



601 W. Cornhusker Hwy.
Lincoln, NE 68521

Certificate of Compliance Finished Good Packaging

Page 1 of 1
Printed 2/25/2025 1:51 PM

Document #: COC-02	Approval Signatures on file per 2709073	Issue Date 22Feb23	Supersedes 20Feb23
------------------------------	--	------------------------------	------------------------------

Material #: 10011203	Product: Felocell CVR (RUS)	1 Dose
FG Packaged Lot #: 815208		Secondary Brazil Batch Number:

Serial(s) #:	802940A	775507
Assembly Date:	30/DEC/24	25/NOV/24
Fill Date:	02/JAN/25	26/NOV/24
Expiration Date:	30/JUN/26	30/JUN/26

Final Expiration Date: 30/JUN/26	☒	Inventory: <u>57875</u>	☒
---	-------------------------------------	-------------------------	-------------------------------------

Lot Trace:

☒ Lot trace completed, printed and reviewed.

Batch Record / Packaging Material Review: RN 21Mar25

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

☒ Confirm Audit Trail Reconciliation.

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

ETS 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: Russia(2887710), Australia

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

Release for sale by Quality Assurance: Dobryshay Date: 24Mar25

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 4	2. LICENSE OR PERMIT 190
	4. FILL DATE Jan 02, 2025	5. PRODUCT CODE NUMBER 16D1.20
	6. EXPIRATION DATE Jun 30, 2026	7. SERIAL OR SUBSERIAL 802940A
8. TRUE NAME OF PRODUCT Feline Rhinotracheitis-Calici-Panleukopenia 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)	
68,131	1	68,131 Doses	
TOTAL 68,131		TOTAL 68,131	

12. DISPOSITION BY FIRM:

Eligible for Release

13. AUTHORIZED FIRM REPRESENTATIVE Ms Carolyn L Hoy	14. TITLE Compliance Specialist	15. DATE February 12, 2025
16. DISPOSITION BY APHIS: Not to be Tested		
17. AUTHORIZED APHIS REPRESENTATIVE Kurt Kreutzer	18. TITLE Biologics Specialist	19. DATE February 14, 2025

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: 16D1.20
Serial Number: 802940A
Title (True Name): FELINE RHINOTRACHEITIS-CALICI-PANLEUKOPENIA VACCINE, MODIFIED LIVE VIRUS

Quantity / Dose Size / Total: 68,131 / 1 DOSE(S) / 68,131 DOSE(S)

Expiration Date: 30-Jun-2026

Fill Date: 02-Jan-2025

TEST REFERENCE	On Date	Off Date	RESULTS	STATUS
				S-SATISFACTORY U-UNSATISFACTORY I-INCONCLUSIVE NT-NO TEST
V.A. 113.27	Jan 10, 2025	Jan 24, 2025	10/10 No Growth w/ 0.2 mL in $\geq$ 120 mL of SCDM at 30-35°C 10/10 No Growth w/ 0.2 mL in $\geq$ 50 mL of SCDM at 20-25°C	S
V.A. 113.28	Jan 14, 2025	Feb 11, 2025	Negative for Mycoplasma	S
V.B. 113.33	Jan 15, 2025	Jan 22, 2025	8/8 Mice Remained Healthy w/ 0.50 mL IP	S
V.B. 113.39	Jan 9, 2025	Jan 23, 2025	2/2 Cats Remained Healthy w/ 10 doses SQ	S
V.C. 113.304	Jan 15, 2025	Jan 22, 2025	Validity Criteria FPL: At least 80% of the test wells are positive at the lowest dilution = Pass At least 80% of the test wells are negative at the highest dilution = Pass All negative control wells are negative = Pass Potency Assay Control = 7.4 Log ₁₀ TCID ₅₀ /mL FPL Potency 4.2 Log ₁₀ TCID ₅₀ /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.

TEST REPORT

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



Est. License No: 190
Product Code: 16D1.20
Serial Number: 802940A
Title (True Name): FELINE RHINOTRACHEITIS-CALICI-PANLEUKOPENIA VACCINE, MODIFIED LIVE VIRUS

TEST REFERENCE	On Date	Off Date	RESULTS	STATUS
				S-SATISFACTORY U-UNSATISFACTORY H-INCONCLUSIVE NT-NO TEST
V.C. 113.315	Jan 10, 2025	Jan 20, 2025	Validity Criteria FVR: At least 80% of the test wells are positive at the lowest dilution = Pass At least 80% of the test wells are negative at the highest dilution = Pass All negative control wells are negative = Pass Potency Assay Control = 6.9 Log10 TCID50/mL FVR Potency 7.0 Log-10 TCID50/dose	S
V.C. 113.314	Jan 15, 2025	Jan 22, 2025	Validity Criteria FCV: At least 80% of the test wells are positive at the lowest dilution = Pass At least 80% of the test wells are negative at the highest dilution = Pass All negative control wells are negative = Pass Potency Assay Control = 7.7 Log10 TCID50/mL FCV Potency 7.4 Log-10 TCID50/dose	S
V. Identity 113.300	Jan 15, 2025	Jan 22, 2025	FPL Positive by FA Microscopy	S
V. Identity 113.300	Jan 10, 2025	Jan 13, 2025	FVR Positive by FA Microscopy	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: 16D1.20
Serial Number: 802940A
Title (True Name): FELINE RHINOTRACHEITIS-CALICI-PANLEUKOPENIA VACCINE,MODIFIED LIVE VIRUS

TEST REFERENCE	On Date	Off Date	RESULTS	STATUS
				S-SATISFACTORY U-UNSATISFACTORY I-INCONCLUSIVE NT-NO TEST
V. Identity 113.300	Jan 15, 2025	Jan 17, 2025	FCV Positive by FA Microscopy	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: S075
Serial Number: 775507
Title (True Name): Sterile Diluent

Quantity / Dose Size / Total: 1,303,790 / 1 DOSE(S) / 1,303,790 DOSE(S)
Expiration Date: 24-Nov-2029
Fill Date: 26-Nov-2024

TEST REFERENCE	On Date	Off Date	RESULTS	STATUS
				S-SATISFACTORY U-UNSATISFACTORY I-INCONCLUSIVE NT-NO TEST
Section III.	Dec 3, 2024	Dec 17, 2024	10/10 No Growth w/ 0.5 mL in >= 50 mL of EFTM at 30-35°C	S
			10/10 No Growth w/ 0.5 mL in >= 50 mL of SCDM at 20-25°C	
Internal	Dec 2, 2024	Dec 2, 2024	Characteristics - clear liquid Pass	S

Remarks: