

CERTIFICATE OF ANALYSIS

VERIFIED COPY

BY: OMA DATE: 11/4/07

PRODUCT INFORMATION

Name: Adenovirus 5 WT Reference Material Master Virus Bank (MVB)

ATCC Ascension No.: VR-1517

Canji Lot Number: 59AAS

Canji Part Number: WN0011

Manufacturer: Canji, Inc.

Product Size: 10 mL per 30 mL container

No. of Containers: 303

Container/Closure: 30 mL Sterile PETG Bottles
(Nalge Nunc Cat. No. 2019-0030)

Storage Conditions: ≤ -55°C

Production Cell Line: WCB UAB HEK 293 (WN0010)

TESTING SUMMARY

Item No.	Test Category	Test Description	Specification	Result	Result Reported By
Adenovirus 5WT Master Virus Bank (MVB) – Bulk Harvest Prior to Benzonase Treatment					
1	Safety	Mycoplasma Assay (Points to Consider Test)	Negative	Direct: Negative Indirect: Indeterminate ¹	MDS PharmaServices, Inc.
2	Safety	Detection of Adeno-associated virus (AAV) by PCR	None Detected	None Detected	Q-One Biotech
3	Safety	Detection of B19 Parvovirus by PCR	None Detected	None Detected	Q-One Biotech
4	Safety	Detection of Human Immunodeficiency Virus Type 1 Specific Sequences by Quantitative PCR (HIV-1)	None Detected	None Detected	Q-One Biotech
5	Safety	Detection of Human Immunodeficiency Virus Type 2 Specific Sequences by Quantitative PCR (HIV-2)	None Detected	None Detected	Q-One Biotech
6	Safety	Detection of Hepatitis B Specific Sequences by Quantitative PCR (HBV)	None Detected	None Detected	Q-One Biotech
7	Safety	Detection of Hepatitis C (HCV) by Polymerase Chain Reaction (PCR)	None Detected	None Detected	Q-One Biotech

¹ The test article, replication competent Adenovirus Type 5, was cytopathic for the Vero target cells in the indirect portion of the Mycoplasma Assay (P-2911). The indirect portion of the Protocol, P-2911, cannot be successfully completed with this test article.

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8	Safety	Detection of Epstein-Barr Virus (EBV) by Polymerase Chain Reaction (PCR) Amplification of Bam W	None Detected	None Detected	Q-One Biotech
9	Safety	Detection of Cytomegalovirus by PCR (CMV)	None Detected	None Detected	Q-One Biotech
10	Safety	Detection of HTLV-I by Q-PCR	None Detected	None Detected	Q-One Biotech
11	Safety	Detection of HTLV-II by Q-PCR	None Detected	None Detected	Q-One Biotech
Adenovirus 5WT Master Virus Bank (MVB) – Filled Final Containers					
12	Safety	USP and 21 CFR 610.12 Sterility Test by Direct Transfer Method including Bacteriostasis Fungistasis Test	Pass	Pass	MDS PharmaServices, Inc.
13	Safety	<i>In Vivo</i> Detection of Adventitious Viruses in Mice, Guinea Pigs, and Eggs	Negative	Negative	MDS PharmaServices, Inc.
14	Identity	Adenovirus Genomic Structure by RFLP	Pass; Consistent with adenovirus genomic structure	Pass; Consistent with adenovirus genomic structure	Canji, Inc.
15	Identity	Adenovirus Protein Expression in 293 Cell Lysates via Western Blot	Pass; Expression of Adenovirus proteins confirmed	Pass; Expression of Adenovirus proteins confirmed	Canji, Inc.
16	Dose Particle Concentration	Particle Concentration by Resource Q HPLC	Report Result (Particles/mL)	9.75 x 10 ¹⁰ Particles/mL	Canji, Inc.
17	Bioactivity	Infectivity Assay for Adenovirus Using Flow Cytometry	Report measured titer (IU/mL)	3.96 x 10 ¹⁰ NAS IU/mL	Canji, Inc.
18	Bioactivity	Determination of Particle Number to Infectious Titer Ratio	≤ 30:1	2:1	Canji, Inc.

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PRODUCT DISPOSITION

<input checked="" type="checkbox"/>	RELEASE
<input type="checkbox"/>	REJECT
<input type="checkbox"/>	OTHER

SIGNATURES

MANUFACTURING: *Paul Shabram* Date: 10/4/01
Paul Shabram, Manufacturing Functional Supervisor, Canji, Inc.

QUALITY CONTROL: *Nancy Sajjadi* Date: 10/4/01
Nancy Sajjadi, Quality Control Functional Supervisor, Canji, Inc.

QUALITY ASSURANCE: *Jonna Ellsworth* Date: 10/4/01
Jonna Ellsworth, Quality Assurance Functional Supervisor, Canji, Inc.