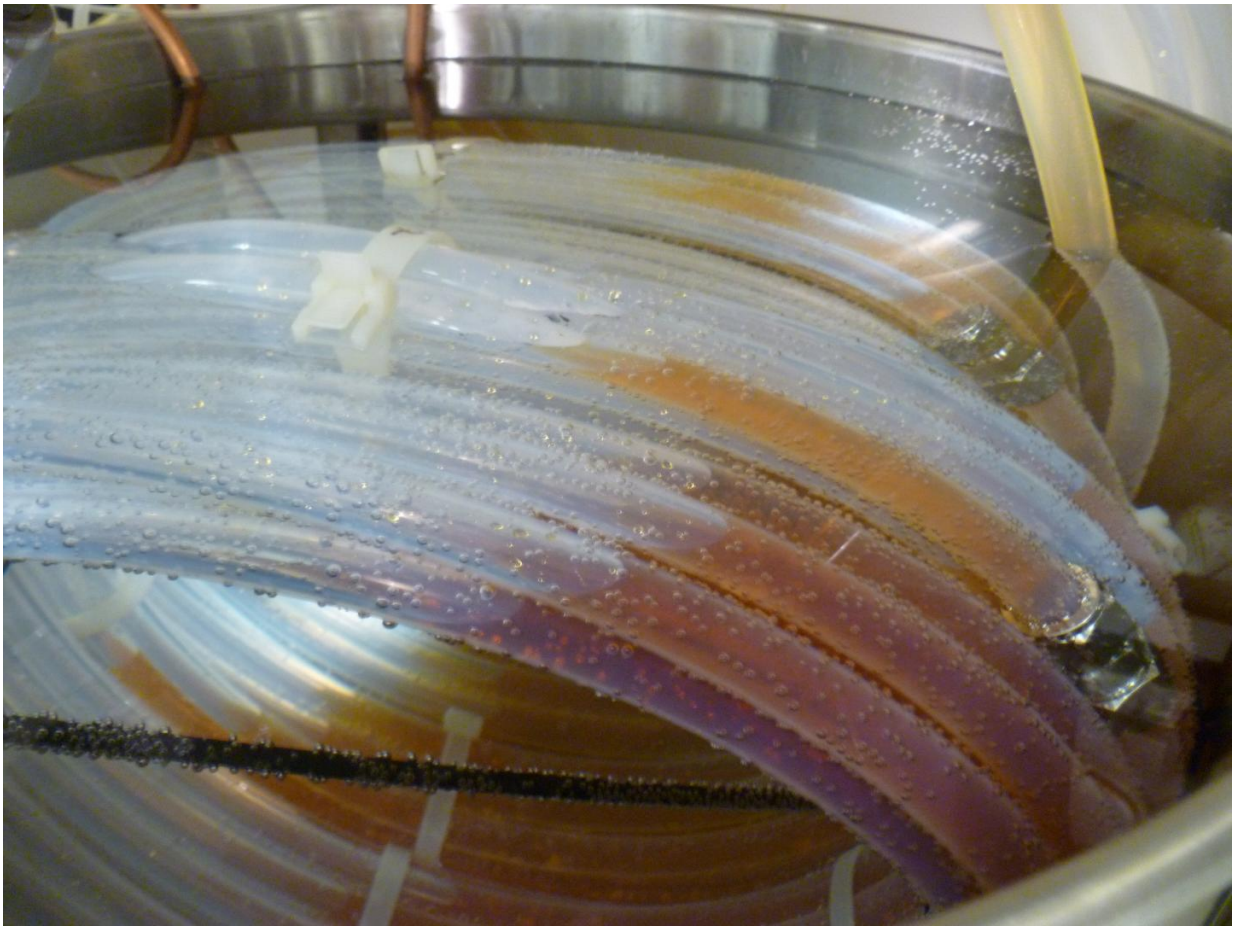
Eli Lilly develops continuous manufacturing process for chemotherapy drug

June 16 2017, by Bob Yirka



Photograph of deprotection gas/liquid reactor during processing. Credit: Eli Lilly and Company.

Researchers at pharmaceutical giant Eli Lilly have developed a continuous manufacturing process for a chemotherapy drug, officials with the company recently announced. In their paper published in the journal *Science*, the research team describes the process, how it works and possibilities for further projects.

Making legal drugs is big business, and huge pharmaceutical companies such as Eli Lilly have invested a lot of money in streamlining the process. Most drugs are made on a mammoth scale in step-wise processes designed to produce the largest amount possible of a drug at the lowest cost. But sometimes, that approach is not optimal—such as when a company wishes to conduct a clinical trial to test a new drug. In such a scenario, huge amounts of drugs are not involved which means drug companies face a tough choice: produce much more of the drug than is needed in a traditional production facility or make it in a small lab by hand. Both options are very costly. For this reason, drug companies have been looking at a new way to produce drugs called continuous manufacturing. In this approach, drugs are made in a continuous process rather than as a series of steps. Creating such processes has proved to be challenging, however, because making drugs is not just a matter of mixing ingredients in a tub. It involves inducing chemical reactions, for example, or growing crystals. In this new effort, the researchers at Eli Lilly report a technique to make small amounts of prexasertib monolactate monohydrate—a drug to be tested in a clinical trial for use as part of chemotherapy for cancer patients.

To be useful, a continuous manufacturing process must meet what are known as Good Manufacturing Practices, in which important parts of the process can be monitored by quality control systems. In the case of the new system, the research team chose prexasertib specifically because it is challenging to make—one of the parts of the process involves using hydrazine, an ingredient in rocket fuel. Also, the finished product is toxic, which presents problems for workers trying to make it.

The researchers report that the system is able to produce 3 kg of the drug per day, enough for use in their proposed clinical trials. They also report that moderate human intervention is required to keep the system running.

More information: *Science* 16 Jun 2017: Vol. 356, Issue 6343, pp. 1144-1150. DOI: 10.1126/science.aan0745 , science.sciencemag.org/content/356/6343/1144

Abstract

Advances in drug potency and tailored therapeutics are promoting pharmaceutical manufacturing to transition from a traditional batch paradigm to more flexible continuous processing. Here we report the development of a multistep continuous-flow CGMP (current good manufacturing practices) process that produced 24 kilograms of prexasertib monolactate monohydrate suitable for use in human clinical trials. Eight continuous unit operations were conducted to produce the target at roughly 3 kilograms per day using small continuous reactors, extractors, evaporators, crystallizers, and filters in laboratory fume hoods. Success was enabled by advances in chemistry, engineering, analytical science, process modeling, and equipment design. Substantial technical and business drivers were identified, which merited the continuous process. The continuous process afforded improved performance and safety relative to batch processes and also improved containment of a highly potent compound.

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