

Traditional methods of assessment of the physical and structural properties of a freeze-dried cake are limited to subjective, qualitative tests that do not necessarily provide evidence of robustness to transport and handling.

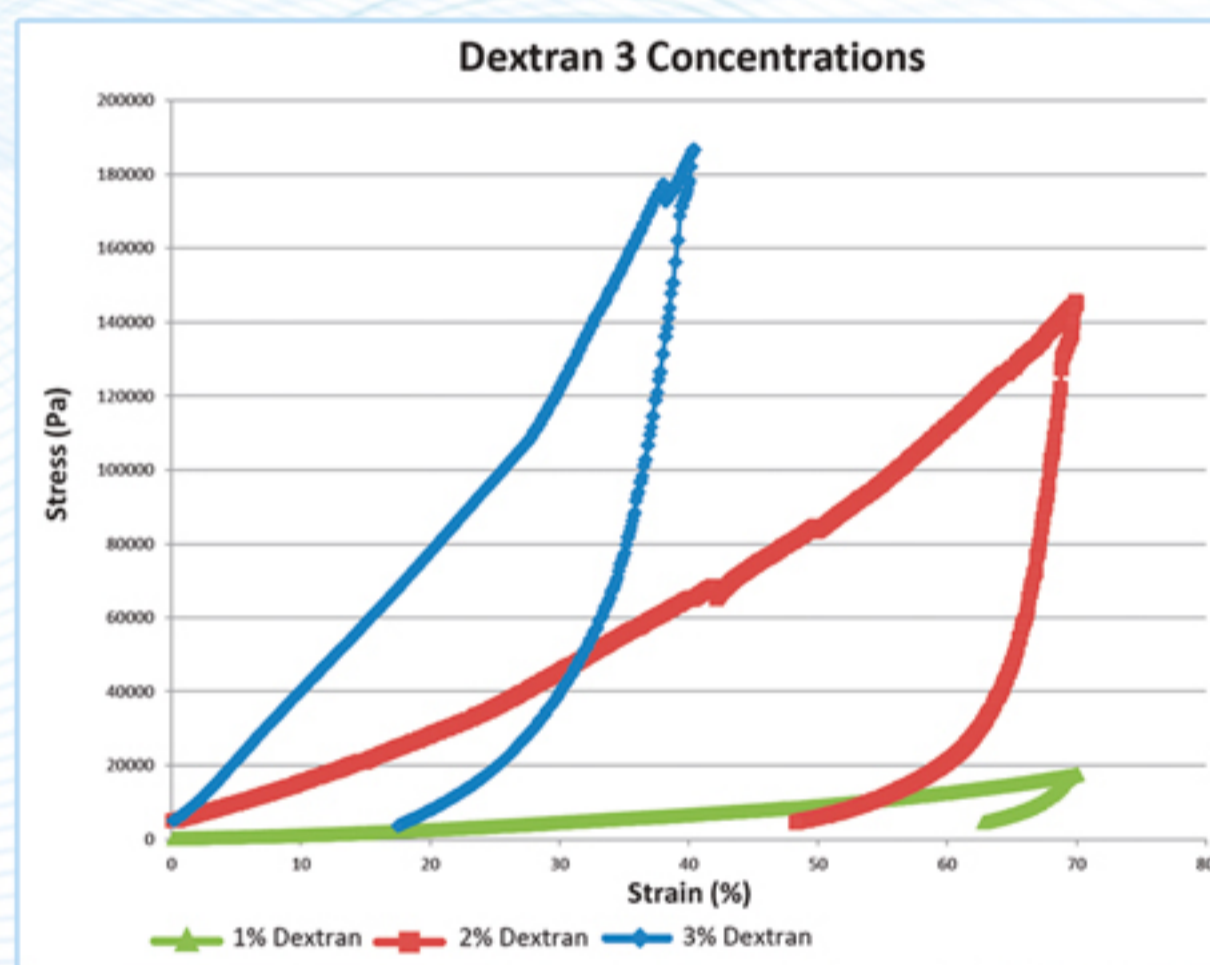


### Our solution

Biopharma Group has developed a quantitative method for determining the stiffness (Young's Modulus) and strength (max stress at failure) of lyophilized cakes. The MicroPress uses a linear actuator to gently compress the cake while a load cell accurately measures the force applied. The resulting stress-strain profile captured by the integrated software is then exportable to Microsoft Excel for further interpretation and analysis. By performing this analysis, the user can determine how the cake will behave during handling and shipment.

### Cake strength can be affected by:

- Freezing conditions (cooling rate, temperature, use of annealing)
- Excipients used, their concentration and relative proportions
- Collapse or microcollapse occurring during lyophilization
- Location within the dryer itself due to heat transfer differences



A graph showing mechanical properties of different concentrations of Dextran

### Key benefits

- Determine key parameters for cake quality
- Easily measure physical properties
- In situ analysis – no sample prep required
- Shelf mapping
- Ensure product quality during storage
- Batch QA/QC
- Quick analysis time (less than 1 minute)
- Identify vials with microcollapse
- Quickly compare multiple vials
- Determine cakes with a weaker structure which may not stand up to shipping
- Ensure product quality to the point of delivery
- Batch reproducibility

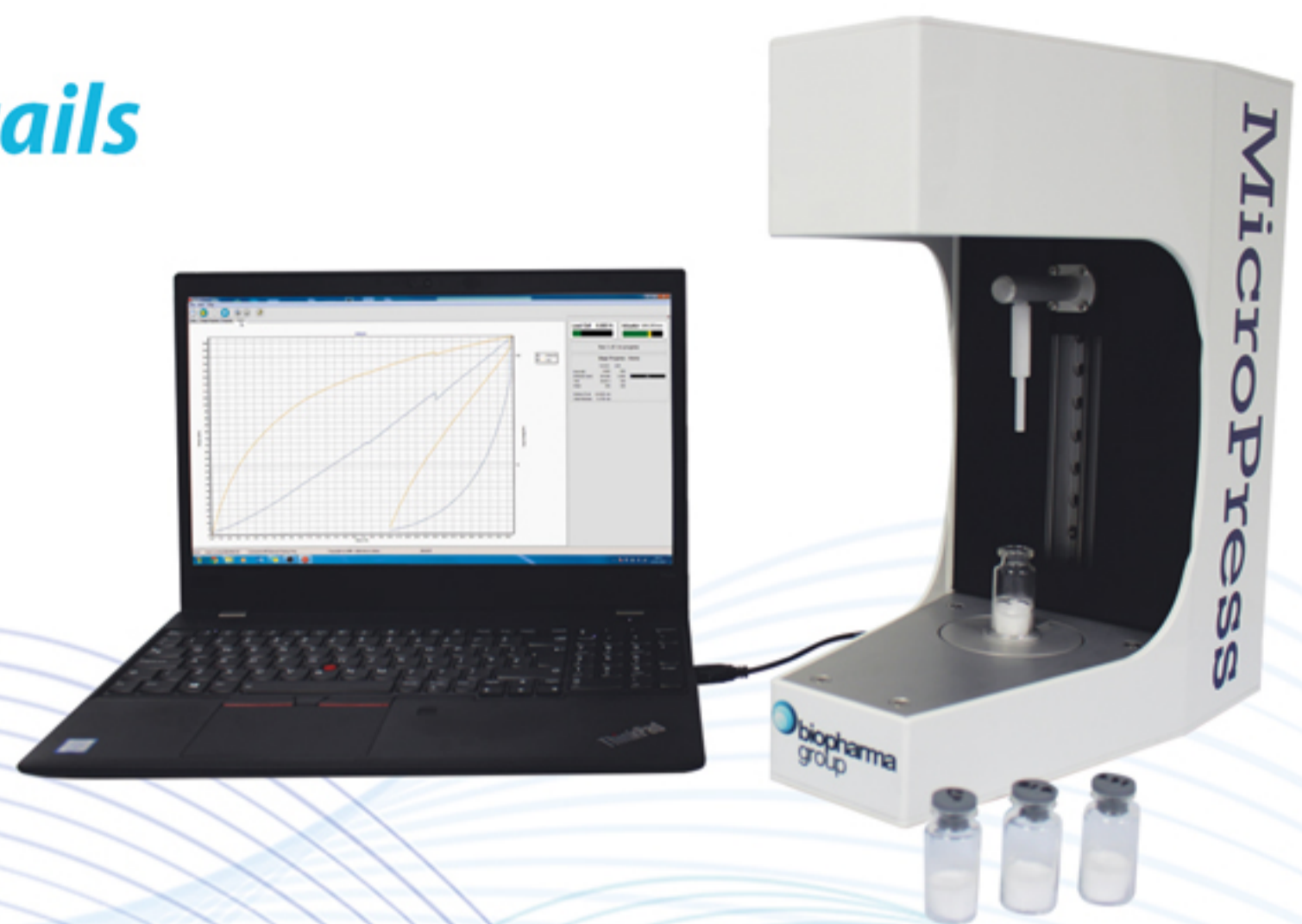
To request more details or discuss your requirements further, please contact our specialists at [www.biopharmagroupcdmo.com](http://www.biopharmagroupcdmo.com)

# MICROPRESS

## QUANTIFYING LYO CAKE ROBUSTNESS

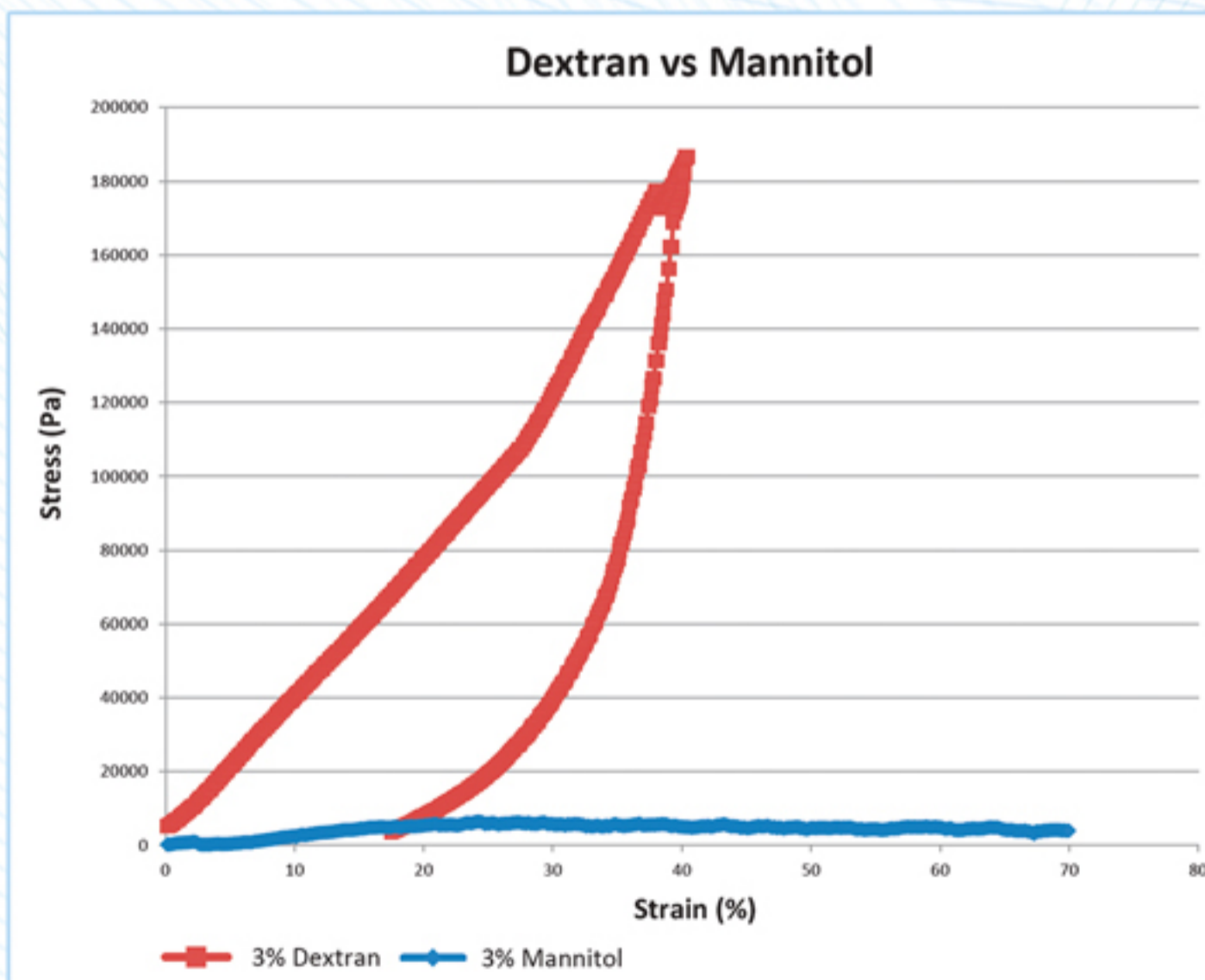
### Micropress Technical Details

- Speed: 0.0012-10mm/s
- Force: 0.1-5 N
- Accuracy:  $\pm 0.03\%$
- Up to 25 samples per group
- Calibrates to any size vial
- Custom indenters available
- Analysis time: 30-90 seconds
- 9 customisable parameters
- 21CFR part 11 compliance (optional)
- Operating Temperature:  $-10^{\circ}\text{C}$  -  $+40^{\circ}\text{C}$

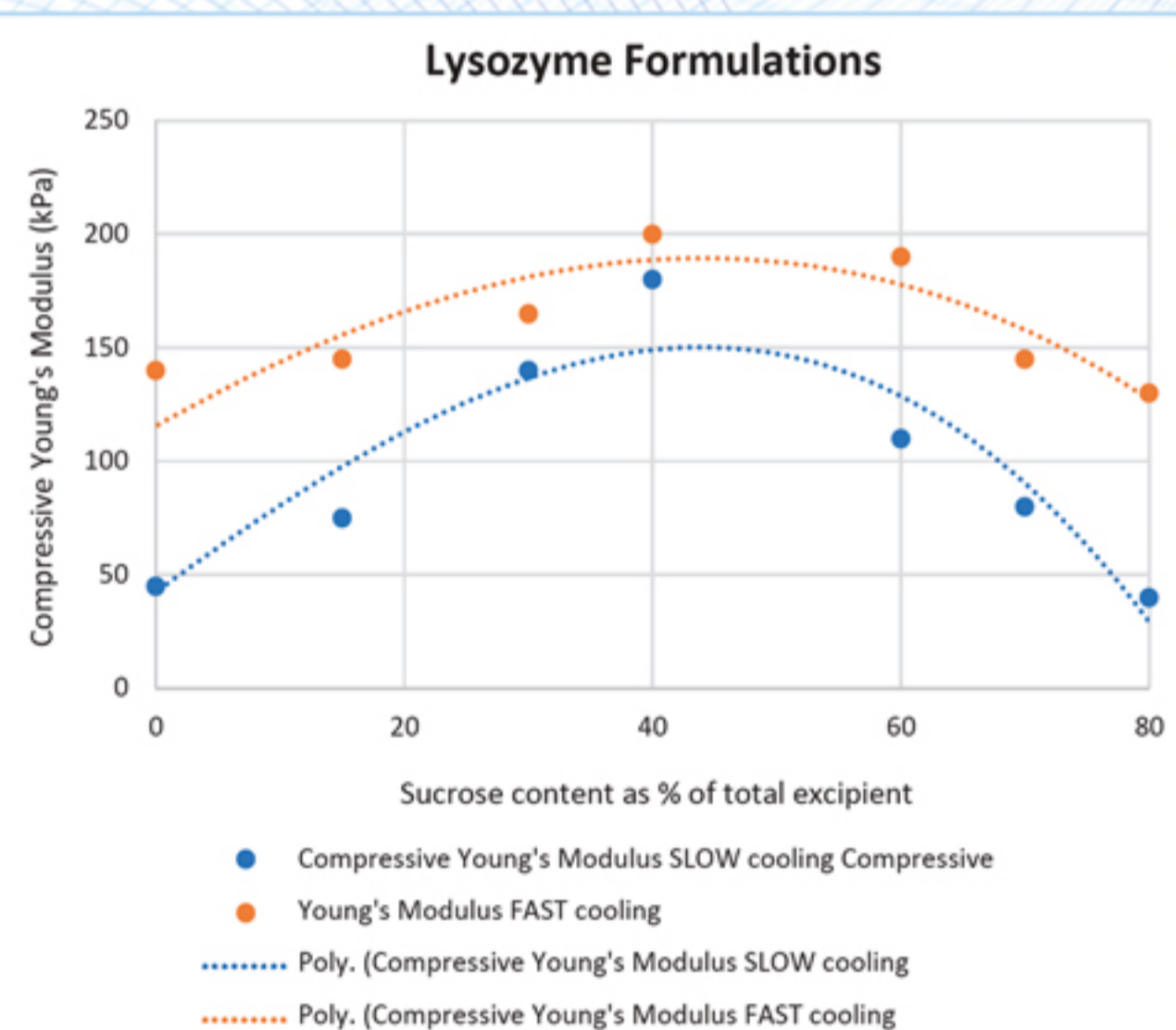


Event/Instrument	DSC	KF	SEM/TEM	Visual Inspection	MicroPress
Micro Collapse	X	X	✓	X	✓
Collapse	X	X	✓	✓	✓
Moisture content	X	✓	X	X	✓*
Glass Transition	✓	X	X	X	X
Quantitative data	✓	✓	X	X	✓

\* When calibrated against Karl Fischer



A graph showing stiffness of Dextran vs. Mannitol freeze-dried from the same starting concentrations.



A graph showing elastic properties of Lysozyme formulations where two different cooling rates were used in the freezing phase of the lyo cycle.



Adapted from McCartney, S. (2014) Mechanical characterisation of freeze-dried biopharmaceuticals  
PhD thesis, Imperial College London.

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