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INTERNATIONAL *update*

Cosmetics | Healthcare | Household | Pharmaceuticals

January/February 2026 Vol. 33 No. 1

A Binsted Publication

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NUTRACEUTICAL BLENDING CYCLES CUT

With increasing demand for its health and wellness nutraceutical supplements, A&Z Pharmaceutical built a 2483m² wing and production line here dedicated to nutraceutical products that were previously produced at another site. The company cut blending times on a new production line over 90 percent by opting for Rotary Batch Mixing over the V-cone blending employed on other lines.

“Chiefly, A&Z needed uniform blends of dry ingredients without compacting them,” says Marian Vija, director research & development. “We make claims of uniformity for all the actives in our formulations and have to meet those claims in the final product - capsule, tablet, and powder drink.” The company also desired shorter mixing cycle times with no product damage or segregation of materials.

The V-cone blenders did the job on the existing calcium and vitamin D production lines but typically were taking 45 to 60 minutes per batch to achieve the desired uniformity, prompting the purchase of a 1133L capacity stainless steel model 700-TS-40-SS Rotary Batch Mixer from Munson Machinery.

The unit contains internal mixing flights that tumble, cut, turn and fold the batch, causing particles to recombine 288 times per minute, achieving batch uniformity in four minutes, or 11 to 15 times faster than the company’s V-cone blenders. The company also gained production flexibility, as the mixer is equally efficient from 100% down to 15% of rated capacity.

On the production line, an operator starts the empty mixer and uses a drum lift to transfer ingredients from fibre drums into the mixer’s stationary inlet in a prescribed order, following the steps in the master batch record.

“Half of the time they are very fluffy materials that would occupy the whole volume of the machine. So we load them in and add another material to reduce the volume,” explains Vija.

For products intended for tablets or capsules, a dry lubricant such as magnesium stearate powder is added to the ingredients. This is a critical parameter in the mixing procedure, because one gram of the additive can lubricate 7 to 9 m³ of material. Excessive lubricant or overmixing will prevent product particles from sticking together in tableting. Adding lubricant extends the mixing time in the Rotary Batch Mixer by about half a minute, versus five minutes in the V-blenders. “The shorter mixing time makes overmixing and/or over-lubricating less likely,” says Vija.

The blended batch is unloaded into the same fibre drums in which the ingredients arrived. Lined with GMP compliant plastic bags, the drums are staged beneath the mixer’s discharge gate and filled as one operator at the control panel adjusts the mixer to rotate slowly, while a second operator positions each fibre drum below the gate.

A&Z established a protocol that complies with FDA Good Manufacturing Practices for sanitising and preventing cross-contamination. Once the mixing

vessel is emptied, it is put under vacuum to remove residual dust. Large access doors on opposite sides of the mixing vessel are then opened and any remaining product is vacuumed, after which the interior is pressure washed with hot water, and the vessel is rotated for several minutes. After the water is drained, a hot-water cleaning solution is added, and the mixer is rotated for several additional minutes. That solution is removed and the interior is again hosed down and drained and/or softly brushed as necessary. For a final rinse, hot water is added and the blender is rotated for several minutes, then drained. One litre of 70% isopropyl alcohol is then added, the mixer is rotated 10 times and drained. This step is then repeated, after which the mixer is dried under vacuum for two hours, and ready for another cycle.

The large doors of the vessel allow unobstructed access for cleaning and visual inspection of all product contact surfaces, which Vija says can be accomplished without moving the drum.

Actual A&Z nutraceutical ingredients were tested at the manufacturer’s facility using a laboratory-sized Rotary Batch Mini Mixer, with four minutes established as the optimum mixing time. A&Z also performed content uniformity studies on commercial batches made in the Rotary Batch Mixer in production. “We obtained excellent results: uniformity and a good mixing procedure,” Vija says. “The blends are suitably robust for compressing and encapsulation.”

 www.munsonmachinery.com