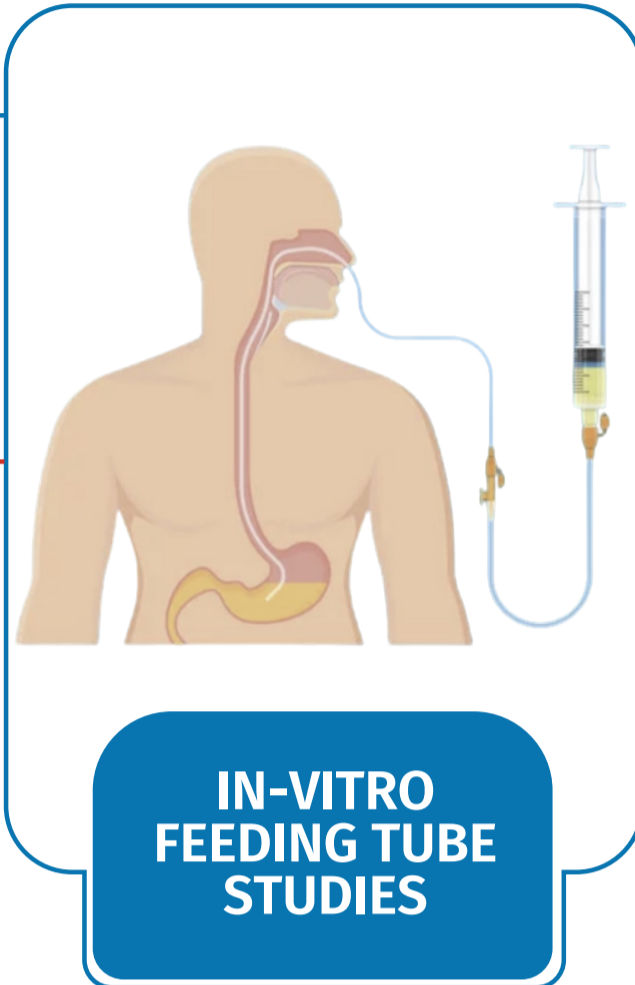


IN-VITRO FEEDING TUBE STUDIES

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.



IN-VITRO FEEDING TUBE STUDIES

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 and redispersibility testing

At Raptim, we have developed and established in-vitro feeding tube studies which include:

- ✓ Different sizes (6 FR to 24 FR) and materials of tubes (PVC, Silicone and Polyurethane)
- ✓ Different design (open or closed distal end; single or double lumen, number of eyes)
- ✓ Different types of Dispersion media (e.g. water, apple juice, dextrose)
- ✓ 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

- Ticagrelor EMA
- Rivaroxaban USFDA
- Rivaroxaban EMA
- Apixaban EMA
- Apixaban USFDA
- Ticagrelor USFDA
- Dexlansoprazole USFDA

ON-GOING PROJECTS

- Mycophenolate mofetil USFDA
- Rivaroxaban USFDA/EMA
- Carglumic acid USFDA
- Esomeprazole USFDA/EMA



NG TUBE USED AT RAPTIM IN DIFFERENT STUDIES

KANGAROO FEEDING TUBE 8FR. 60CM

COVIDIEN SALEM SUMP 61 CM

VYGON 8 FR. NG TUBE

NEO MED 8 FR. NG TUBE 60 CM

NEO MED NG TUBE 90 CM

KANGAROO FEEDING TUBE 8FR. 91CM

COVIDIEN SALEM SUMP 16FR.X 48

CORFLO NASOGASTRIC FEEDING TUBE

COVIDIEN ARGYLE TUBE (ENFIT)

COVIDIEN ARGYLE TUBE 16FR.X 48

VYGON VALUE LIFE TUBE

BARD NASOGASTRIC SUMP TUB

G TUBE USED AT RAPTIM IN DIFFERENT STUDIES

CAPSULE MONARCH NON- BALLON

KANGROO Y-PORT

MINI BALLON BUTTON LOW PROFILE

MIC GASTROSTOMY FEEDING TUBE WITH ENFIT CONNECTORS

MIC GASTROSTOMY FEEDING TUBE

BARD TRI-FUNNEL REPLACEMENT GASTROSTOMY TUBE