

Process development is a critical stage in scaling up pharmaceutical manufacturing processes. Time and API is precious in process development and it is critical that all major risk factors are identified before tech transfer to manufacturing. Traditionally, scale up facilities are used in process development. A more modern approach to process development is to use laboratory-scale simulators that closely mimics commercial production but can operate more quickly and with less API. The rich data collected from laboratory-scale simulators supports Pharma 4.0 initiatives through quickly gaining process knowledge, rapidly develop scalable PAT models. These data can also input into digital twins.

One proven example of a laboratory-scale simulator is the FFSim™ from Expo Process Analytics to simulate tablet press feed frames. Used by the world's leading pharmaceutical innovators, the FFSim™ reduces API usage, speeds up process development, and enables PAT and Quality by Design approaches for blend uniformity or content uniformity.

- ▶ Highly configurable for process development or general powder characterization
- ▶ Supports up to two spectroscopic PAT probes, including NIR, Raman, UV, and LIF
- ▶ Installation for benchtop, fumehood, or high containment areas
- ▶ ~ 300 mL chamber volume reduces material requirements and cGMP equipment usage by 90%
- ▶ Configurable inlet and outlet ports for accurate flow-through simulations.



## The Feed Frame is comprised of five main parts:

1. The measurement chamber.
2. The drive housing for the rotational Spider Wheel.
3. The Spider Wheel (various designs available).
4. Precise probe positioning interfaces for several common spectrophotometer types.
5. A bottom exit valve capable of precise control of the bottom exit cavity size enabling flow through work.

The Feed Frame simulator can be supplied with spider wheels that mirror the wheels in a range of tablet press types. The ability to swap out these wheels, aids the simulator to more accurately represent different brands of commercial press.

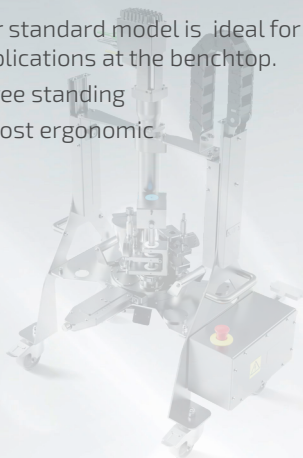
The system is fully compliant for industrial safety regulations. The optical probes and spectrometers are supplied separately by specialist manufacturers.

## FFSim™ Variants:

### Standard

Our standard model is ideal for most applications at the benchtop.

- Free standing
- Most ergonomic



### Compact

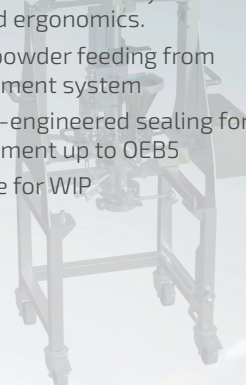
This is shorter than the standard model and is well-suited for installation in a fume hood or glovebox for increased containment.



### FlexCon5

Also for high containment but remains outside containment system for improved ergonomics.

- Direct powder feeding from containment system
- Fully re-engineered sealing for containment up to OEB5
- Suitable for WIP



## Technical Specifications

The system's structural frame allows safe, easy access and ergonomic operation. All product-contact materials are FDA-compliant.

<b>Contact Materials</b>	316L stainless steel	
<b>Finish</b>	0.4 RA / 0.8 RA	
<b>Run Speed</b>	0-100 rpm	
<b>Ambient Temperature</b>	+10oC to +40oC	
<b>Electrical Supply</b>	110-240V (50-60Hz)	
<b>Dimensions</b> Standard   Compact   FlexCon5	<b>Height</b>	120   80   113 cm
	<b>Width</b>	75   75   73
	<b>Depth</b>	60   60   54
	<b>Weight</b>	52   52   66 kg
<b>ATEX</b>	Zone 21 internal, Safe Area external	
<b>Connectivity</b>	MODBUS TCP	
<b>Containment</b> FlexCon5 only	Up to OEB5	
<b>Control Unit</b>	270 x 456 x 230 mm 25 kg	

## PAT Probe Compatibility

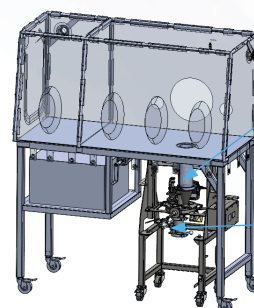
<b>Probe Configuration</b>	Allows up to 2 probes for simultaneous measurement
<b>Supported Probe Types</b>	NIR, Raman, LIF, UV Contact & non-contact; list of adaptors available on request

## Spider Wheel Option



Additional designs available on request

## FlexCon5 Containment



Inlet funnel connected to containment system with hygienic tri-clamp

Outlet valve for contained Wash In Place (WIP)

Containment system shown for demonstration purposes only.



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ATEX   IEC  cGMP