Monoclonal Antibody (mAb) Lot Release Testing for CHO Cell-Derived Products

Minaris Advanced Testing

Flyer

A Comprehensive Testing Panel for Confident Release

Ensuring the safety, quality, and consistency of monoclonal antibodies (mAbs) produced in Chinese Hamster Ovary (CHO) cells is fundamental to successful clinical and commercial biologics programs. A robust lot release testing strategy confirms that each batch meets predefined specifications for identity, purity, potency, safety, and regulatory compliance.

Because mAbs are complex glycoproteins expressed in living cells, their quality attributes are influenced by cell line stability, upstream and downstream processing, and product-specific critical quality attributes (CQAs) such as glycosylation patterns, charge variants, and aggregation levels. A comprehensive and well-controlled testing program is therefore essential to ensure product comparability, patient safety, and consistent therapeutic performance.

Requirements Differ by Product Stage

While core assays—such as identity, purity, potency, and safety—remain central throughout development and commercialization, the scope and stringency of testing evolve across bulk harvest (BH), drug substance (DS), drug product (DP), and stability stages.

At bulk harvest, testing emphasizes in-process controls and safety assessments, including bioburden, mycoplasma, and adventitious agent testing, as well as monitoring of host cell protein (HCP) and host cell DNA clearance.

For drug substance release, testing focuses on confirmation of molecular identity (e.g., peptide mapping, mass spectrometry), purity and heterogeneity (e.g., SEC for aggregates, CE-SDS, charge variants), glycosylation profiling, residual impurities (HCP, DNA, Protein A), potency through mechanism-of-action–relevant bioassays, and compendial safety testing such as sterility and endotoxin.

Drug product release builds upon DS testing with additional assessments of formulation-specific attributes, container closure integrity, particulate matter, and stability-indicating assays. Stability programs then verify that the mAb maintains its critical quality attributes—including structural integrity, biological activity, and safety profile—throughout its labeled shelf life under defined storage conditions.

Together, these stages form an integrated control strategy that ensures consistent mAb quality from cell culture through final patient administration.

Why Minaris?

Minaris Advanced Testing combines decades of biosafety and biologics testing expertise with advanced analytical and cell-based assay capabilities to deliver comprehensive lot release solutions for CHO-derived monoclonal antibodies. Our GMP-compliant laboratories support complete characterization and release testing panels, including molecular identity, impurity profiling, glycan analysis, potency bioassays, and compendial microbiological testing.

With expertise in host cell–related impurity testing, orthogonal analytical platforms, and stability-indicating methods, Minaris provides reliable, regulatory-ready data to support clinical development and commercial supply. Our integrated approach helps ensure consistent product quality, accelerated timelines, and confidence in every lot released to patients.

Attribute	Full Assay Name	BH	DS	DP	Stability	SAP Assay Number	Sample Requirements	TAT (days)
Safety	Isolator Sterility Testing by Direct Inoculation USP<71> (GMP) - (Up to 100mL TA or 20 Vials)	✓	✓	✓	✓	3000004994	Per USP guidelines	21
Safety	Bacteriostasis and Fungistasis (Direct Method) (GMP)[1]		✓	✓		3000004996	Varies depending on fill/volume	21
Safety	EP, JP, and USP Mycoplasma Detection (GMP)	✓				3000005147	1x15mL & 1e6 cells/mL	35
Safety	EP, JP, and USP Mycoplasma Detection with Mycoplasmastasis (GMP)	✓				3000007121	1x45mL & 1e6 cells/mL	35
Safety	Analysis of Bacterial Endotoxin Contamination Using Endosafe® nexgen-PTS™ (GMP)		✓	✓		3000005222	1mL	7
Safety	Analysis of Bacterial Endotoxin Contamination Using the Endosafe® nexgen-PTS™ - Test for Interfering Factors (GMP)		✓	✓		3000005260	1mL	14
Safety	Microbiological Examination: Microbial Enumeration Test according to USP<61> (GMP)	✓				3000005066	2x specification	14
Safety	Microbiological Examination of Non-sterile products: Microbial Enumeration Test Suitability <61> (GMP)	✓				3000005068	8x routine	21
Safety	In Vitro Assay for Adventitious Virus Contaminants - MRC-5, VERO, and CHO Cells with Hemadsorption and Hemagglutination Endpoints (GMP) - Extended Duration	✓				3000005092	2x6mL at 1e7 cells/mL	35
Safety	In Vitro Assay for Adventitious Viral Contaminants - (3 Cell Lines) in Plates - Standard Duration (GMP)	✓				3000004802	2x6mL at 1e7 cells/mL	24
Safety	MVM DNA Detection by qPCR using TaqMan (GMP)	✓				3000005740	1e7 cells frozen	12
Purity	CHO Host Cell Protein by ELISA (GMP)		✓			3000004862	1mL	14
Quality	Determination of Appearance According to the USP (GMP)			✓	✓	3000005469	2mL	8
Quality	USP<785> Determination of Osmolality (GMP)			✓	✓	3000007457	0.1 mL	8
Quality	USP <791> Determination of the pH and Appearance (GMP)			✓	✓	3000004853	1mL	8
Quality	USP<697> and EP 2.9.17 Determination of Extractable Volume in Containers (GMP)			✓	✓	3000005712	Depends on volume and # of vials[2]	14
Strength	Determination of Protein Concentration using the Micro BCA Protein Assay Reagent Kit (GMP)		✓	✓	✓	3000004829	1mL	21
Identity	Custom Identity and Characterization (GMP)			✓		Custom	Varies	TBD
Potency	Custom Potency (GMP)		✓	✓	✓	Custom	Varies	TBD

[1] Ingress Study may need to be conducted if the container has not been previously validated.
[2] 1 container if contents are 10mL or more; 3 containers if volume is between 3 mL and <10mL; 5 containers if volume is <3mL.

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