (PVC, Silicone and Polyurethane)
 - ✓ Different design (open or closed distal end; single or double lumen)
 - ✓ Different types of Dispersion media (e.g. water, apple juice)
 - ✓ Variation in soaking time prior to administration
 - ✓ Different rinsing volumes

REPRESENTATIVE IMAGE OF IN-VITRO FEEDING TUBE STUDY



WHY PARTNER WITH US?

- Dedicated team with in-depth expertise to handle the in-vitro feeding tube studies
- Established infrastructure to conduct the in-vitro feeding tube studies
- All activities to be captured with DSLR camera as per the requirement of regulatory agency
- Ability to rectify challenges for such a complex study procedure

RAPTIM EXPERIENCE

- Mycophenolate mofetil oral suspension
- Lansoprazole delayed release capsule
- Dexlansoprazole delayed release capsule
- Ticagrelor tablet

UPCOMING PROJECTS

- Pantoprazole delayed release granules for oral suspension
- Rivaroxaban tablets
- Carglumic acid tablets