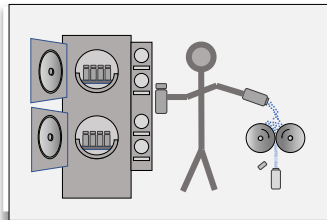
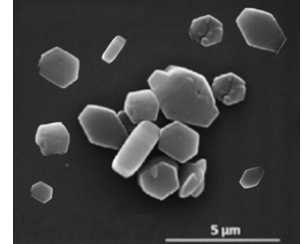




CASE STUDY: Optical Steroid Sterilization Autoclave Vs Continuous Thermal Sterilization...CTS

The Problem:

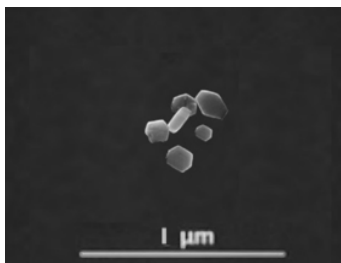
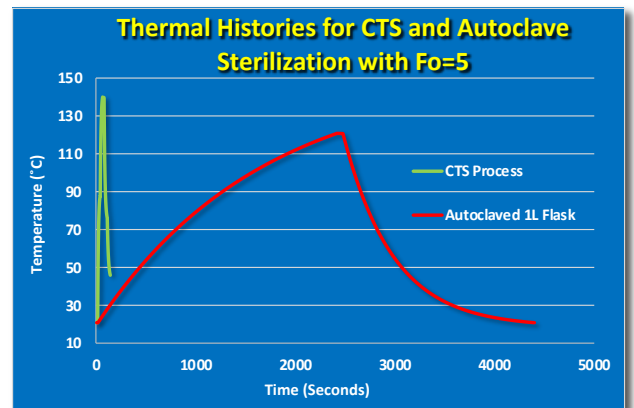
A global optical steroid manufacturer found that, after autoclave sterilization, their steroid suspension was not usable. The particles had grown during sterilization cycle. The suspension began with the right size particles, but their batch sterilization process took too long, and the particles grew much larger than their one-micron limit. The only solution was to mill the sterile steroid to attain a usable product.



This provided salable product but with a known failure level from the extra processing. It also required extensive monitoring and production controls. The milling method itself was cumbersome, requiring specialized clean-room facilities, personnel and practices. All led to significant ongoing expenses and known level of risk.

The Simple Solution:

Continuous Thermal Sterilization (CTS) from MTI BioScience appeared to be an excellent alternative. The manufacturer conducted a CTS trial. The test revealed that sterilization by CTS was so brief that it retained the original particle size below one-micron (Below). The solution did not require any further size reduction and the associated control steps.



Added Benefits:

This eliminated complex clean-room activity that was a known source of contamination. It also eliminated risks and reduced monitoring, simplified production and reduced expenses. Further review showed that the CTS process could be refined to increase assurance levels and the associated product safety.

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