

	<b>Title:</b> Adenovirus 5 WT Master Virus Bank Specification		<b>Doc. No.</b> DRAFT	<b>Page:</b> 1 of 3
	<b>Name/ Date</b>	<b>Name/ Date</b>	<b>Effective Date:</b>	
<b>Name/ Date</b>	<b>Name/ Date</b>			

**Name:** Adenovirus 5 WT Master Virus Bank (MVB)

**Canji Part Number:** to be assigned

**Manufacturer:** Canji, Inc.

**Production Cell Line:** to be determined

**Container/Closure:** 30 mL Sterile PETG Bottles

**Product Size:** 10 mL per 30 mL container

**Storage Conditions:** ? 55 °C

**Re-Certification Date:** 5 years from date of fill

Test Category	Test Description	Method	Amount tested	Specification
<b>Adenovirus 5 WT Master Virus Bank (MVB) – Pooled Bulk Harvest Prior to Benzonase Treatment</b>				
Safety	Mycoplasma	Per Contract Laboratory	Points to Consider <sup>1</sup>	Negative
	PCR- AAV	Per Contract Laboratory	0.5 µg DNA	None Detected
	PCR- B19	Per Contract Laboratory	0.5 µg DNA	None Detected
	PCR- HIV-1	Per Contract Laboratory	0.5 µg DNA	None Detected
	PCR- HIV-2	Per Contract Laboratory	0.5 µg DNA	None Detected
	PCR- Hepatitis B	Per Contract Laboratory	0.5 µg DNA	None Detected
	RT PCR- Hepatitis C	Per Contract Laboratory	0.5 µg RNA	None Detected
	PCR- EBV	Per Contract Laboratory	0.5 µg DNA	None Detected
	PCR- CMV	Per Contract Laboratory	0.5 µg DNA	None Detected
	PCR- HTLV-I	Per Contract Laboratory	0.5 µg DNA	None Detected
	PCR- HTLV-II	Per Contract Laboratory	0.5 µg DNA	None Detected
<b>Adenovirus 5 WT Master Virus Bank (MVB) – Final Product</b>				
Safety	Confirmation of Sterility	Per 21 CFR 610.12	The greater of 1% or 2 vials	Pass
	<i>In Vivo</i> Detection of Adventitious Viruses	Per Contract Laboratory	Test article diluted to 3.9 x 10 <sup>9</sup> particle/mL	None Detected
Identity	Adenovirus Genomic Structure by RFLP	Canji SOP	Between 1 x 10 <sup>12</sup> and 2 x 10 <sup>12</sup> particles	Pass; Consistent with adenovirus genomic structure

[1] Testing to be performed as per Points to Consider. Dilution of test article may be required to avoid toxicity caused by adenoviral protein component. Contract lab to devise appropriate dilution scheme based on particle concentration provided for the test article

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<i>Test Category</i>	<i>Test Description</i>	<i>Method</i>	<i>Amount tested</i>	<i>Specification</i>
<b>Adenovirus 5 WT Master Virus Bank (MVB) – Final Product - Continued</b>				
Identity	Adenovirus Protein Expression via Western Blot	Canji SOP	Between $1 \times 10^9$ and $1.2 \times 10^{10}$ particles	Pass; Expression of Adenovirus proteins confirmed
Dose Particle concentration	Resource Q HPLC	Canji SOP: QC0008	1800 $\mu$ L sample from each of two vials	$\geq 7.0 \times 10^{10}$ particles/mL
Bioactivity	Infectious titer assay using FACS (Hexon expression)	Canji SOP	Between $8 \times 10^6$ and $3.5 \times 10^7$ particles	Report measured titer (IU/mL)
	Particle to Infectious Titer Ratio: Resource Q HPLC to FACS Infectivity	Canji SOP	Calculated	$\leq 100:1$

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**Name:** Adenovirus 5 WT Master Virus Bank (MVB)

**Canji Part Number:** to be assigned

**Manufacturer:** Canji, Inc.

**Canji Lot Number:** to be assigned

**Container/Closure:** 30 mL Sterile PETG Bottles

**Product Size:** 10 mL per 30 mL container

**Storage Conditions:** ? 55 °C

**Number of Containers:** \_\_\_\_\_

<b>FINAL CERTIFICATE OF ANALYSIS</b>				
<i>Test Category</i>	<i>Test Description</i>	<i>Specification</i>	<i>Result</i>	<i>Result Reported By</i>
<b>Adenovirus 5 WT Master Virus Bank (MVB) – Pooled Bulk Harvest Prior to Benzonase Treatment</b>				
Safety	Mycoplasma	Negative		Contract Laboratory
	PCR- AAV	None Detected		Contract Laboratory
	PCR- B19	None Detected		Contract Laboratory
	PCR- HIV-1	None Detected		Contract Laboratory
	PCR- HIV-2	None Detected		Contract Laboratory
	PCR- Hepatitis B	None Detected		Contract Laboratory
	RT PCR- Hepatitis C	None Detected		Contract Laboratory
	PCR- EBV	None Detected		Contract Laboratory
	PCR- CMV	None Detected		Contract Laboratory
	PCR- HTLV-I	None Detected		Contract Laboratory
	PCR- HTLV-II	None Detected		Contract Laboratory
<b>Adenovirus 5 WT Master Virus Bank (MVB) – Final Product</b>				
Safety	Confirmation of Sterility	Pass		Contract Laboratory
	<i>In Vivo</i> Detection of Adventitious Viruses	None Detected		Contract Laboratory
Identity	Adenovirus Genomic Structure by RFLP	Pass; Consistent with adenovirus genomic structure		Canji, Inc.
Identity	Adenovirus Protein Expression via Western Blot	Pass; Expression of Adenovirus proteins confirmed		Canji, Inc.
Dose Particle concentration	Resource Q HPLC	$\geq 7.0 \times 10^{10}$ particles/mL		Canji, Inc.
Bioactivity	Infectious titer assay using FACS (hexon expression)	Report measured titer (IU/mL)		Canji, Inc.
	Particle to Infectious Titer Ratio: Resource Q HPLC to FACS Infectivity	$\leq 100:1$		Canji, Inc.

## Final Product Disposition

**? Release**

**? Reject**

Prepared by: \_\_\_\_\_ (Title) \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_  
                   Manufacturing

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_  
                   Quality Control

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_  
                   Quality Assurance