

# Hot off the press

The new D series research powder analyser from Gamlen Instruments speeds up the process of advanced tableting research. Created by **Dr Michael Gamlen**, Head of Tablet Development at the Wellcome Foundation Ltd for 15 years, it has been demonstrated to generate data which accurately predict the behaviour of pharmaceutical powders when compressed in production conditions.

**P**ressing pharmaceuticals into tablets as a way of creating an easy-to-administer form of solid dosage has a long history; tablets are now the most popular method of administration, making up a third of all dispensed prescriptions. They provide a remarkably efficient way to deliver an

accurate dose to a specific site, but their manufacture is not without its challenges.

## FORM AND FUNCTION

As well as the active chemical for treatment, each tablet contains excipients (inactive substances that serve as a vehicle for a drug or improve the processing behaviour of the

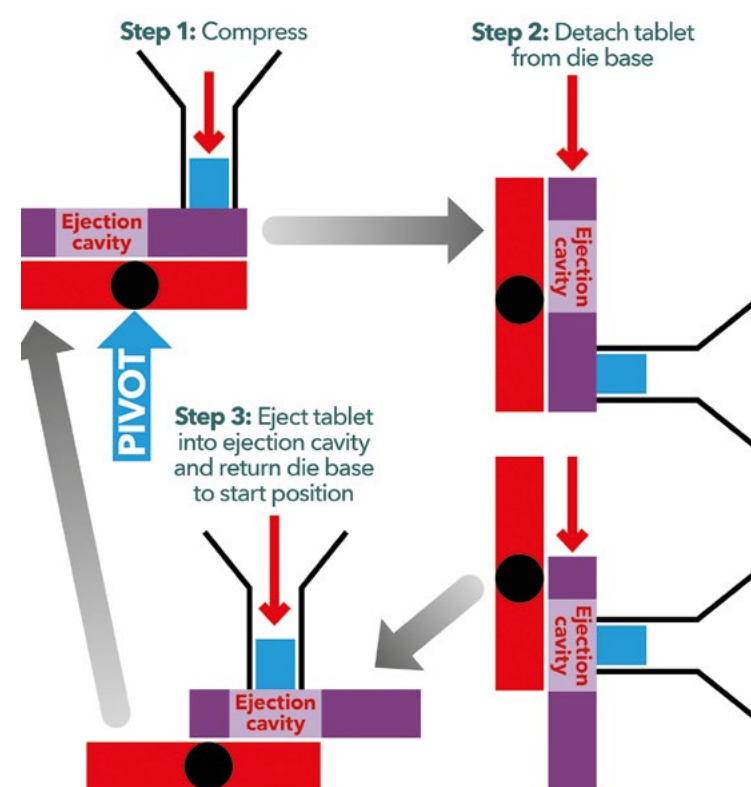
formulation). Examples of these may include diluents, binders, lubricants, disintegrants (to enhance tablet break up) and sweeteners, or other substances to improve palatability. Tablet design and manufacture is therefore a complex science, combining these ingredients to produce a quality product.

## AN EXPERIENCED OPERATOR

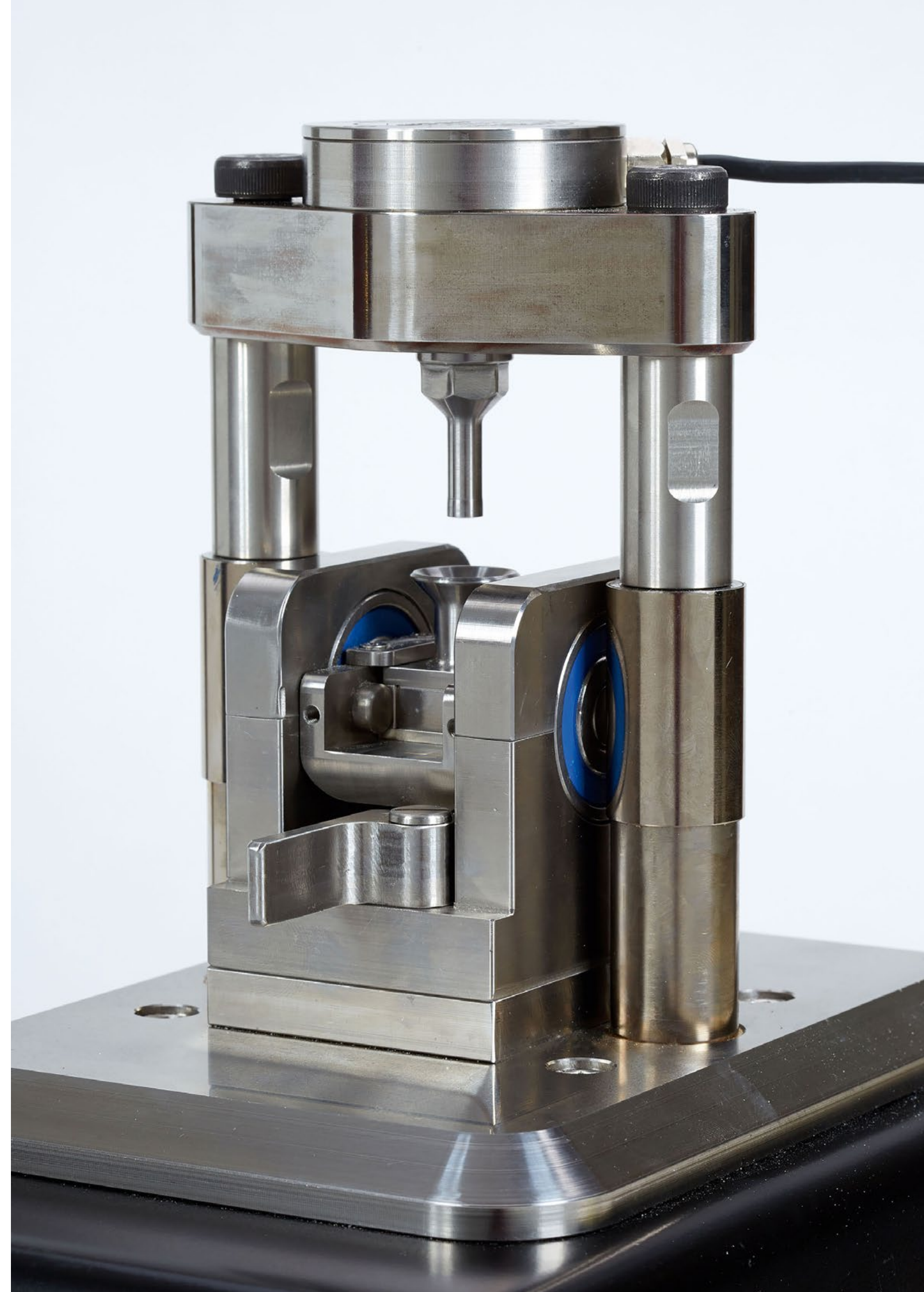
This research has been brought to the cutting edge by Dr Michael Gamlen's innovation. Having specialised in pharmaceutical engineering as a pharmacy undergraduate, Dr Gamlen completed his PhD at the renowned Nottingham University. From there he pursued a career in product development, tablet formulation and process optimisation studies, becoming Head of Tablet Development at the London-based Wellcome Foundation for biomedical research and consulting for other biotech companies. Using his years of experience in tablet design and manufacture, he created the first computer-controlled desktop tablet press through a lengthy and painstaking process of research and development. This has recently been enhanced by the launch of the Gamlen D series powder compaction analyser.

The new instrument has been shown by independent tests to simulate the behaviour of a production tablet press and provide complete control of the compaction process using only small amounts of material. It generates precise measurements of material compressibility and lubrication by capturing tablet compression force, detachment and ejection force measurements. In addition, the Gamlen D Series can be linked to the Tablet Tensile Analyser and an analytical

## Operation of the Gamlen D Series



**The D Series provides complete control of the compaction process – it generates precise measurements of compressibility and lubrication by capturing tablet compression force, detachment and ejection force measurements**







balance to provide an integrated assessment of tablet properties. The system utilises a 4-figure analytical balance and digital micrometer to automatically capture and send thickness, weight and fracture data to the computer in real time. Dynamic powder compaction analysis can also be carried out using the unique Gamlen punch position and force measurement combination.

#### A PRESS INTO SERVICE

With a wide range of die sizes available (3–15 mm), the Gamlen D Series provides accurate compaction data as it presses the tablet into shape. The die is then rotated for measurement of detachment force as the die base is slid across the tablet. This centres the formed tablet, still held within the die, over the ejection cavity. The die is then rotated back to the starting position and the tablet is ejected in the same direction as the compaction event while measuring the ejection force. These steps are analogous to detachment and ejection on a conventional tablet press, and provide vital data for pre-production testing.

The ability to test out variations in the composition of powders prior to tablet manufacture, and using small quantities of materials, saves time and money. Using the system, researchers can quickly make incremental adjustments to the composition until the desired quality is achieved. It is also useful for studying tablet excipients, and using model systems to understand the compaction process.

#### THE DEVELOPMENT IS IN THE DETAIL

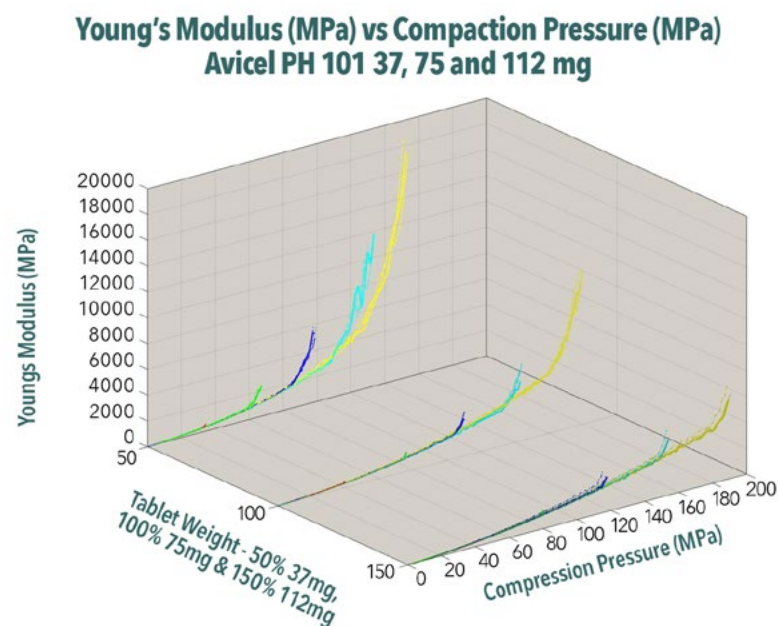
The principal advantage of the D Series

**The principal advantage of the D Series system is the ability to bring all of the compaction and lubrication data into a single manufacturability analysis which helps the operator understand the product**

is the ability to bring compaction and lubrication data together in a single analysis to help the operator understand the product. Through accurate measurement of tablet weight and dimensions using the balance and digital micrometer supplied, the Tensile Stress Analyser is linked to the compaction system to provide the user with calculated values for tablet density, tensile

fracture stress, solid fraction and G ratio (a new assessment of tablet quality developed by Gamlen).

Using the proprietary software, users are able to plot these values against each other to generate curves of important production characteristics such as compaction (tablet solid fraction vs tensile fracture stress),



## Q&A

#### Why are tablets such a popular format for drug delivery?

Because they are cheap to make, easy to transport, and can be made with a wide range of different properties

#### What are the principal challenges in creating a preparation for tablet manufacture?

To improve tablet quality the principal challenge is to measure the difference between a good and a bad tablet. This is only possible using an instrument which controls the force used to make the tablet. It simulates compaction of the tablet on the production tablet press.

#### How does the Gamlen D Series assist in overcoming these challenges?

The Gamlen D series allows the user in the laboratory to compare powders and products at controlled compaction force, and predict the properties of the product in full production.

#### What additional benefits does the D Series provide for tablet research?

By acting as a compaction simulator,

tableting (compaction pressure vs tensile strength) and compressibility (compaction force vs solid fraction). Researchers in Japan have recently published data for studies using exactly this technique to assess the tableting properties of a wide range of products. At least eight full scientific papers and at least 30 posters demonstrating the applicability of the instruments have been published.

By identifying ranges within which the tableting properties of a powder are considered optimal, the researchers are able to investigate how different excipients affect tablet formation. These data can then be used to support the known properties of the substances when considering inclusion in preparations and to predict the properties of the product in production, preventing failures during manufacture such as sticking, capping or binding and helping to create tablets that resist damage during packaging and transit.

the instrument allows the user to study the impact of material and process changes without needing to run full-scale production tests, saving time and money.

#### What are the key differences between the D series instrument and the initial tablet press you designed when you first set up Gamlen Tableting Ltd?

The key improvements in our system are the development of the detachment system, for comprehensive study of lubrication problems, and the increase in operating speed to improve productivity and throughput.

#### What are the next steps for Gamlen Tableting?

We will be launching a new compaction analysis software suite including a number of completely new ways to study the tableting process and simplify the process for improving tablet quality.

## Detail

#### RESEARCH OBJECTIVES

Dr Gamlen's research focuses on improving tablet quality through design, formulation and development. Following the extensive success of his initial research tablet press, Dr Gamlen has made it his mission to update and streamline the development process for tablet manufacture further using his newly updated D series powder compaction analyser.

#### FUNDING

Innovate UK

#### COLLABORATORS

- King's College London
- GlaxoSmithKline
- Pfizer
- Sawai Pharmaceutical Company

#### BIO

Dr Michael Gamlen has had an extensive career within scientific research and tablet development. After studying for his PhD at Nottingham University, he became the Head of

Tablet Development at the Wellcome Foundation Ltd and a consultant to Vanguard Medica Ltd. Following this, he realised people needed a more reliable way to improve tablet quality under controlled laboratory conditions, and he knew how to do so. This resulted in the Gamlen product series.

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