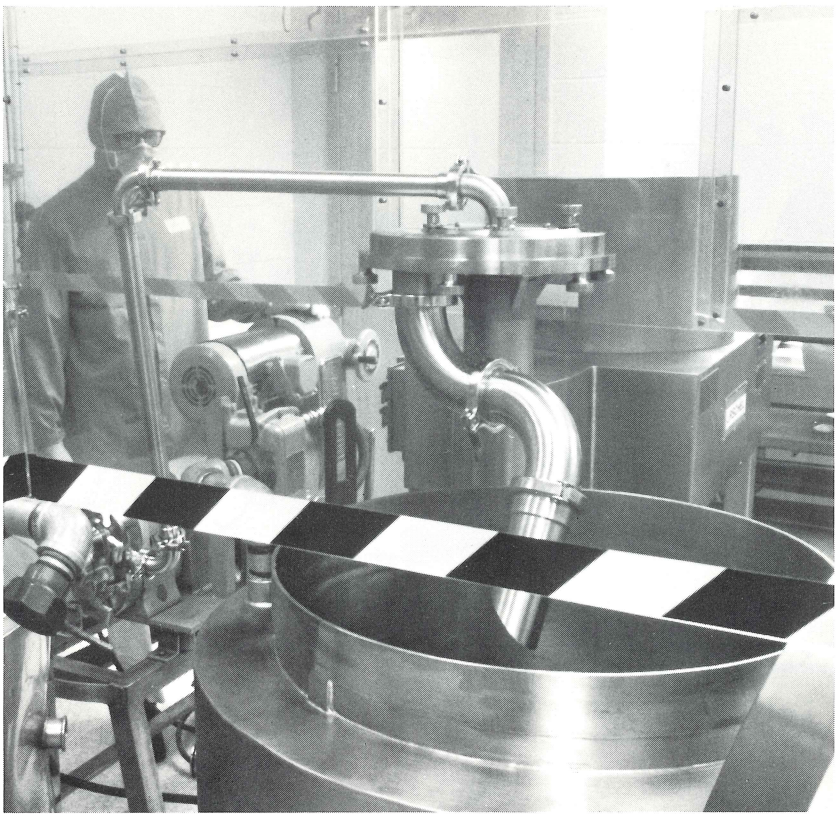
Uniformly small particles essential to pharmaceutical process



The sterile ointment is pumped from holding tank through the unit's microcut comminuting head and discharged into a second tank

Size reduction unit achieves better results in less time

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New Solutions to Plant Problems

Problem: One of Eli Lilly's processes that places some of the strictest demands on the production function is the manufacture of sterile ophthalmic ointments. These ointments must meet Lilly's quality standards, which include maintaining sterility and exercising rigid control over particle size, since these ointments are designed to be used in the human eye.

The company's previous method of production called for the ointment, base material plus active ingredient, to be passed continuously through a three roll mill until the desired particle size was achieved. The operation took 30 to 40 minutes for 40 lb (18 kg) of product. Production time and the need for consistent and critical machine adjustments to the three roll mill caused Lilly to search for a new method of size reduction. In addition to the production requirements for a new size reduction unit, ease of sterilization was also an important attribute sought.

Solution: A project was begun to study available size reduction equipment to find a solution to this production problem. One of the many machines analyzed by Lilly's engineering, production and technical service people was a machine that operates on a principle involving centrifugal force and a cutting action. The unit's operating principle makes it unique among mills in use throughout the pharmaceutical industry. With it, controlled size reduction is accomplished by a high-speed impeller that creates the centrifugal force that holds the product in contact with the sharp edges of the cutting blades.

Ultimately, the machine of this type that was decided upon by Lilly for use in the ointment process was a 15 hp model (various Comitrol® models can be fitted with motors from 10 to 100 hp depending on the application), with an impeller speed set for 9540 rpm, thereby developing 7759 G's of centrifugal force. Lilly purchased the unit with two microcut comminution heads, one designed to make a 0.0015″ (0.0381 mm) depth of cut; the other 0.0012″ (0.0305 mm). A wide range of heads is available for the unit.

The entire product-contact assembly of the machine can be removed from the unit for sterilization. By design, there is no metal-to-metal contact and no operating adjustments are necessary. Once the unit is assembled, after sterilization, the operator simply starts the machine and the process continues uninterrupted.

Results: With the use of this machine, the particle size reduction, which formerly required 30 to 40 minutes to achieve, is now accomplished in 5 to 10 minutes. The finished ointment is examined under a 30X microscope to assure that it contains no visible particles.

Eli Lilly and Company processes all of its sterile ointments made using powdered active ingredients in this manner. The size reduction machine provides sterility and excellent control over particle size and shape uniformity with no metal-to-metal contact and little need for operator adjustments. ■

For additional information about the Comitrol® size reduction unit, contact: Urschel Laboratories, Inc., P.O. Box 2200, Valparaiso, Indiana 46384-2200, USA. Telephone: (219) 464-4811, Fax: (219) 462-3879

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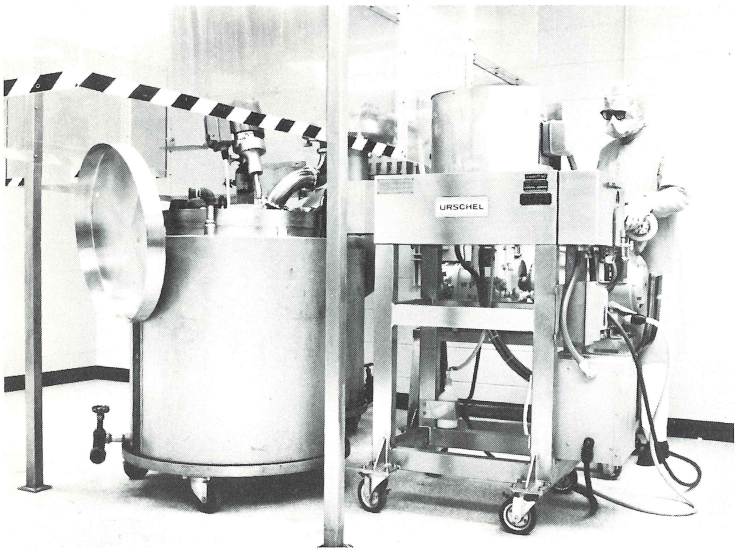
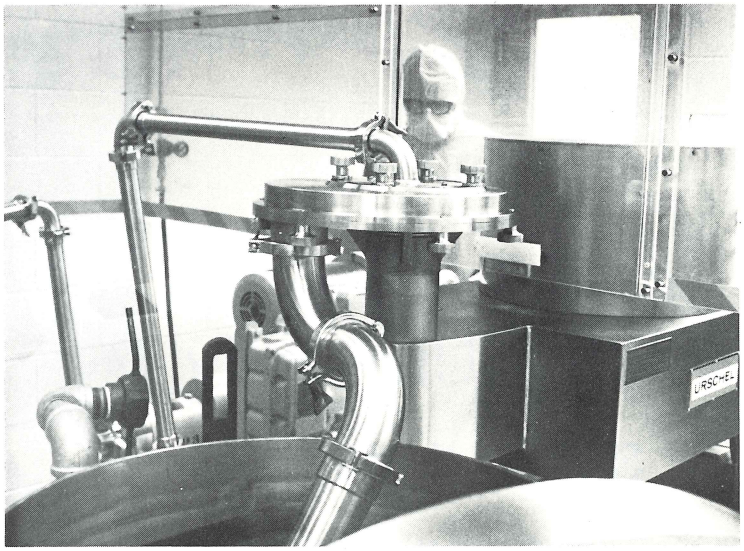
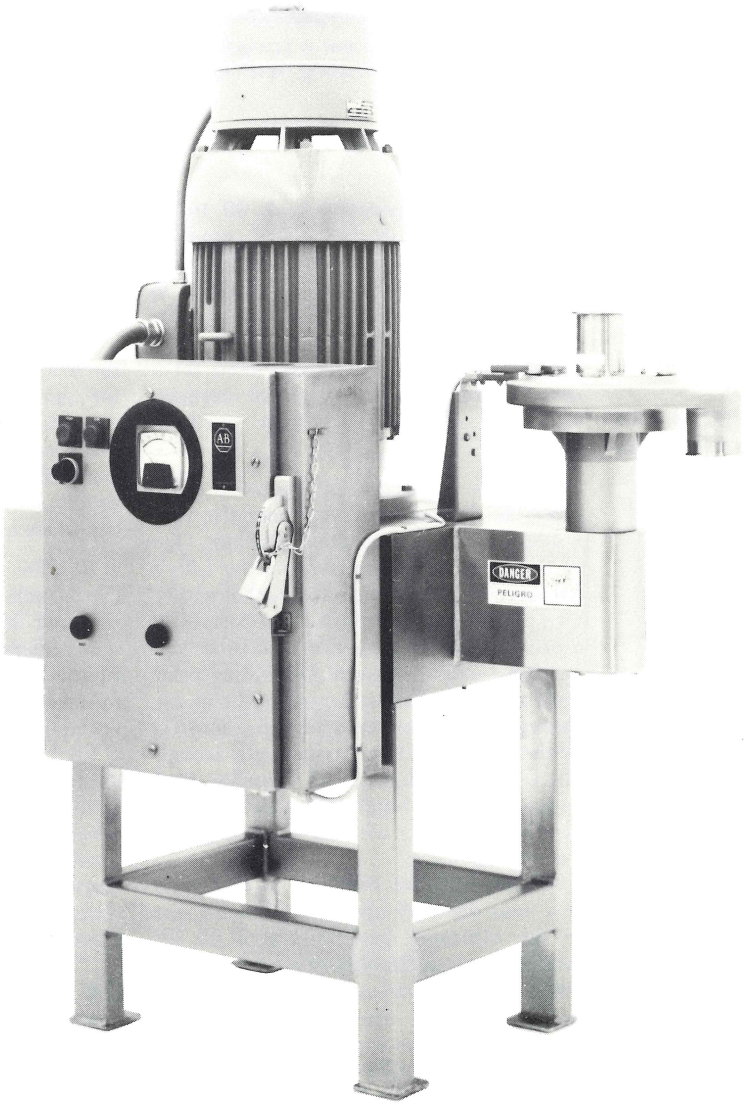


Urschel Comitrol® size reduction unit used in production of sterile ophthalmic ointments at Eli Lilly and Company (Indianapolis, Indiana). Shown here in sterile processing area, the portable compact unit was easily installed under Laminar flow hood.



The sterile ointment is pumped from holding tank through the Comitrol® unit's microcut comminuting head and discharged into a second tank.



Comitrol® Processor Model 1500
By Urschel Laboratories