



Monoclonal Antibody (mAb)-related *USP-NF* Standards and Analytical Reference Materials

Below is a current list of mAb-related USP official standards published in the *United States Pharmacopeia-National Formulary (USP-NF)*, with related USP Reference Standards or ARMs.

USP-NF Documentary Standard and Proposed Standards	Related USP Reference Standards / ARMs (USP catalog #)
<u>mAb Overview</u>	
<u><129> Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies</u>	Monoclonal IgG System Suitability RS (1445550) BSA for Protein Quantitation RS (1076192)
	USP mAb 001, Monoclonal IgG1 RS (1445539) USP mAb 002, Monoclonal IgG1 RS (1445547) USP mAb 003, Monoclonal IgG1 RS (1445595) USP mAb 004, Monoclonal IgG4 RS (1457499) – NEW
<u>Glycan Analysis</u>	
<u><210> Monosaccharide Analysis</u>	N-Acetylneuraminic Acid RS (1612619) N-Glycolylneuraminic Acid RS (1294284) Oligosaccharide System Suitability Mixture A RS (1478210)
<u><212> Oligosaccharide Analysis</u>	Oligosaccharide System Suitability Mixture A RS (1478210)



<u><1084> Glycoprotein and Glycan Analysis—General Considerations</u>	
Intact Mass	
<u><736> Mass Spectrometry</u>	
<u><1736> Applications of Mass Spectrometry</u>	
Charge Variants	
<u><1053> Capillary Electrophoresis</u>	
<u><1055> Biotechnology-Derived Articles-Peptide Mapping</u>	
<u><1065> Ion Chromatography</u>	
Size Variants	
<u><1430> Analytical Methodologies Based on Scattering Phenomena—General</u>	
Impurity Analysis	
<u><509> Residual DNA Testing</u>	CHO Genomic DNA RS (1130710) E. coli Genomic DNA RS (1231557)
<u><1023> Evaluation Strategy for Trace Elements in Cell Culture Media used in the Manufacture of Recombinant Therapeutic Proteins*, in PF 48(5)</u>	
<u><1130> Nucleic Acid-Based Techniques—Approaches for Detecting Trace Nucleic Acids (Residual DNA Testing)</u>	
<u><1132> Residual Host Cell Protein Measurement in Biopharmaceuticals</u>	
<u><1132.1> Residual Host Cell Protein Measurement in Biopharmaceuticals by Mass Spectrometry, in USP-NF (Official as of 01-MAY-2025)</u>	<u>Host Cell Proteins</u> CHO Null Cell Harvest Cell Culture Fluid (HCCF) ARM (1544913) Purified Recombinant CHO Phospholipase B-like 2 protein (PLBL2) [HIS] ARM (1582716) CHO HCP PLBL2 Peptide ARM (1: 1130796) CHO HCP Cathepsin D Heavy Peptide 1 ARM (1130704) – NEW



	<p>CHO HCP Clusterin Peptide ARMs (1: 1130730; 2: 1130741; 3: 1130752)</p> <p>CHO HCP Glutathione-S-Transferase P1 Heavy Peptide 1 ARM (1130711) – NEW</p> <p>CHO HCP Lipoprotein Lipase Peptide ARMs (1: 1130763; 2: 1130774; 3: 1130785)</p> <p>CHO HCP Peroxiredoxin 1 Heavy Peptide 3 ARM (1130725) – NEW</p> <p>CHO HCP Protein Disulfide Isomerase (PDI) Peptide ARM (2: 1130727)</p>
Higher Order Structure (HOS)	
<u><782> Vibrational Circular Dichroism Spectroscopy</u>	
<u><854> Mid-Infrared Spectroscopy</u>	
<u><1430.3> Analytical Methodologies Based on Scattering Phenomena—Dynamic Light Scattering</u>	
Potency & Biological Activity	
<u><111> Design and Analysis of Biological Assays</u>	
<u><1030> Biological Assay Chapters—Overview and Glossary</u>	
<u><1032> Design and Development of Biological Assays</u>	
<u><1033> Biological Assay Validation</u>	
<u><1034> Analysis of Biological Assays</u>	
<u><1108> Assays to Evaluate Fragment Crystallizable (FC)—Mediated Effector Function</u>	
	Etanercept (Recombinant TNF Receptor II Fc Fusion Protein) for Bioassays RS (1255900)



* = in development; specific *PF* listed when available (note: these are not official and may never become official)

Analytical Reference Materials are different from USP Reference Standards and not required for compendial compliance.