



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. Included in the table below are some of the monographs and general chapters currently under development or in revision (labeled with an *).

USP-NF Documentary Standard	Related USP Reference Standards / ARMs
mAb Overview	
<129> Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies	Monoclonal IgG System Suitability RS BSA for Protein Quantitation
	USP mAb 001, Monoclonal IgG1 USP mAb 002, Monoclonal IgG1 USP mAb 003, Monoclonal IgG1
Glycan Analysis	
<210> Monosaccharide Analysis	N-Acetylneuraminic Acid N-Glycolylneuraminic Acid Oligosaccharide System Suitability Mixture: A
<212> Oligosaccharide Analysis	Oligosaccharide System Suitability Mixture: A
(1084) Glycoprotein and Glycan Analysis—General Considerations	
Intact Mass	
<736> Mass Spectrometry	
<1736> Applications of Mass Spectrometry	
Charge Variants	
<1053> Capillary Electrophoresis	
<1055> Biotechnology-Derived Articles-Peptide Mapping	
<1065> Ion Chromatography	
Size Variants	
<1430> Analytical Methodologies Based on Scattering Phenomena—General	
Impurity Analysis	
<509> Residual DNA Testing	CHO Genomic DNA E. coli Genomic DNA
<1023> Evaluation Strategy for Trace Elements in Cell Culture Media used in the Manufacture of Recombinant Therapeutic Proteins*, in PF 48(5)	
<1130> Nucleic Acid-Based Techniques—Approaches for Detecting Trace Nucleic Acids (Residual DNA Testing)	
<1132> Residual Host Cell Protein Measurement in Biopharmaceuticals	
<1132.1> Residual Host Cell Protein Measurement in Biopharmaceuticals by Mass Spectrometry*, in PF 49(3)	Host Cell Protein Purified Recombinant CHO Phospholipase B- like 2 protein (PLBL2) [HIS]
Higher Order Structure (HOS)	
<782> Vibrational Circular Dichroism Spectroscopy	



<854> Mid-Infrared Spectroscopy	
<1430.3> Analytical Methodologies Based on Scattering Phenomena—Dynamic Light Scattering	
Potency & Biological Activity	
<111> Design and Analysis of Biological Assays	
<1030> Biological Assay Chapters—Overview and Glossary	
<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	
* = in development; specific PF listed when available	

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