

GAMLEN
D-SERIES
POWDER
COMPACTION
ANALYSER

Understand how your powders will behave before full scale manufacture

Make It Better. Make It Gamlen.







# TAME YOUR POWERS

## GET A BETTER UNDERSTANDING OF HOW POWDERS WILL BEHAVE

Accurate compaction data gives you certainty on how your APIs and excipients will behave during manufacture. Saving you time, saving you materials, saving you money.

Make It Better. Make It Gamlen.





#### **MAKE IT FASTER**

Launch to market sooner. Get ahead of your competitors. Reduce clinical trial time lines. Save on development costs. Get the knowledge and understanding to make high quality products faster.

#### **MAKE IT SMARTER**

Reduce waste. Protect valuable APIs. Select cheaper, more readily available excipients. Shorten development time. Make informed formulation decisions with accurate compaction data.

#### **MAKE IT EASIER**

Ensure consistent tablet quality. Avoid tableting problems. Reduce press down time. Get USP <1062> compliant data. Use with very little training. Get results with minimal sample volumes.



# 3 STEPS TO UNDERSTANDING HOW YOUR POWDERS WILL COMPACT

## STEP 1 MAKE THE TABLETS



Make the tablets using the Gamlen D1000 or D500. Maximum compaction load for the D1000 is 1000 kg and 500 kg for the D500. The D500 is recommended for minitabs.

The Gamlen D-Series compacts tablets to a set force or thickness. It then measures the force required to detach and eject the tablets.

## STEP 2 MEASURE THE TABLETS



Tablet thickness and mass are measured using a micrometer and balance.

All measurements are captured automatically by the software for faster analysis.
Alternatively, the system can be configured for manual data entry to use a pre-existing balance and/or micrometer.

## STEP 3 BREAK THE TABLETS



The Gamlen TTA
(Tablet Tensile Analyser)
measures tablet
diameter and breaks
the tablets to measure
tablet tensile fracture
stress. Values are
automatically captured
by the software.

All calculations take tablet size and shape into account so data can be compared across different tooling types.

#### UNDERSTAND YOUR POWDERS



The Gamlen Dashboard software automatically captures and analyses all data. No data entry is required during testing and the software aids result interpretation. No compaction experience or expertise is required.

- Training time <2 hr.</li>
- Testing time ~30 min
- Typical sample mass required <2 g</li>



"Powder compression is a critical process in manufacturing the tablet dosage form. Although this process has been used routinely for over a century, problems related to powder compression in pharmaceutical formulation development and manufacturing persist."

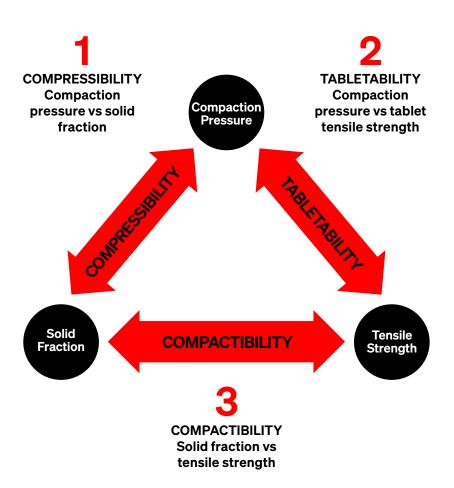
**USP <1062> Tablet Compression Characterisation** 



## **COMPACTION ANALYSIS**

#### The science behind better tablets

To avoid tableting failures, USP <1062> recommends the generation of the data summarised in the compaction triangle. This consists of 3 relationships...

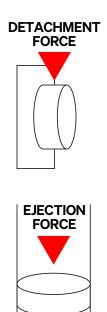


All compaction triangle profiles are automatically generated when using the D-Series with the Gamlen Dashboard software. This data lets you compare the compaction behaviour of powders and will tell you if your tablets are...

- Sufficiently strong to withstand processing
- Reasonably porous to allow dissolution
- At risk of over-compaction

The Gamlen D-Series also provides data on blend lubrication. After each tablet is compacted, the D-Series measures the forces required to detach the tablet from the base of the die and to eject the tablet out of the die. These measurements enable you to evaluate lubrication efficacy. Poor lubrication is the main cause of sticking and picking during production.

The in-die elastic recovery of the tablet is also measured during testing. Excessive elastic recovery (tablet expansion) after compaction has been linked to capping and lamination.





"We were impressed with the way the Gamlen Tablet Press could simulate a number of conditions that real tablet production involves, without requiring high volumes. For a teaching environment, we need to be able to manufacture small batches, at high frequency and by various different users and this machine has been able to meet these needs."

Professor Daryl Williams, Director of the Discovery Space, Imperial College London

## MAKE IT FASTER

"The Gamlen Tablet Press helps us to speed up tablet compression screening in reformulation projects"

Dr Petr Zámostný, Associate Professor, Department of Organic Technology, University of Chemistry and Technology, Prague



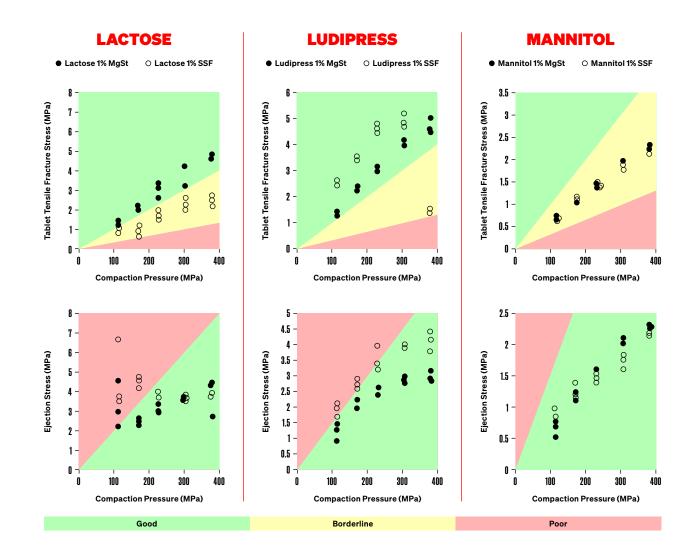
## **MAKE IT FASTER**

#### Gamlen data cuts formulation time

Make informed formulation decisions quickly with the Gamlen D-Series.

In this example the lubrication efficacy of magnesium stearate (MgSt) and sodium stearyl fumate (SSF) is compared. Each lubricant (1%) was blended, separately, with lactose, Ludipress and mannitol.

For lactose, the SSF tablets were significantly weaker and less well lubricated than the MgSt tablets. The Ludipress tablets lubricated with SSF were also found to be more poorly lubricated compared to the MgSt tablets but the SSF tablets were stronger in this case. However, at compaction pressures >300 MPa, over-compaction is observed for the SSF tablets causing a sharp drop in tablet tensile strength. No significant difference was observed in the compaction behaviour of mannitol blended with MgSt or with SSF.





# "Thus, problems predicted by the Gamlen Tablet Press were confirmed in actual tableting."

Takashi Osamura, Sawai Pharmaceutical, Japan

Osamura, T., et all., Formulation design of granuals prepared by wet granulation method using a multi-functional single-punch tablet press to avoid tableting failures.. Asian J. Pharm. Sci., 2018, 13(2): p. 113-119.

## MAKE IT SMARTER

"The Gamlen Tablet Press allows you to understand the relationship between the properties of substances, the composition of a formulation and the manufacturing process."

Prof. Margaret Sznitowska, Department of Applied Pharmacy, Medical University of Gdansk



## **MAKE IT SMARTER**

#### Gamlen data predicts plant behaviour

Gamlen data has been shown to predict how material will behave during compaction on full scale tablet presses.

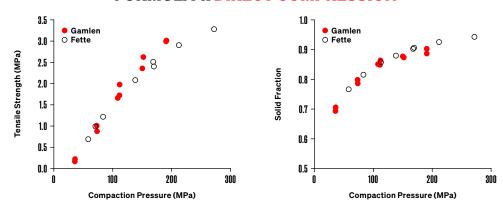
A study compared the compaction behaviour on a Gamlen compaction analyser and on a Fette rotary tablet presses for two formulations.

Formula 1 was a direct compression formulation. The Gamlen tablets were flat-face cylindrical tablets, either 5 or 6 mm in diameter. 100 mg of powder was used to produce each tablet. The tablets manufactured on the full scale press were 8 times larger at 800 mg and were caplet shaped.

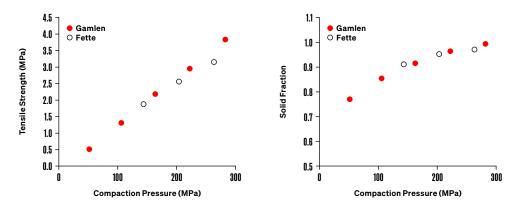
Formula 2 was manufactured by wet granulation. The Gamlen compressed 80 mg of the blend per tablet and again, the tablets were flat-faced cylinders 5 or 6 mm in diameter. By contrast the tablets produced on the Fette were round convex tablets and weighed 350 mg.

For both formulations, despite significant differences in tablet size and shape, the compaction data from the Gamlen was super-imposable on the full scale tablet press data. The Gamlen data was found to be predictive of plant behaviour.

#### **FORMULA 1: DIRECT COMPRESSION**



#### **FORMULA 2: WET GRANULATION**



Pitt, K., et al., Compression prediction accuracy from small scale compaction studies to production presses. Powder Technology, 2015. 270: p. 490-493.



# "Compression, ejection, and detachment data can be measured with precision accuracy but at the same time the machine is easy to operate."

Dr. Andreas Sauer, Technical Manager, Shin-Etsu

## MAKE IT EASIER

"The Gamlen D-Series tablet press has become a standard part of Materials Science characterisation for commercial products. We have used it to evaluate API manufacturing process changes, investigate tablet manufacturing problems and to compare material suppliers."

Rachael Webber, Materials Scientist, GSK



## **MAKE IT EASIER**

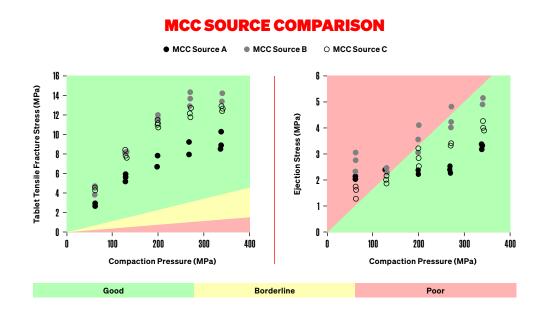
#### Gamlen data simplifies new supplier assessments

Being able to identify viable alternative sources of excipients or APIs allows you to keep costs down while maintaining high levels of product quality.

Compaction data from the Gamlen D-Series makes this process quick and easy. Instead of inferring how a powder will behave during compaction from its physical properties, you can measure it directly. This allows you to compare the compaction behaviour of your current material with alternatives. Then, when you make the change, you can be confident in your knowledge of how it will impact the compaction process.

Here, samples of MCC (microcrystalline cellulose) MCC from different sources are compared. The MCC samples varied significantly in terms of tabletability and ejection stress. This indicates that the samples would have varying lubrication requirements and produce tablets of differing hardness.

This information is invaluable when trying to select a suitable alternative material supplier for a compacted formulation.



"The Gamlen D-Series is an additional and valuable supplement in the preformulation toolbox in our department."

Dr. Aaron Ruff, Lab Head at Merck Healthcare



## **MAKE IT BETTER**

The Gamlen D-Series is made better so you can make better formulations, better tablets and better products

The Gamlen D-Series was invented by Dr Michael Gamlen FRPharmS based on over 40 years of experience in tablet formulation and manufacture. Driven by the belief that the right instrument could revolutionise tablet development, Michael designed an instrument that, quite simply, could measure the difference between good and bad compaction behaviour.

- Punch position and applied force measured in real time
- Light weight and portable with an exceptionally small benchtop footprint
- High performance load cells (load cell resolution 1:5000)
- Options for increased hold times, precompressions and multiple compressions (for layered tablets)
- Precision engineered in Nottingham, UK





The patented integrated detachment mechanism consists of a rotating die and simple lever. This allows compaction, detachment and ejection operations to be carried out with no need for awkward re-configuration.



## **BETTER SOFTWARE**

The Gamlen Dashboard software quantifies compaction behaviour quickly and easily

### THE GAMLEN DASHBOARD

- Designed to enable fully automated analysis for faster testing
- Eliminates possibility of data entry errors
- Displays how a material compares with industry norms
- "Good" and "poor" compaction behaviour zones aid result interpretation
- Evaluate formulation and process changes at a glance and
- Easily compare the compaction behaviour of your APIs, excipients and formulations





## PUNCH AND DIE OPTIONS

Punches and dies are supplied as matched sets and made to order



LARGE DIES
Suitable for any
Gamlen instrument
our large dies

range from



# FIND THE GAMLEN D-SERIES PACKAGE THAT'S RIGHT FOR YOU



#### **GAMLEN D500**

Best suited to minitab testing, can apply compaction loads up to 500 kg. Punch size range 0.85-10 mm. Auto detachment available for punch sizes 3-6 mm.



#### **GAMLEN D1000**

The versatile D1000 has a max compaction load of 1000 kg. Punch size range 3-15 mm. Auto detachment available for punch sizes 3-10mm.

### **BRONZE**PACKAGE

- Gamlen D500 or D1000
- Manual Dashboard Software
- GamPette Powder Dispenser
- Gamlen Tablet Tensile
  Analyser (TTA)
- Automated
  Micrometer
- Automated Balance or Interface for Existing Balance
- Ideally suited to users with some experience of compaction analysis
- · Data capture is not automated
- · Tablet hardness tester required
- Generate USP <1062> data
- Measure detachment and ejection stress

### SILVER PACKAGE

- Gamlen D500 or D1000
- Manual Dashboard Software
- GamPette Powder Dispenser
- Gamlen Tablet Tensile
  Analyser (TTA)
- Automated
  Micrometer
- Automated Balance or Interface for Existing Balance
- Avoid time consuming powder weighing
- All the benefits of the bronze package with the addition of a GamPette precision powder pipette
- GamPette typically dispenses powder with 2% accuracy or better

#### GOLD PACKAGE

- Gamlen D500 or D1000
- Automated Dashboard Software
- GamPette Powder Dispenser
- Gamlen Tablet Tensile
  Analyser (TTA)
- Automated Micrometer
- Automated Balance or Interface for Existing Balance
- Fast, fully automated compaction analysis
- Suited to compaction experts and novices
- Full USP <1062> and lubrication data
- Software aids data interpretation
- · Requires minimal user input



# GAMLEN D-SERIES SPECIFICATIONS



#### **GAMLEN D500**

Maximum load: 500 kg

Auto detachment punch size range: 3-6 mm diameter

Punch size range: 0.85 - 10 mm diameter

Compaction rate: 0.01 - 3 mm/s

Data capture rate: 200 Hz
Load cell travel: 30 mm
Load cell resolution: 1:5000

Calibration: Dead weights or proving ring
Power requirements: 90-240 VAC 3.15A
Instrument dimensions: 310 × 270 × 375 mm

Instrument weight: 16 kg

Shipping size: 380 × 345 × 372 mm Shipping weight approx: 20 kg



#### **GAMLEN D1000**

Maximum load: 1000 kg

Auto detachment punch size range: 3 - 10 mm diameter

Punch size range: 3 – 15 mm diameter Compaction rate: 0.01 – 3 mm/s

Data capture rate: 200 Hz

Load cell travel: 40 mm

Load cell resolution: 1:5000

Calibration: Dead weights or proving ring
Power requirements: 80-260 VAC 3.15A
Instrument dimensions: 320 × 285 × 388 mm

Instrument weight: 24kg

Shipping size:  $390 \times 350 \times 470 \text{ mm}$ 

Shipping weight approx: 28kg





Request a demo at gamlentableting.com/contact

Contact us for a quote at sales@gamlentableting.com