***Evaluation and Licensing Opportunities***

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***Patent Literature***

International Patent Publication No. WO/2007/010238

US Patent 8,092,222

European Patent 1,907,108

Canada Patent 2,613,980

# The Dynamic Gastric Model

The Dynamic Gastric Model (DGM) is a bench-top computer controlled *in vitro* system that simulates digestion in the human stomach, allowing accurate prediction and understanding of the behaviour of foods or drug preparations within the human gut during digestion in real time. The DGM was developed at the Quadram Institute Bioscience (formerly the Institute of Food Research) and is the first known *in-vitro* model developed to combine emerging scientific knowledge of the physical, mechanical and biochemical environments experienced by the luminal contents of the human stomach, in a single predictive system.

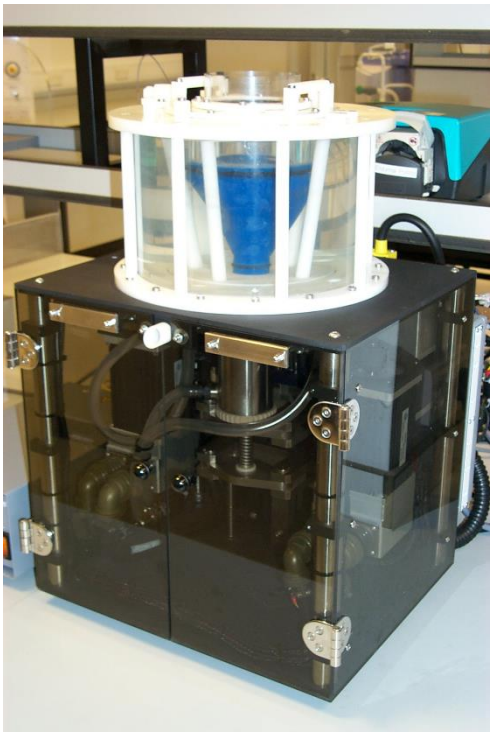
The DGM fully replicates both the complex biochemical conditions and the array of gastric forces crucial for the prediction of the bio-behaviour of API's and dosage forms for oral delivery (e.g. capsule, tablet, powder and liquid). Samples can be taken at any time during the process and analysed to predict the availability for uptake (bio-accessibility) of active components such as nutrients and drugs.

As in the human stomach, masticated material is processed in functionally distinct zones. Within the fundus/main body of the DGM, gastric acid and enzyme secretions are introduced around the outside of the food bolus which is subjected to gentle, rhythmic massaging. Secretion rates adapt dynamically to the changing conditions within this compartment (acidification, fill state). Portions of gastric contents are then moved into the DGM antrum where they are subjected to physiological shear and grinding forces before ejection from the machine for further analysis.

The DGM is based on many years of underpinning MRI studies in humans and has been validated for food and pharmaceutical applications in both the commercial and academic sectors, providing a physiological, cost effective and ethical alternative to animal studies.

**Key Features:**

- Accurate replication of gastric mixing, shear rates and peristalsis.
- Provides an accurate biochemical environment for gastric contents, allowing for fed and fasted comparisons of the behaviour of dosage form with varying food types.
- The ability to investigate the digestion of multiphase meals (i.e. real foods and/ or orally administered pharmaceutical preparations) as opposed to homogenised samples.
- Automated dynamic adjustment of gastric residence time, acid and enzyme addition (quantity and rate) and physiological processing depending on the food matrix.
- Controllable gastric emptying and discharge.
- Full access for sampling at all stages of digestion allowing real time collection and detailed analysis, compartment specific modelling.
- Fully automated, simple to use and sterilise.
- Provides QA reporting on the digestive process, including residence time, emptying profiles, pH gradients, gastric additions/flow rates.



The DGM offers a physiologically relevant screening tool that will provide valuable data for evaluating novel and existing foodstuffs, diets and pharmaceutical preparations. The DGM provides an accurate and meaningful method for predicting the fate of compounds, nutrients and formulae prior to absorption and therefore will become an invaluable tool for mechanistic, stability and bioaccessability studies during product development. The DGM can be applied to a wide range of product development, drug discovery and development projects, including those concerned with novel and functional foods, pharmaceutical delivery and bioavailability of active compounds and nutrients. Performance of reformulated products can be directly compared to original products as can performance of generic drugs to innovator drugs.

**Application Areas:**

- Bioequivalence and behaviour of oral formulations e.g. enteric coated.
- Bio-relevant disintegration and dissolution testing of dosage forms.
- Modified release dosage form development, mechanical integrity, drug release.
- Evaluation of food-drug interactions and dose-dumping potential.
- Alcohol induced interactions (dose-dumping).
- Evaluation of gastro-retentive dosage forms.
- Metabolic stability of pro-drug systems and gastric delivery API's.
- Dissolution characterisation for low solubility API's (particularly BCS class II and IV)
- Microbial survival under gastro-intestinal condition's (e.g. probiotics, live vaccines).
- Survival of allergenic proteins in food.
- Determination of Glycaemic Index in different food formulations or processes.

Under licence from PBL, the Danish Contract Research Organisation (CRO) Bioneer A/S utilises the DGM to provide pharmaceutical services and contract R&D within the field of drug development.

***DGM units can be built to order and supplied to the research and development community. For more information and to receive a quotation, please contact Dr Georgina Pope.***

**Selected paper references regarding the development and application of the Dynamic Gastric Model**

***Papers with pharmaceutical focus are highlighted in Bold.***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