

VBC

As described in the FDA/CBER "Points to Consider" (PTC), each lot of product should be Quality-Control monitored and tested (21 CFR 600.3(x)) at specific intermediate production steps, as follows:

Unprocessed Bulk Lots

The following tests should be performed on each crude material harvest:

- ❖ Sterility
- ❖ HPLC-SEC
- ❖ Adventitious Virus Contamination (with three indicator cell line.
- ❖ Mouse Antibody Production (MAP) or Hamster Antibody Production (HAP)
- ❖ Retroviral Contamination

Purified Product Lots

Routine testing of purified bulk lots of antibody should include the following:

- ❖ Purity (SDS-PAGE reduced and non-reduced)
- ❖ HPLC-SEC
- ❖ Isoelectric Focusing (IEF)
- ❖ Sterility
- ❖ Viral and Retroviral Contamination (if found in cell banks)
- ❖ DNA Content (must be less than 100 pg/dose)
- ❖ Western Blot (recommended) - pH and Appearance (recommended)

Final-Filled Product Lots*

The following tests should be performed on the contents of final containers from each filled lot (21 CFR 600.3(y)):

- ❖ Protein Concentration

Lot-to-Lot Quality Control Monitoring of Monoclonal Antibodies (PTC)

VBC

- ❖ Polyacrylamide Electrophoresis (Native and Reduced)
- ❖ Sterility
- ❖ General safety test (21 CFR 600.11)
- ❖ HPLC-SEC (recommended)
- ❖ Western Blot (recommended)
- ❖ pH and Appearance (recommended)
Isoenzyme

* Complex formulations, freezing, and lyophilization may change the protein and may require additional testing.

For more information contact:

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Lot-to-Lot Quality
Control Monitoring
of Monoclonal
Antibodies (PTC)

Vista Biologicals Corporation
Biotechnology Services

We can assist you with: