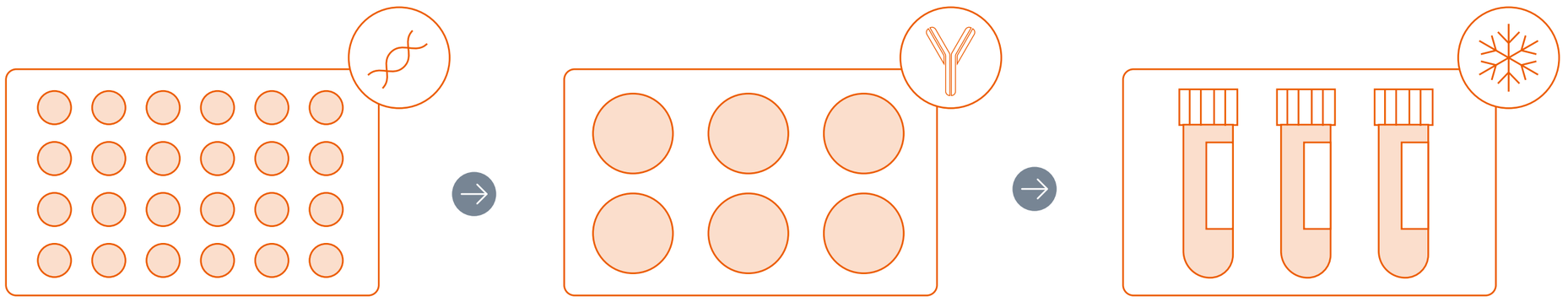
Ensuring quality in monoclonal antibody therapeutics with USP standards

1 CELL LINE DEVELOPMENT & EXPANSION



Cell Line Selection ⓘ
<1048>

Clone & Banking ⓘ
<1042>* <1050> <1237>

Expansion & Cryopreservation ⓘ
<1044>

ANTIBODY CHARACTERIZATION

Identity & Structure ⓘ 2
<736> *Mass Spectrometry*
<1736> *Intact & Reduced Mass*
<1055> *Peptide Mapping*
<210> <212> <1084> *Glycan Profiling* 1
<1052> *Amino Acid Analysis*
<1054> *IEF (pI determination)*
<1102> <1103> *Identity ELISA*
<1105> *Surface Plasmon Resonance*
<891> *Thermal Analysis*
<761> *NMR Spectroscopy*
<1853> *Fluorescence Spectroscopy*
<1430.3> *Dynamic Light Scattering*

General Properties ⓘ
<507> <1057> *Protein Concentration*
<785> *Osmolality*
<791> *pH*
<631> *Color/Clarity*
<790> *Appearance*

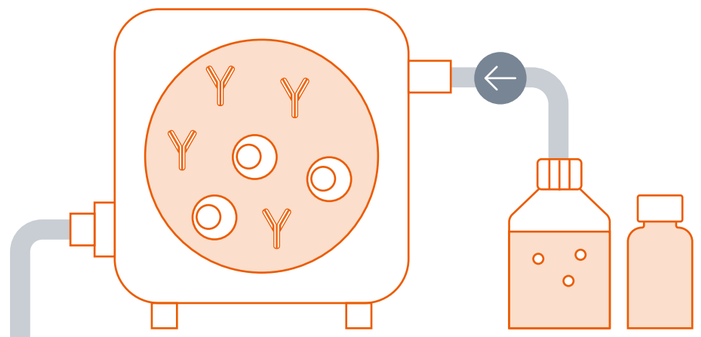
Product-Related Impurities ⓘ
<129> *SEC HPLC, CEX/cIEF, CE SDS, Aggregation & Degradation* 2
<621> *Chromatography*
<1053> *Capillary Electrophoresis*

Process-Related Impurities ⓘ
<1132> *Host Cell Proteins (HCP)*
<1132.1> *HCP by Mass Spec (in PF 49(3))*
<509> *Host Cell Residual DNA (HCD)* 3
<1130> *Residual DNA Testing*

Potency ⓘ
<111> *Design & Analysis of Biological Products*
<1032> <1033> <1034> *Potency Bioassay*
<1108> *FcRn*

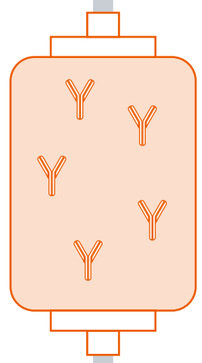
Contaminants ⓘ
<85> *Endotoxins* 4
<63> *Mycoplasma*
<1237> *Virus Testing*
<61> <62> <1229.3> *Bioburden*

2 UPSTREAM PRODUCTION



Bioreactors ⓘ
<665>* <1665>*

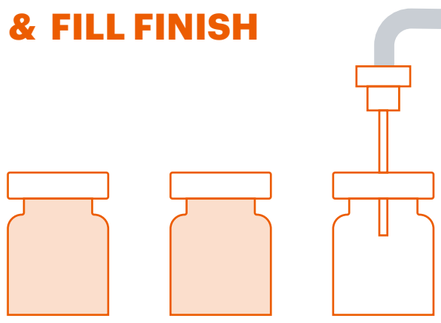
Raw Material & Cell Substrate Qualification ⓘ
<1043> <1050> <1050.1>



3 DOWNSTREAM PRODUCTION

Purification
Protein A
IEX Chromatography

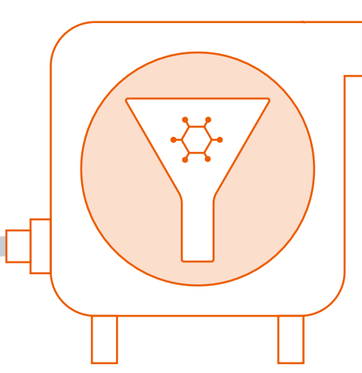
4 FORMULATION & FILL FINISH



Formulation ⓘ
<1059> <1231>

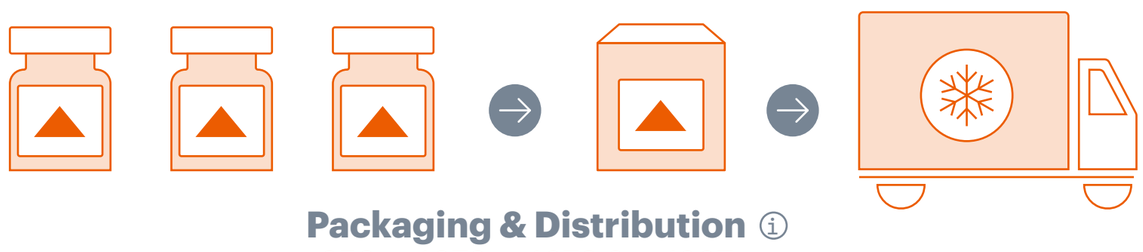
Sterile Filtration & Filling ⓘ
<1> <71> <787> <788> <1116> <1211> <1229.4> <1787>

Stability ⓘ
<1049> <1049.1> *Proposed*



Purification ⓘ
Virus Inactivation
Filtration
<1050> <1050.1>

5 PACKAGING & DISTRIBUTION



Packaging & Distribution ⓘ
<659> <1079> <1079.2> <1207>

Physical Materials

1 Glycan Profiling
N-Acetylneuraminic Acid (Cat # 1612619)
N-Glycolylneuraminic Acid (Cat # 1294284)
Oligosaccharide System Suitability Mixture A (Cat # 1478210)
Oligosaccharide System Suitability Mixture B (Cat # 1478221)
Oligosaccharide System Suitability Mixture C (Cat # 1478232)
Oligosaccharide System Suitability Mixture D (Cat # 1478243)

2 Monoclonal Antibodies
Monoclonal IgG Suitability (Cat # 1445550)
Monoclonal IgG1, mAb 001 RS (Cat # 1445539)
Monoclonal IgG1, mAb 002 RS (Cat # 1445547)
Monoclonal IgG1, mAb 003 RS (Cat # 1445595)

3 Impurities
PLBL2 HCP (Cat # 1582716)
CHO Genomic DNA (Cat # 1130710)
E. coli Genomic DNA (Cat # 1231557)

4 Adventitious Agents
Endotoxin (Cat # 1235503)

Download the Complimentary Chapter <129>
go.usp.org/l/323321/2018-10-16/xxzsl

For more details contact:
USPBiologics@USP.org

* In-Process Revision

Effective 19 JUL 2023

Ensuring quality in monoclonal antibody therapeutics with USP standards

List of Chapters

1 CELL LINE DEVELOPMENT AND EXPANSION

<1042> *Cell Banking (In Pharmacopeial Forum 47(1)- In-Process Revision)*
<1044> *Cryopreservation of cells*
<1048> *Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products*

2 UPSTREAM PRODUCTION

<665> *Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products. (In Pharmacopeial Forum 46(5)- In-Process Revision)*
<1043> *Ancillary Materials for Cell, Gene, and Tissue-engineered Products*
<1665> *Characterization of Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products Ancillary materials (In Pharmacopeial Forum 46(5)- In-Process Revision)*

3 DOWNSTREAM PRODUCTION

<1050> *Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin*
<1050.1> *Design, evaluation, and characterization of viral clearance procedures*
Cell media analysis-critical attributes and trace metals

4 FORMULATION & FILL FINISH

<1> *Injections*
<71> *Sterility Tests*
<787> *Subvisible Particulate Matter in Therapeutic Protein Injections*
<788> *Particulate Matter in Injections,*
<1049> *Quality of Biotechnological Products—Stability Testing of Biotechnological/Biological Products*
<1049.1> *Design of Stability Studies for Biotechnology Product Development and Lifecycle Management (Proposed)*
<1059> *Excipient Performance*
<1116> *Microbiological Control and Monitoring of Aseptic Processing Environments*
<1211> *Sterility Assurance*
<1229.4> *Sterilizing Filtration of Liquids*
<1231> *Water for Pharmaceutical Purposes*
<1787> *Measurement of Subvisible Particulate Matter in Therapeutic Protein Injection*

5 PACKAGING & DISTRIBUTION

<659> *Packaging and Storage Requirements*
<1079> *Risks and mitigation strategies for the storage and transportation of finished drug products*
<1079.2> *Mean kinetic temperature in the evaluation of temperature excursions during storage and transportation of drug products.*
<1207> *Package integrity evaluation—sterile products*

ANTIBODY CHARACTERIZATION

Identity & Structure

<736> *Mass Spectrometry*
<1736> *Applications of Mass Spectrometry*
<1055> *Peptide mapping: Biotechnology Derived Articles—Peptide Mapping*
<210> *Monosaccharide Analysis*
<212> *Oligosaccharide Analysis*
<1084> *Glycoprotein and Glycan Analysis—General Considerations*
<1052> *Biotechnology-Derived Articles—Amino Acid Analysis*
<1054> *Biotechnology-derived articles—Isoelectric Focusing*
<1102> *Immunological Test Methods—General Considerations*
<1103> *Immunological Test Methods—ELISA*
<1105> *Immunological Test Methods—Surface Plasmon Resonance*
<891> *Thermal Analysis*
<761> *Nuclear Magnetic Resonance Spectroscopy*
<1853> *Fluorescence Spectroscopy -Theory and Practice*
<1430.3> *Analytical Methodologies Based on Scattering Phenomena—Dynamic Light Scattering*

General Properties

<507> *Protein Determination Procedures*
<631> *Color and Achromicity*
<785> *Osmolality and Osmolarity*
<790> *Visible Particulates in Injections*
<791> *pH*
<1057> *Biotechnology-Derived Articles—Total Protein Assay*

Product Related Impurities

<129> *Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies*
<621> *Chromatographic procedures*
<1053> *Biotechnology-Derived Articles—Capillary Electrophoresis*

Process Related Impurities

<509> *Residual DNA Testing*
<1130> *Nucleic Acid-based Techniques - Approaches For Detecting Trace Nucleic Acids (Residual DNA Testing)*
<1132> *Residual Host Cell Protein Measurement in Biopharmaceuticals*
<1132.1> *HCP by Mass Spec (in PF 49(3))*

Potency

<111> *Design and Analysis of Biological Assays*
<1032> *Design and Development of Biological Assays*
<1033> *Biological Assay Validation*
<1034> *Analysis of Biological Assays*
<1108> *Assays to Evaluate Fragment Crystallizable (Fc)—Mediated Effector Function*

Contaminants

<61> *Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests*
<62> *Microbiological Examination of Nonsterile Products: tests for Specified Microorganism*
<63> *Mycoplasma Tests*
<85> *Bacterial Endotoxins test*
<1229.3> *Monitoring of Bioburden*
<1237> *Virology Test Methods*

Effective 19 JUL 2023