

Evaluation and Licensing Opportunities

For further information on this technology and evaluation / licensing opportunities please contact:

Dr Georgina Pope
georgina@pbltechnology.com
Tel: +44 (0)1603 456500

Tech ID: 02.301

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.



Image Courtesy: Bioneer A/S, www.bioneer.dk

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.

Ballance S *et al.* (2013). Evaluation of gastric processing and duodenal digestion of starch in six cereal meals on the associated glycaemic response using an adult fasted dynamic gastric model. *Eur J Nutr*; 52(2): 799-812. <https://doi.org/10.1007/s00394-012-0386-5>

Burnett G R *et al.* (2002). Interaction between protein allergens and model gastric emulsions. *Biochem Soc Trans*; 30(Pt 6): 916-918. <https://doi.org/10.1042/bst0300916>

Butler J *et al.* (2019). *In vitro* models for the prediction of *in vivo* performance of oral dosage forms: Recent progress from partnership through the IMI OrBiTo collaboration. *Eur J Pharm Biopharm*; 136: 70-83. <https://doi.org/10.1016/j.ejpb.2018.12.010>

Chessa S *et al.* (2014). Application of the Dynamic Gastric Model to evaluate the effect of food on the drug release characteristics of a hydrophilic matrix formulation. *Int J Pharm*; 466(1-2): 359-367. <https://doi.org/10.1016/j.ijpharm.2014.03.031>

Edwards CH *et al.* (2021). Structure-function studies of chickpea and durum wheat uncover mechanisms by which cell wall properties influence starch bioaccessibility. *Nat Food*; 2: 118-126. <https://doi.org/10.1038/s43016-021-00230-y>

Grassby T *et al.* (2017). *In vitro* and *in vivo* modeling of lipid bioaccessibility and digestion from almond muffins: The importance of the cell-wall barrier mechanism. *Journal of Functional Foods*; 37: 263-271. <https://doi.org/10.1016/j.jff.2017.07.046>

Knopp MM *et al.* (2023). Combining the Dynamic Gastric Model (DGM) with the Biorelevant Gastrointestinal Transfer (BioGIT) System to Evaluate the Performance of Three Nurofen® Ibuprofen Products. *AAPC PharmSci 360 [2023 Conference Poster]*. [2023 PharmSci 360 Meeting](#)

Knopp MM *et al.* (2025). Evaluating the gastric integrity of Capsugel® Enprotect® capsules in fasted and fed state using the Dynamic Gastric Model (DGM). *5th European Conference of Pharmaceutics [2025 Conference Poster]*. [Evaluating the gastric integrity of Capsugel® Enprotect® capsules](#)

Knopp MM *et al.* (2025). Predicting the pharmacokinetics and food effect of oral drug products using the dynamic gastrointestinal model (DGM). *European Journal of Pharmaceutics and Biopharmaceutics*, 212;114723. <https://doi.org/10.1016/j.ejpb.2025.114723>

Lo Curto A *et al.* (2011). Survival of probiotic lactobacilli in the upper gastrointestinal tract using an *in vitro* gastric model of digestion. *Food Microbiology*; 28(7): 1359-1366. <https://doi.org/10.1016/j.fm.2011.06.007>

Mandalari G *et al.* (2008). Potential prebiotic properties of almond (*Amygdalus communis* L.) seeds. *Appl Environ Microbiol*; 74(14): 4264-4270. <https://doi.org/10.1128/AEM.00739-08>

Mandalari G *et al.* (2013). Bioaccessibility of pistachio polyphenols, xanthophylls, and tocopherols during simulated human digestion. *Nutrition*; 29(1): 338-44. <https://doi.org/10.1016/j.nut.2012.08.004>

Mandalari G *et al.* (2016). The effect of sun-dried raisins (*Vitis vinifera* L.) on the *in vitro* composition of the gut microbiota. *Food & Function*; 7: 4048-4060. <https://doi.org/10.1039/c6fo01137c>

Mandalari G *et al.* (2018 Epub 2016). Durum wheat particle size affects starch and protein digestion *in vitro*. *Eur J Nutr*; 57(1): 319-325. <https://doi.org/10.1007/s00394-016-1321-y>

Mandalari G *et al.* (2018). Understanding the Effect of Particle Size and Processing on Almond Lipid Bioaccessibility through Microstructural Analysis: From Mastication to Faecal Collection. *Nutrients*; 10(2): 213. <https://doi.org/10.3390/nu10020213>

Marciani LG *et al.* (2007). Enhancement of intragastric acid stability of a fat emulsion meal delays gastric emptying and increases cholecystokinin release and gallbladder contraction. *American Journal of Physiology-Gastrointestinal and Liver Physiology*; 292(6): G1607-1613. <https://doi.org/10.1152/ajpgi.00452.2006>

Marciani LG *et al.* (2001). Effect of meal viscosity and nutrients on satiety, intragastric dilution, and emptying assessed by MRI. *American Journal of Physiology-Gastrointestinal and Liver Physiology*; 280(6): G1227-G1233. <https://doi.org/10.1152/ajpgi.2001.280.6.g1227>

Mason LM *et al.* (2016). Use of the Dynamic Gastric Model as a tool for investigating fed and fasted sensitivities of low polymer content hydrophilic matrix formulations. *International Journal of Pharmaceutics*; 510(1): 210-220. <https://doi.org/10.1016/j.iipharma.2016.06.034>

Mercuri A *et al.* (2008). Dynamic gastric model (DGM): a novel in vitro apparatus to assess the impact of gastric digestion on the droplet size of self-emulsifying drug-delivery systems. *J Pharm Pharmacol*; 60 Supplement 1: A-2

Mercuri A *et al.* (2009). Assessing drug release and dissolution in the stomach by means of Dynamic Gastric Model: a biorelevant approach. *J Pharm Pharmacol*; 61 Supplement 1: A-5

Mercuri A *et al.* (2011). The effect of composition and gastric conditions on the self-emulsification process of ibuprofen-loaded self-emulsifying drug delivery systems: a microscopic and dynamic gastric model study. *Pharm Res*; 28(7): 1540-1551. <https://doi.org/10.1007/s11095-011-0387-8>

Mills CE *et al.* (2021). Palmitic acid-rich oils with and without interesterification lower postprandial lipemia and increase atherogenic lipoproteins compared with a MUFA-rich oil: A randomized controlled trial. *Am J Clin Nutr*; 113(5):1221-1231. <https://doi.org/10.1093/ajcn/nqaa413>

Pitino I *et al.* (2010). Survival of *Lactobacillus rhamnosus* strains in the upper gastrointestinal tract. *Food Microbiol*; 27(8): 1121-1127. <https://doi.org/10.1016/j.fm.2010.07.019>

Pitino L *et al.* (2011). Survival of *Lactobacillus rhamnosus* strains inoculated in cheese matrix during simulated human digestion. *Food Microbiol*; 28(7): 1359-66. <https://doi.org/10.1016/j.fm.2012.02.013>

Pultz IS *et al.* (2021). Gluten Degradation, Pharmacokinetics, Safety, and Tolerability of TAK-062, an Engineered Enzyme to Treat Celiac Disease. *Gastroenterology*; 161(1): 81-93. <https://doi.org/10.1053/j.gastro.2021.03.019>

Rodes L *et al.* (2014). Enrichment of *Bifidobacterium longum* subsp. *infantis* ATCC 15697 within the human gut microbiota using alginate-poly-L-lysine-alginate microencapsulation oral delivery system: an *in vitro* analysis using a computer-controlled dynamic human gastrointestinal model. *J Microencapsul*; 31(3): 230-238. <https://doi.org/10.3109/02652048.2013.834990>

Salt LJ *et al.* (2023). Mechanisms of interesterified fat digestibility in a muffin matrix using a dynamic gastric model. *Food & Function*; 14(22): 10232-10239. <https://doi.org/10.1039/d3fo02963h>

Thuenemann EC *et al.* (2015). Dynamic Gastric Model (DGM). In: Verhoeckx K *et al.* (eds). The Impact of Food Bioactives on Health: in vitro and ex vivo models [Internet]. Cham (CH): Springer; 2015. Chapter 6. https://doi.org/10.1007/978-3-319-16104-4_6

Vardakou M *et al.* (2011). Achieving antral grinding forces in biorelevant *in vitro* models: comparing the USP dissolution apparatus II and the dynamic gastric model with human *in vivo* data. *AAPS PharmSciTech*; 12(2): 620-626. <https://doi.org/10.1208/s12249-011-9616-z>

Vardakou M *et al.* (2011). Predicting the human *in vivo* performance of different oral capsule shell types using a novel *in vitro* dynamic gastric model. *Int J Pharm*; 419(1-2): 192-199. <https://doi.org/10.1016/j.iipharma.2011.07.046>

Wickham MJS *et al.* (2012). The Design, Operation, and Application of a Dynamic Gastric Model. *Dissolution Technologies*; 19(3): 15-22. <https://doi.org/10.14227/DT190312P15>

Zhang Q *et al.* (2014). Differential digestion of human milk proteins in a simulated stomach model. *J Proteome Res*; 13(2): 1055-1064. <https://doi.org/10.1021/pr401051u>