

Vista Biologicals recommends that one lot of bulk drug product be created to serve as a standard reference lot prior to assay development and validation (Since this material may be required prior to full or any purification development, it may have to be purified by affinity chromatography). This material should be thoroughly characterized and will be used as a comparison standard in each subsequent step of the drug development.

It is necessary, however, to determine the reasonable stability of the monoclonal antibody early in the process. We recommend the following course for the initial characterization:

SDS-PAGE (Reduced/Non-Reduced)	Purity / Identity
HPLC-SEC	Identify Initial Aggregates and Fragments / Purity
Isoelectric Focusing (IEF)	Purity / Heterogeneity (Highly Recommended by the FDA/CBER)
Western Blot	Identifies Bands as Product Related

Once the purity and initial characterization of the bulk reference lot has been determined, it will be necessary to determine the extinction coefficient of the antibody (usually 0.8 to 1.6 OD/mg). This can be done by absorbance determination of serial dilutions coupled with amino acid analysis. Once the extinction coefficient is determined, the absorbance data can be used to determine the concentration of unknown samples, as well as validate the Bicinchronic Acid test (BCA).

Characterization of a Recombinant Protein Bulk Reference Lot

VBC

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Characterization of
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Protein Bulk
Reference Lot

Vista Biologicals Corporation
Biotechnology Services

We can assist you with: