Continuous Mixing of Solids

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Outline

- Continuous Acoustic Mixer (CAM) System Configuration
- Continuous Mixing Principles
- The Transition from Batch to Continuous
- Considerations:
  - Orifice Area
  - Acceleration
- Examples of Continuous Powder Mixing

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Beyond Batch Mixing

- Batch Mixing Provides Suitable Processing for Materials, but Limitations in the Amount of Material That Can Be Manufactured Are Imposed by the Batch Vessel Size
- Approach Taken to Overcome the Limitation is to Extend the RAM Technology into Continuous Processing

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Continuous Mixing System Requirements

- System Requirements - Develop a Continuous Mixing System that
  - Uses the universal RAM technology platform
  - Has flexibility for use with all forms of materials
  - Does not have 'moving' parts
  - Is modular and customizable
- System Outcome - A Continuous Mixing System has been Developed that
  - Meets all of the above requirements
  - Has high mixed material throughput capabilities

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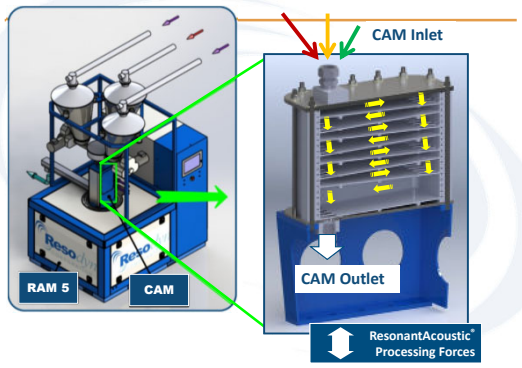
Continous Acoustic Mixer (CAM) Configuration



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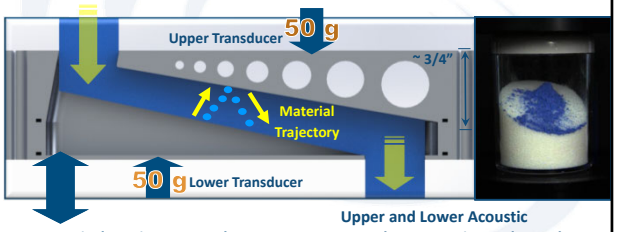
Continuous Acoustic Processor



60 Hz Vertical Motion Imposed on Transducer Stack by RAM Platform

Upper and Lower Acoustic Transducers Continuously Work on the Materials Being Mixed

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CAM Module

- The Fundamentals between Batch and Continuous Mixing are the Same
- RAM Technology Creates Up to 0.55 Inch Oscillating Displacement at ~60 Hz
- Mixing Occurs through Random High Energy Particle Collisions

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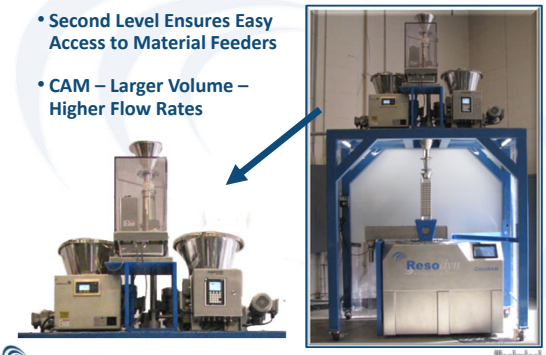
Prototype OmniRAM PharmaCAM System

- Second Level Ensures Easy Access to Material Feeders
- CAM – Larger Volume – Higher Flow Rates



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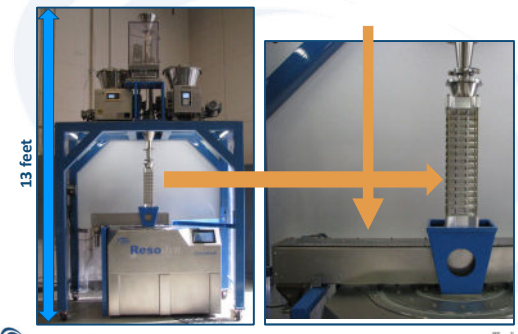
Prototype OmniRAM PharmaCAM System



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Conveyer System

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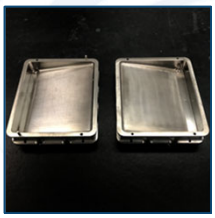
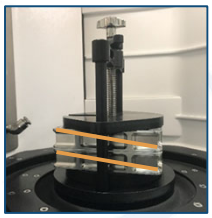
Single CAM Module



Single Open CAM Module



Side View

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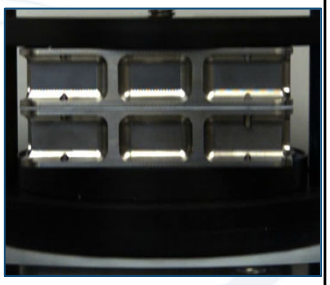
The Transition



80 *g* of Acceleration, 60 fps

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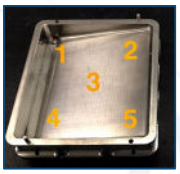
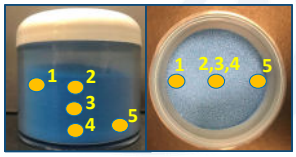
Thermal Gravimetric Analysis

- Thermal Gravimetric Analysis (TGA) Provides a Reliable and Reproducible Measure of Homogeneity within a Mix
- A Mix of Two Proprietary Materials
  1. 80% Inorganic Material
  2. 20% Organic Material





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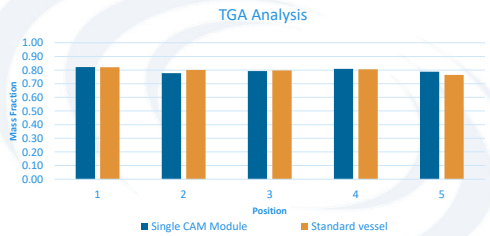
CAM Plate Results



Single CAM Module	
Average	79.8%
Standard Deviation	2.05%
RSD	2.58 %

Standard vessel	
Average	79.8%
Standard Deviation	1.76%
RSD	2.21 %

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Design Considerations

- Loss in Weight Feeders
- Conveyor Design and Belt Speed
- Material Properties
- Area Considerations
  - Orifice Size/Number
- Acceleration Considerations

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Orifice Size

- At the lower End of Each Plate there is a Transition Hole
- Either a Large Slot or Series of small holes
- Affect the Flow Rate

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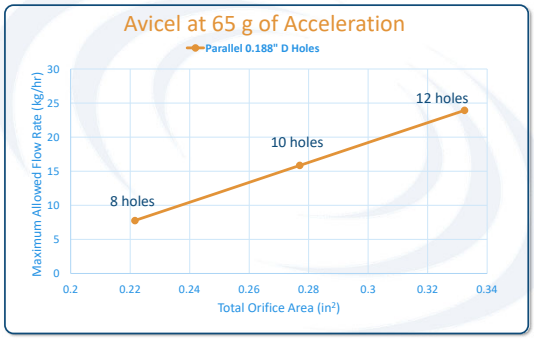
Orifice Size/Number of Holes on Max Flow Rate



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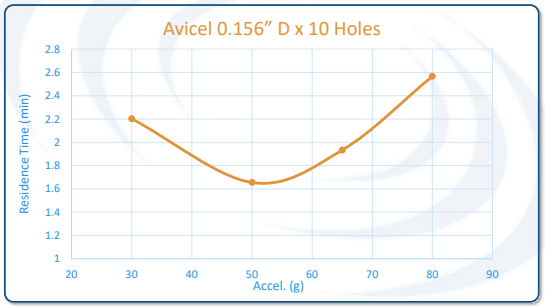
Acceleration and Residence Time

- Driving forces of movement down the plates



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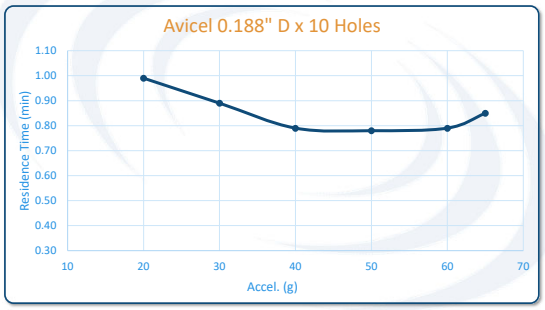
Acceleration and Residence Time



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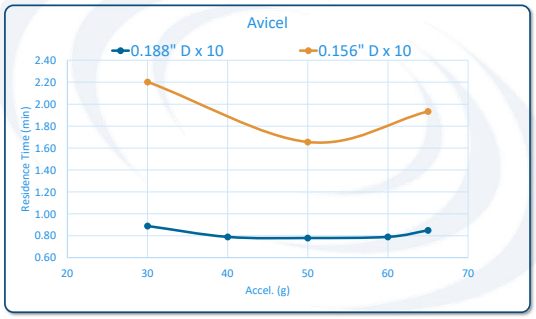
Acceleration and Residence Time



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Processing Rates

- Capacity of CAM/Residence Time = Flow Rate
- Example: OmniRAM
  - Residence Time: 1 minute
  - CAM Capacity: 5 kg
  - 5 kg/1 min= 5kg/min or 300 kg/hr

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Processing Rates

- Capacity of CAM/Residence Time = Flow Rate
- Example: RAM5
  - Residence Time: 1 minute
  - CAM Capacity: 36 kg
  - 36 kg/1 min= 36kg/min or 2,160 kg/hr

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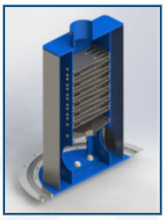
Solid-Solid Mixing: Uniform Particle Size

- White Sand and 9.1% Dyed Sand
  - White sand in at 3.2 kg/min
  - Red dyed sand (260 ppm) in at 0.32 kg/min
  - 12 plates in CAM
  - 30 g acceleration
  - Collected samples every 5 sec from exit orifice



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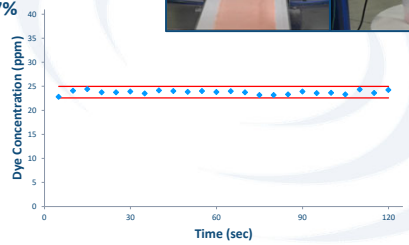
Solid-Solid Mixing: Uniform Particle Size

- Average at Outlet 23.8 ppm, 95% CI = ±0.18 ppm
- RSD 1.7%



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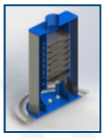
RAM Batch Compared to CAM

Comparisons Between Batch and Continuous RAM Mixer Methods Demonstrate Similar Mixing Results



Batch Mixing	Continuous Mixing
4.2 wt% Glucose w/ 0.25% EH-5	4.2 wt% Glucose w/ 0.25% EH-5
95.8 wt% Avicel PH-200	95.8 wt% Avicel PH-200
Low head height	N/A
80g's	60g's
25 seconds	25 seconds
%RSD = 3.7	*%RSD = 2.7*

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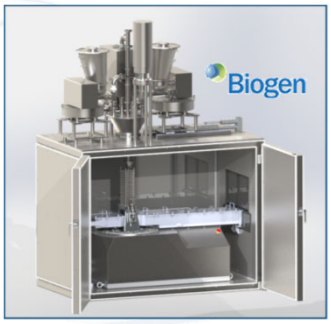
Biogen *Omni*RAM Continuous Pharmaceutical Mixer

- Continuously Mixes From 10 to 20 kg/hr
- Residence Time Variable from < 30 sec to >120 sec
- Multiple and Complex Excipient Feeds
- Very Low Percentage Active Ingredient
- Exceptional RSD (<2%)
- Integrated with Upstream and Downstream Product Manufacturing Processes



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Summary

- Platform of the CAM Remains the Same
- Design Considerations
  - Orfice Area
  - Acceleration
- Confidence from Batch to Continuous

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Thank you for your time and attention.

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