

Certificate of Compliance – Finished Good Packaging

Quality Assurance

-13 Canada Scan Packaging Actuals w/CoC

Material #: 10011115	Product: Vanguard Plus 5/L	1 Dose
FG Packaged Lot #: 515731		Secondary Brazil Batch Number:

Serial(s) #:	485588B	464489
MFG / Fill Date	24/FEB/21	30/DEC/20
Expiration Date:	23/AUG/22	17/MAY/23

Final Expiration Date: 23/AUG/22	<input checked="" type="checkbox"/>	Inventory: 71000	<input checked="" type="checkbox"/>
----------------------------------	-------------------------------------	------------------	-------------------------------------

Lot Trace:

☒ Lot trace completed, printed and reviewed.

Batch Record / Packaging Material Review:

☒ Packet review of Packaging Materials with APHIS approval review complete.

Any outstanding issues found during lot trace and packaging review have been investigated and resolved.

ETS / RAN Review:

☒ **No** No further requirements.

☐ **Yes** ETS Parent # _____
ETS# _____

Outstanding countries have been identified and restrictions entered into SAP. ☐ Suitable for / Not suitable for

Item/Product country restrictions communicate to Logistics at time of release: _____

Attached document has been reviewed for the above criteria and is considered eligible for release.

Release for sale by Quality Assurance: Ronda Perry Date: 26 Apr 21

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES		VETERINARY BIOLOGICS PRODUCTION AND TEST REPORT	
3. NAME AND ADDRESS OF LICENSEE OR PERMITTEE Zoetis Inc. 601 West Cornhusker Highway, Lincoln, NE 68521-3577		1. Page 1 OF 2	2. LICENSE OR PERMIT 190
		4. FILL DATE Feb 24, 2021	5. PRODUCT CODE NUMBER 13D1.22
		6. EXPIRATION DATE Aug 23, 2022	7. SERIAL OR SUBSERIAL 485588B
8. TRUE NAME OF PRODUCT Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus			

9. TEST DATA (for test data see additional pages)

10. INVENTORY FOR RELEASE			11. REMARKS
NUMBER OF CONTAINERS (A)	CONTAINER SIZE (DOSES, ML OR UNITS) (B)	TOTAL DOSES, ML OR UNITS (C)	First sub-serial testing reported on Zoetis Test Report, serial 485588A
176,176	1	176,176 Doses	
TOTAL 176,176		TOTAL 176,176	

12. DISPOSITION BY FIRM:

Eligible for Release

13. AUTHORIZED FIRM REPRESENTATIVE Ms Tammy J Doran		14. TITLE Compliance Specialist	15. DATE April 15, 2021
16. DISPOSITION BY APHIS: Not to be Tested			
17. AUTHORIZED APHIS REPRESENTATIVE Michelle Harland		18. TITLE Biologics Specialist	19. DATE April 22, 2021

This report is equivalent to an APHIS Form 2008 signed by an Authorized APHIS Representative and is appropriate for marketing authorizations. See Veterinary Services Memorandum 800.53, Release of Biological Products, for more information.

For Official Use Only

TEST REPORT

Zoetis, Inc
601 W. Cornhusker Highway
Lincoln, NE 68521-3577



Est. License No: 190
Product Code: 13D1.22
Serial Number: 485588B
Title (True Name): CANINE DISTEMPER-ADENOVIRUS TYPE 2-PARAINFLUENZA-PARVOVIRUS VACCINE, MODIFIED
LIVE VIRUS

Quantity / Dose Size / Total: 176,176 / 1 DOSE(S) / 176,176 DOSE(S)
Expiration Date: 23-Aug-2022
Fill Date: 24-Feb-2021

<u>TEST REFERENCE</u>	<u>On Date</u>	<u>Off Date</u>	<u>RESULTS</u>	<u>STATUS</u> S-SATISFACTORY U-UNSATISFACTORY I-INCONCLUSIVE NT-NO TEST
V.A. 113.27	Mar 8, 2021	Mar 22, 2021	10/10 No Growth w/ 0.2 mL in >= 400 mL of SCDM at 30-35°C 10/10 No Growth w/ 0.2 mL in >= 50 mL of SCDM at 20-25°C	S
V.C. 113.306	Mar 19, 2021	Mar 24, 2021	CDV Potency 4.5 Log-10 TCID50/dose	S
V.C. 113.305	Mar 26, 2021	Apr 2, 2021	CAV2 Potency 5.0 Log-10 TCID50/dose	S
V.C. 113.316	Mar 19, 2021	Mar 24, 2021	CPI Potency 6.9 Log-10 TCID50/dose	S
V.C. 113.317	Mar 11, 2021	Mar 15, 2021	CPV Potency 7.9 Log-10 TCID50/dose	S

Remarks:

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies.
Distribution to third parties without prior permission is prohibited.

VETERINARY BIOLOGICS PRODUCTION AND TEST REPORT

3. NAME AND ADDRESS OF LICENSEE OR PERMITTEE Zoetis Inc. 601 West Cornhusker Highway, Lincoln, NE 68521-3577	1. Page 1 OF 3	2. LICENSE OR PERMIT 190
	4. FILL DATE Dec 30, 2020	5. PRODUCT CODE NUMBER 2671.00
	6. EXPIRATION DATE May 17, 2023	7. SERIAL OR SUBSERIAL 464489

8. TRUE NAME OF PRODUCT
Leptospira Canicola-Icterohaemorrhagiae Bacterin

9. TEST DATA (for test data see additional pages)

10. INVENTORY FOR RELEASE			11. REMARKS
NUMBER OF CONTAINERS (A)	CONTAINER SIZE (DOSES, ML, OR UNITS) (B)	TOTAL DOSES, ML, OR UNITS (C)	
609,919	1	609,919 Doses	
TOTAL 609,919		TOTAL 609,919	

12. DISPOSITION BY FIRM:
Eligible for Release

13. AUTHORIZED FIRM REPRESENTATIVE

Ms Ronda E Perry

14. TITLE

Compliance Specialist

15. DATE

February 12, 2021

16. DISPOSITION BY APHIS:

Not to be Tested

17. AUTHORIZED APHIS REPRESENTATIVE

Brian Campbell

18. TITLE

Biologics Specialist

19. DATE

February 16, 2021

This report is equivalent to an APHIS Form 2008 signed by an Authorized APHIS Representative and is appropriate for marketing authorizations. See Veterinary Services Memorandum 800.53, Release of Biological Products, for more information.

For Official Use Only

TEST REPORT

Zoetis, Inc
601 W. Cornhusker Highway
Lincoln, NE 68521-3577



Est. License No: 190
Product Code: 2671.00
Serial Number: 464489
Title (True Name): LEPTOSPIRA CANICOLA-ICTEROHAEMORRHAGIAE BACTERIN

Quantity / Dose Size / Total: 609,919 / 1 DOSE(S) / 609,919 DOSE(S)
Expiration Date: 17-May-2023
Fill Date: 30-Dec-2020

TEST REFERENCE	On Date	Off Date	RESULTS	STATUS S-SATISFACTORY U-UNSATISFACTORY I-INCONCLUSIVE NT-NO TEST
V.A. 113.26	Jan 20, 2021	Feb 3, 2021	10/10 No Growth w/ 0.5 mL in \geq 400 mL of FTM at 30-35°C 10/10 No Growth w/ 0.5 mL in \geq 150 mL of FTM at 20-25°C	S
V.B. 113.38	Jan 20, 2021	Jan 27, 2021	2/2 Guinea Pigs Remained Healthy w/ 2.0 mL SQ	S
V.C. Outline	Feb 4, 2021	Feb 4, 2021	Validity Criteria L. ictero: Avg First Dilution of Reference (L. ictero) = 1.3 Avg OD for reagent blanks = 0.03 Blank corrected OD MR PC and Serial wells = Pass MR, PC curves = Pass Serial curves = Pass Minimum absolute slope value Ref \geq 0.2 = Pass PC \geq 0.2 = Pass Serial \geq 0.2 = 1.11 Slope ratio PC:Ref = 1.02 Slope ratio Serial:Ref = 0.98 r-squared Reference \geq 0.90 = Pass r-squared PC = 0.99 r-squared Serial = 0.99 RP of Positive Control = 0.48	S
V.C. Outline	Feb 4, 2021	Feb 4, 2021	RP 0.73Lepto ictero SoftMax Potency (Ref. IRP 542 (06))	S

Remarks:

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies.
Distribution to third parties without prior permission is prohibited.

TEST REPORT

Zoetis, Inc
601 W. Cornhusker Highway
Lincoln, NE 68521-3577



Est. License No: 190
Product Code: 2671.00
Serial Number: 464489
Title (True Name): LEPTOSPIRA CANICOLA-ICTEROHAEMORRHAGIAE BACTERIN

<u>TEST REFERENCE</u>	<u>On Date</u>	<u>Off Date</u>	<u>RESULTS</u>	<u>STATUS</u> S-SATISFACTORY U-UNSATISFACTORY I-INCONCLUSIVE NT-NO TEST
V.C. Outline	Feb 4, 2021	Feb 4, 2021	Validity Criteria L. canicola: Avg First Dilution of Reference (L. canicola)= 1.1 Avg OD for reagent blanks = 0.06 Blank corrected OD MR PC and Serial wells = Pass MR, PC curves = Pass Serial curves = Pass Minimum absolute slope value Ref>=0.2 = Pass PC >=0.2 = Pass Serial >=0.2 = 0.92 Slope ratio PC:Ref = 1.03 Slope ratio Serial:Ref = 1.01 r-squared Reference >= 0.90 = Pass r-squared PC = 0.98 r-squared Serial = 0.94 RP of Positive Control = 5.34	S
V.C. Outline	Feb 4, 2021	Feb 4, 2021	RP 2.67Lepto canicola SoftMax Potency (Ref. IRP 555 (07))	S
V. Viricidal 113.35	Jan 8, 2021	Jan 13, 2021	CD Viricidal: 0.7 Log-10 Titer reduction	S
V. Viricidal 113.35	Jan 8, 2021	Jan 15, 2021	CAV2 Viricidal: 0.2 Log-10 Titer reduction	S
V. Viricidal 113.35	Jan 8, 2021	Jan 13, 2021	CPI Viricidal: 0.5 Log-10 Titer reduction	S
V. Viricidal 113.35	Jan 4, 2021	Jan 8, 2021	CPV Viricidal: 0.3 Log-10 Titer increase	S

Remarks:

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies.
Distribution to third parties without prior permission is prohibited.