

APPLICATION BULLETIN

BACKGROUND/ CHALLENGE

An international manufacturer of active pharmaceutical ingredients (APIs) and excipients approached Sturtevant to manufacture a Pharmaceutical Micronizer[®] jet mill to be used in their pharmaceutical manufacturing facility. The company manufactures compressed tablets and must reduce the particle size of several solid pharmaceutical ingredients. The manufacturer needed a mill that could reduce their ingredients to a uniform size of less than 10-microns. Reducing to a uniform particle size increases surface area which enhances dissolution rate and bioavailability. The rate of dissolution of the tablet or capsule is crucial and inadequacies in bioavailability can mean that the ingredients are ineffective or worse, potentially dangerous, leading to toxic overdose. It is also imperative while milling to avoid degradation and change in polymorphic form caused by excessive heat generation.



STURTEVANT[®] PERFORMANCE

The pharmaceutical company consulted with Sturtevant, the company that invented the Micronizer, having over 75 years of experience with Micronizing. Sturtevant operates a full-service testing facility to analyze material characteristics, verify results, and to aid in specifying the right equipment solutions. Sturtevant can test APIs in batches of 2 grams up to several hundred pounds with excellent yields. The Pharmaceutical Micronizer is scalable from initial R&D phases through commercial launch and is listed with the USDA as compliant with the standards for sanitary design and accessibility.

EQUIPMENT RECOMMENDATIONS

SANITARY MICRONIZER[®]

MILL SIZE	AIR COMPRESSOR SIZE ¹ Compressed Air SCFM (SCMH)	² bHP	CAPACITY LBS/HR (KG/HR)
Qualification	8 (13.6)	2	1/8 – 1 (.05 – .5)
2"	20 (34)	5	1/2 – 2 (.2 – .9)
4"	55 (93.5)	13	2 – 40 (.9 – 18)
8"	130 (221)	31	10 – 100 (4 – 45)
12"	260 (442)	62	30 – 250 (13 – 113)

¹- Volume of free air at 60°F (16°C), 14.7 psi compressed to 100 PSIG. Includes air consumed by feed injector nozzle.

²- Brake HP necessary to generate 100 PSIG compressed air.

Larger sizes are available, for a complete list see the Micronizer[®] Product Bulletin.

SUMMARY

Once testing was complete, Sturtevant recommended the 4-inch Pharmaceutical Micronizer to best meet the customers' specific needs. The Pharmaceutical Micronizer reduced the particle size of the customer's APIs and improved the flow properties of their raw materials and tablet-to-tablet content uniformity. The increased surface area enhanced the actives dissolution rate and bioavailability and improved color and active ingredient dispersion in tablet excipients. The Pharmaceutical Micronizer protects sensitive materials, it does not generate heat and can micronize any pharmaceutical ingredient, even those with a very low melting points.