Dynamic gastric Model

Biorelevant Gastro-Intestinal Modelling

The Dynamic Gastric Model (DGM) is a bench-top AI-driven *in vitro* system that simulates digestion in the human stomach, allowing accurate prediction and understanding of the behaviour of foods or drug preparations during digestion in real time. The DGM has been extensively validated against human *in vivo* studies and fully replicates both the complex biochemical conditions and the array of gastric forces crucial for the prediction of the bio-behaviour of API's and dosage forms for oral delivery.

The Dynamic Gastric Model supports the acceleration of drug and food development, de-risking clinical trial failure through predictive bioavailability or bioequivalence and providing a fully validated alternative to animal studies.

Key Features:

- Accurate replication of gastric processing parameters, representative gastric emptying and pH profiles, validated against measured *in vivo* human data
- Fed or Fasted state conditions simulated
- Automated dynamic adjustment of gastric acid and enzymes depending on food matrix
- Controllable gastric emptying and discharge, programable stomach to simulate a disease state
- Monitoring in real time and generation of detailed report throughout the digestive process such as enzyme flow rate and pH
- Emptied samples can be utilised for downstream analysis or further digestion studies

Benefits:

- The ability to investigate the digestion of both real foods and/or real pharmaceutical preparations on the laboratory bench
- A large capacity allowing full multiphase meals to be assessed, including the “FDA breakfast”
- Allows sample collection at any time point from both the main body of the stomach and on exit from the antrum, allowing real time collection and detailed analysis
- Provides a physiological, cost effective and ethical alternative to the use of animal studies, supporting the FDA Modernisation Act 2.0
- Easy to clean, with minimum down time
- Fully automated, intuitive user interface

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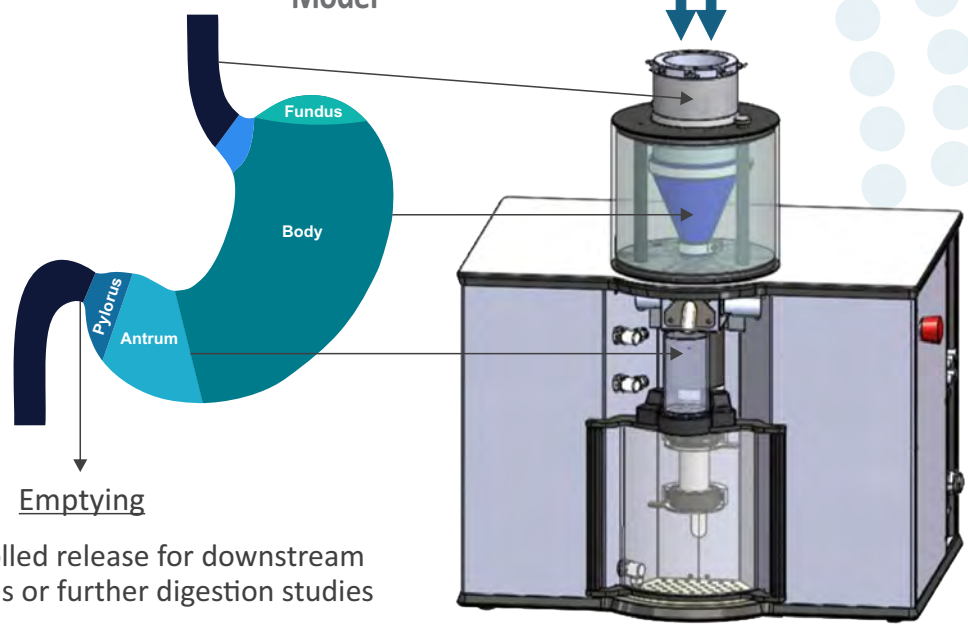

Body/Fundus
- Gentle rhythmic massaging
- Inhomogeneous environment

Antrum
- High sheer forces
- Homogenization
- Contractions

Applications

1. **Food-Drug interactions**
   Assess the effect of food on the bio-performance of API and pharmaceutical dosage forms.

2. **Alcohol induced interactions**
   Determine the extent of alcohol-based interactions with modified release dosage forms. The model can be used to simulate alcohol intake regimes that are not readily evaluable in human studies.

3. **Dissolution testing**
   Evaluate biorelevant disintegration and dissolution of dosage forms. In addition, dissolution characterisation for low solubility APIs such as BCS class II and IV can be modelled.

4. **Bioequivalence**
   Assess bioequivalence and behaviour of oral formulations such as the use of enteric coating.

5. **Dosage form**
   Develop modified release dosage form and gastro-retentive dosage forms through understanding mechanical integrity and drug release.

6. **Metabolic stability**
   Study the metabolic stability of pro-drugs and gastric delivery API's.

7. **Food science**
   Assess health implications of food such as survival of allergenic proteins and determination of Glycaemic Index.

8. **Nutrition**
   Understand the nutritional effects of food after gastric digestion such as bioavailability of nutrients and the behaviour of prebiotics.

Dynamic Gastric Model (DGM) units can be purchased through Plant Bioscience Ltd (UK) and supplied to the research and development community.

For more information including references, please visit:
www.dynamicgastricmodel.com

PBL Technology

Contact:
Dr Georgina Pope | info@dynamicgastricmodel.com | Tel: +44 (0)1603 456500