

Product Manufacturing and Analytical Testing for an Ocular Client

STUDY OVERVIEW

Altasciences has a long-term relationship with an ocular client, for whom we regularly manufacture and perform analytical testing.

METHODS

In order to accurately and consistently meet our client's needs, we manage procurement logistics, manufacture the product, perform analytical testing, and terminally sterilize it for final delivery.

- **Managing procurement logistics**

- We efficiently coordinate and manage the procurement of a wide number of excipients from different suppliers, ensuring that all quantities are received on a schedule that respects the client's timeline.
- Altasciences also has capabilities to procure specialized packaging components for any of our clients, although it is not required in this case.

- **Manufacturing product**

- Our highly trained operators precisely mix the bulk product according to the client's formulation in Altasciences' Grade C compounding room, in a 7.4 kg batch size.
- Batch details for this client are confidential. However, using the latest, state-of-the-art equipment train, including Netzsch Deltavita mills, we can wet-mill your active pharmaceutical ingredient (API) to reduce particles and meet nano size specifications. Altasciences has the facilities and expertise to manufacture batch sizes from 1 kg to 100 kg for ocular products (up to 2000 kg for other therapeutic areas), ready for bulk delivery, clinical trial, or commercial supply.

- **Analytical testing**

- A representative sample of the in-process material is tested for purity, particle size, and several other product quality tests in our onsite analytical lab, using spectrophotometric, chromatographic, and particle size analyzer technology. These tests allow Altasciences to precisely quantify the API and determine that the material has been milled to the correct specifications for downstream processing.
- In the unlikely event that testing determines the product does not meet specifications, an investigation into the root cause is immediately carried out, and a corrective and preventative action plan (CAPA) is put into place to prevent failure of future batches.



CASE STUDY

- **Sterilization (terminal sterilization)**

- For this client, we send the bulk material for terminal sterilization. For other ocular development, we can bottle, apply band seals in a variety of colors or overprint, and package prior to sending for terminal sterilization.

CONCLUSION

Altasciences works in partnership with our clients to simplify the logistics of drug development programs, saving you time and money, and getting your products to market fast. All of our CDMO pharmaceutical manufacturing operations take place on a single campus with analytical, manufacturing, and cGMP warehouse capacity.

ABOUT ALTASCIENCES

[Altasciences](#) is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to [preclinical](#) and [clinical pharmacology](#) studies, including [formulation, manufacturing, and analytical services](#). For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include [preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis](#), program management, medical writing, biostatistics, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.