

MICHIGAN

GOOD MANUFACTURING PRACTICES

Grand River Aseptic Pharmaceutical Packaging (Grand River APP) is a non profit organization associated with the Van Andel Research Institute and Grand Valley State University. Located in Grand Rapids Michigan, we serve the bio/pharmaceutical industry by offering aseptic filling of liquids into single dose vials, lyophilization (freeze drying), client driven custom packaging services and cold storage of products. Our facility features Class 100 clean rooms, fully validated systems and FDA/cGMP regulatory compliance. We specialize in small batch sizes supporting preclinical and clinical trials and also smaller scale commercial products. Lyophilization capacity is 8000 vials per batch, depending on vial size. Our filling process is fully automated to accommodate batches of any size.

MGMP





SERVICES

The facility features aseptic cleanrooms up to Class 100 in a fully validated, FDA/cGMP regulated environment. Our services include:

■ *Fill-Finish*

Client supplied liquid products are sterilized by filtration, then processed through specialized equipment into single dose vials. The vials are capped or crimped, packaged and labeled. Final steps include sterility testing, storage and QA lot release.

■ *Lyophilization*

For certain materials, a lyophilization step (freeze drying) can be incorporated to drive off the liquid phase. This step occurs after filling vials, but before vial crimping. In general, lyophilization stabilizes the product and affords a longer shelf life.

■ *Packaging*

Our packaging services can be customized to meet client requirements. Whatever your need, we can offer an economical and rapid solution.

■ *Cold Storage*

We can provide cold storage of product to assist clients with warehousing and distribution services.

EQUIPMENT

■ Our filler/capper/crimper machines are fully automated and capable of processing vials from 0.5ml to 30ml (10–40mm diameter and 20–100mm height). Throughput is 10–40 vials per minute with a filling accuracy of +/- 0.5%.

■ The lyophilization process utilizes a combination of vacuum and cooling to achieve -40C and 0.1mbar. Capacity is up to 8000 vials per batch, depending on vial size.

ACCESS

All operations are available on a fee-for-service basis. For fill-finish and lyophilization services, clients will supply products which are already formulated. We can also assist with assay development, packaging options and FDA regulatory compliance.

CONTACT INFORMATION

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