AAV Lot Release Testing

Minaris Advanced Testing

Flyer

A Comprehensive Testing Panel for Confident Release

Ensuring the safety, quality, and consistency of adeno-associated virus (AAV) vectors is essential for successful clinical and commercial gene therapy programs. A well-defined lot release testing strategy plays a critical role in confirming that each manufactured batch meets established specifications for identity, purity, potency, safety, and regulatory compliance and achieves its critical quality attributes (CQA).

Requirements Differ by Product Stage

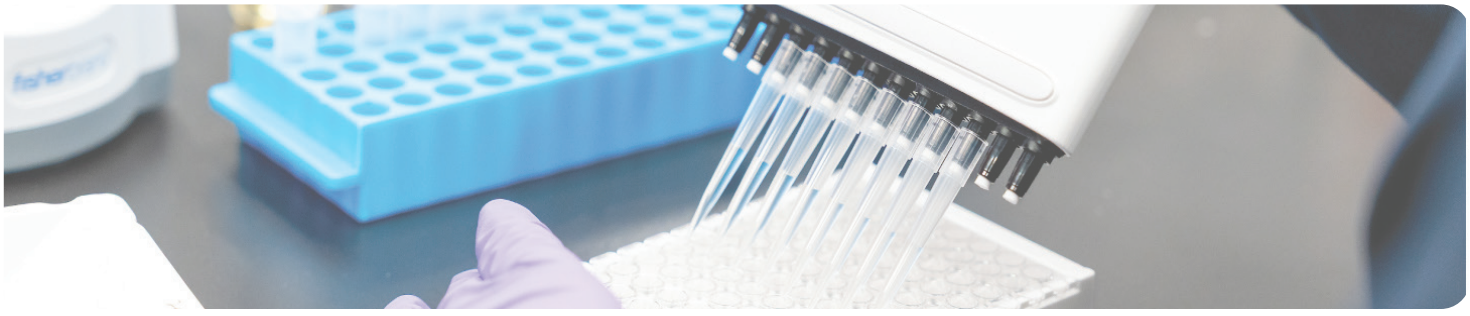
While some core assays (e.g., stage, titer, purity, and safety) are consistently recommended, the scope, purpose, and stringency of testing differ for bulk harvest (BH), drug substance (DS), drug product (DP), and stability studies.

Testing evolves from broad, process-focused monitoring at bulk harvest to highly controlled, specification-based release at the drug substance and drug product stages. Stability testing then ensures that the released product maintains its identity, purity, potency, and safety throughout its shelf life.

Together, these testing stages form an integrated control strategy that ensures consistent AAV vector quality from manufacturing through patient administration.

Why Minaris?

Minaris Advanced Testing combines more than 40 years of biosafety expertise with advanced molecular biology and analytical capabilities to deliver robust and reliable AAV lot release testing. Its GMP-compliant laboratories support comprehensive safety, identity, purity, and potency testing using advanced PCR/ddPCR platforms and orthogonal analytical methods. A strong focus on rapid microbiological methods helps reduce turnaround times, while the adoption of next-generation sequencing enhances viral safety and genome integrity assessments. Together, these capabilities enable efficient, high-quality testing solutions that support AAV programs from early development through commercialization.



Attribute	Full Assay Name	BH	DS	DP	Stability	Test Code	Minimum 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	1x15 mL & 1e6 cells/mL	35
Safety	EP, JP, and USP Mycoplasma Detection with Mycoplasmastasis (GMP)	✓				3000007121	1x45 mL & 1e6 cells/mL	35
Safety	Mycoplasma DNA Detection by MycoSEQ Plus using TaqMan Technology - Cell + Suspension (GMP)	✓				3000004752	30 mL cell suspension	5
Safety	Analysis of Bacterial Endotoxin Contamination Using Endosafe® nexgen-PTS™ (GMP)			✓		3000005222	1 mL	7
Safety	Analysis of Bacterial Endotoxin Contamination Using the Endosafe® nexgen-PTS™ - Test for Interfering Factors (GMP)			✓		3000005260	1 mL	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 Viral Contaminants: MRC-5, VERO, and HEK Cells (Extended Duration) with Hemadsorption and Hemagglutination Endpoints (GMP)	✓				3000005475	2x6 mL at 1e7 cells/mL	35
Safety	In Vitro Assay for Adventitious Viral Contaminants - (3 Cell Lines) in Plates - Extended Duration (GMP)	✓				3000004805	2x6 mL at 1e7 cells/mL	35
Safety	Mycobacterium Tuberculosis DNA Detection by qPCR (GMP)	✓				3000005638	1e7 cells frozen	9
Safety	Replication-Competent AAV (rcAAV) Detection (R&D) Suitability		✓			3000007579	6e10 VG total 0.5mL or above 1e + 12gc/mL	35
Safety	Replication-Competent AAV (rcAAV) Detection (GMP)		✓			3000007581	6e10 VG total 0.5mL or above 1e + 12gc/mL	35
Potency	Cell Based Assay Indicative of MOA (GMP)		✓	✓	✓	Custom	Varies	TBD
Strength	Genomic Titer Assay by ddPCR Targeting Gene of Interest (GMP)	✓	✓	✓	✓	Custom	Varies	TBD
Strength	Genomic Titer Assay by qPCR Targeting Gene of Interest (GMP)	✓	✓	✓	✓	Custom	Varies	TBD
Strength	AAV Infectious Titer Assay on HEK-293 Cells (GMP)	✓	✓	✓	✓	3000007592	0.2 mL	35
Strength	Determination of Adeno-Associated Virus Particles by ELISA for Various Serotypes (GMP)		✓	✓	✓	Varies	1 mL	21
Quality	Sedimentation Velocity Analysis of Adeno-associated Virus (AAV) using Analytical Ultracentrifuge (AUC)		✓	✓		3000005181	0.5mL with a minimum concentration at 1e12 GC/mL	21
Quality	Dynamic Light Scattering Analysis for Determination of Particle Size of Virus Lots (GMP)			✓	✓	3000007812	0.1 mL	8
Quality	Determination of Appearance According to the USP (GMP)			✓	✓	3000005469	2 mL	7

Attribute	Full Assay Name	BH	DS	DP	Stability	Test Code	Minimum Sample Requirements	TAT (days)
Quality	USP<697> and EP 2.9.17 Determination of Extractable Volume in Containers (GMP)			✓	✓	3000005712	Varies[2]	14
Quality	USP<785> Determination of Osmolality (GMP)			✓	✓	3000007458	0.1 mL	8
Quality	USP <791> Determination of the pH and Appearance (GMP)			✓	✓	3000004853	1 mL	8
Quality	EU Appearance of Liquids (GMP)			✓	✓	3000005395	10 mL	14
Identity	High Throughput Sequencing using Ion Torrent Genexus			✓		3000004999	Reference sequence, >/= 2e10 GC	18
Purity	Purified Viral Vector Purity Assessment by Western Blot		✓			Custom	Varies	TBD
Purity	Immunoenzymetric Assay for the Determination of HEK 293 Host Cell Proteins (GMP)		✓			3000004873	0.5 mL	21
Purity	Determination of Sf9 Insect Cell Host Cell Proteins by ELISA (GMP)		✓			3000005149	1 mL	21
Purity	Determination of Residual Capture Ligand by ELISA (GMP)		✓			Varies	Varies	21
Purity	Immunological Detection of Benzonase Endonuclease (GMP)		✓			3000004866	1 mL	8
Purity	Determination of Residual Bovine Serum Albumin (BSA) by ELISA using Bethyl ELISA Kit E11-113 (GMP)		✓			3000004586	0.3 mL	21
Purity	Quantitation of Residual Insect Sf9 DNA using PrepSEQ by qPCR (GMP)		✓			3000004735	0.5 mL	11
Purity	Residual Iodexonal by HPLC (GMP)		✓			Custom	Varies	TBD
Purity	Residual PEI by by HPLC (GMP)		✓			Custom	Varies	TBD
Purity	Quantitation of Residual DNA Using PrepSEQ™ and TaqMan® Technology by qPCR (GMP)-7 Targets 18S (102bp 200bp 254bp 401bp-amplicons)+E1A+SV40+E1B		✓			Varies	1 mL	TBD
Purity	Quantification of Residual DNA using qPCR Targeting the nptII Kanamycin Resistance Gene (GMP)		✓			3000008407	0.1 mL	21
Purity	Determination of Tween Concentration (GMP)		✓			3000005697	1 mL	21

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

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