

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1585.20
True Name	Chlamydia Psittaci Vaccine, Killed Chlamydia
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fel-O-Vax Pn-K - Elanco US Inc.
Date of Compilation Summary	October 16, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

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Study Type	Efficacy
Pertaining to	Feline Chlamydia Psittaci (FCP)
Study Purpose	To demonstrate effectiveness against FCP
Product Administration	Two doses administered 21 days apart subcutaneously (SC) or
	Intramuscular (IM).
Study Animals	Thirty (30) cats, 16 to 20 weeks of age. Cats were allocated into
	one vaccinated group of 20 cats, 10 SC and 10 IM, and one
	group of 10 non-vaccinated controls.
Challenge Description	21 days post second vaccination all cats were challenged with
	FCP.
Interval observed after	Rectal temperatures and clinical signs were observed daily for 28
challenge	days post challenge.
Results	Vaccinates and controls were evaluated per the criteria in 9 CFR
	113.71.(3)
	A significant difference in clinical signs was observed between
	vaccinates and controls using a scoring sytem approved by
	APHIS.
	Requirements of 9 CFR 113.71 (3) were met.
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	Raw Data:
	Data tables are appended to the end of the summary.
TIGO A A	A 3142 1000
USDA Approval Date	April 13, 1990

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		200PC 210PC 220PC 230PC 240PC 250PC 260PC 270PC 280PC	3 103.2	102.0	103.0	103.0	102.2	102.0	102.6	103.0	103.2	7 102.8	103.4	5 103.2	102.4	3 103.2	102.2	102.6	103.8	102.6	102.2	102.6		200PC 210PC 220PC 230PC 240PC 250PC 260PC 270PC 280PC	2 103.6	3 103.6	103.0	3 103.0	103.4	3 103.0	102.0	03.0	3 102.2	3 103.0
		C 27DP	103.3	1018	102.4	102.6	103.0	102.4	102.5	102.4	103.0	102.7	104.2	102.5	102.8	103.8	1018	102.0	103.0	1018	102.4	102.0		C 27DP	103.2	103.3	104.0	104.3	102.6	103.3	102.5	103.3	102.3	103.8
		26DP(	1018	1014	102.2	102.0	102.2	102.4	102.8	1016	102.6	102.8	103.8	102.2	102.4	103.6	102.0	102.0	102.8	1016	103.0	102.2		26DP(	102.8	103.4	103.2	103.4	103.0	103.0	102.8	103.4	103.4	103.4
		250PC	1014	1017	1016	102.2	102.2	102.0	102.2	1018	102.8	102.4	103.0	102.0	102.0	102.8	102.2	103.4	103.4	102.0	102.6	102.2		250PC	103.6	103.8	103.6	104.6	103.2	103.2	103.2	104.6	104.6	104.0
		24DPC	101.6	101.6	101.8	102.0	101.8	102.4	102.2	101.2	102.0	102.0	102.2	101.7	102.0	103.4	101.8	102.0	102.4	101.8	101.8	102.6		24DPC	103.6	104.1	103.0	103.8	103.1	102.8	102.8	103.6	102.6	104.0
		230PC	101.8	101.6	102.4	102.4	102.0	102.0	102.0	102.0	102.0	102.2	102.6	101.8	102.8	104.0	102.0	101.8	102.4	102.0	102.0	102.2		230PC	103.6	104.0	103.4	103.4	103.4	102.4	102.8	103.0	104.0	104.0
		22DPC	102.0	101.4	102.0	101.8	101.4	101.8	102.6	101.0	102.3	102.1	102.6	101.0	102.4	103.4	101.6	101.4	101.8	101.8	101.6	102.2		220PC	102.4	104.4	102.1	103.4	103.2	102.4	103.3	102.8	104.4	101.6
		21DPC	102.6	102.2	102.6	102.0	102.2	101.6	102.6	102.0	102.4	103.0	103.0	102.2	102.2	102.8	102.2	102.8	102.0	102.2	102.2	101.8		21DPC	103.8	103.8	102.6	104.0	102.2	102.6	101.4	103.8	104.0	104.8
		20DPC	101.6	101.8	102.7	102.2	102.2	102.2	102.6	101.8	102.8	102.6	102.2	102.6	102.8	102.5	101.4	102.0	102.8	102.0	101.6	101.6		20DPC	104.8	105.0	103.8	103.2	103.4	103.2	104.6	104.0	103.8	104.5
			102.6	101.7	102.5	102.4	102.4	102.2	1022	101.7	103.2	103.8	103.4	102.2	103.2	102.6	102.4	1022	103.2	102.1	102.4	102.0		19DPC	105.5	105.2	104.6	103.1	103.4	104.2	104.4	104.2	105.0	104.0
		17DPC 18DPC 19DPC	101.6	101.6	102.0	102.4	1022	101.4	101.8	101.4	101.8	102.0	102.0	101.8	102.4	102.6	1022	102.4	101.4	102.4	101.4	101.4		18DPC	104.8	1052	104.8	102.6	103.6	103.0	103.8	104.6	104.6	104.4
enge		7DPC	102.4	1022	102.8	1022	102.4	103.4	1022	101.8	103.0	102.0	102.8	102.2	102.8	1022	105.0	1042	102.8	1032	1022	8700		17DPC	104.2	102.4	104.8	103.6	103.4	102.2	103.2	104.4	105.8	102.8
P Chall		6DPC	102.8	102.4	102.6	102.4	104.0	104.0	102.6	9700	102.6	102.6	102.4	104.4	102.8	102.6	1022	104.2	102.6	103.4	102.6	101.4			1052	104.4	103.8	103.2	104.2	102.8	103.8	104.0	$\overline{}$	104.2
ring FC		13DPC 14DPC 15DPC 16DPC	102.4	102.4	102.4	1022	102.6	9100	102.6	9100	102.6	102.8	103.2	102.0	102.4	101.4	810	1022	103.4	102.6	1022	102.0	slo	5DPC 1	104.2	103.2	104.4	1022	104.2	102.6	102.6	103.8	$\rightarrow$	105.0
Follow	ates	4DPC 1	102.0	102.0	300	8101	102.6	102.0	102.4	1022	1022	NA	NA	1022	1018	9101	9101	1020	102.4	1022	103.0	1022	No Vaccinated Controls	4DPC 1	103.8	102.6	102.8	1018	105.4	102.8	102.6	8101	1020	103.4
atures	Vaccinates	3DPC 1	1020	9750	102.4	102.2	102.0	1022	000	9101	1022	NA	103.0	1018	102.4	1018	104.0	1020	103.0	1018	103.2	101.4	accinat	3DPC 1	104.0	102.8	103.4	102.4	803.8	103.0	102.8	103.2	9700	104.2
emper		12DPC 1	102.6	1013	102.0	103.0	970	103.4	1024	1020	1022	103.3	103.2	9101	102.0	101.7	1024	1022	9101	1024	1018	1023	No V	2DPC 1	9700	103.3	103.4	9336	102.5	101.7	1018	102.8	$\rightarrow$	1024
Daily Rectal Temperatures Following FCP Challenge		1DPC 1:	102.0	8101	102.2	102.6	102.0	102.0	102.0	1018	1018	102.0	103.0	102.4	102.6	1018	1018	102.8	102.4	102.0	102.0	102.0		1DPC 1:	102.8	102.8	102.6	102.8	102.0	1018	102.0	102.4	$\rightarrow$	102.2
Daily F		10DPC 11DPC	102.8	102.2	102.4	102.6	102.8	102.6	102.4	102.0	102.8	102.6	102.6	102.8	102.6	102.2	103.0	102.4	102.2	102.2	103.0	102.4		10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC	103.0	102.8	102.6	102.0	102.0	103.2	102.6	102.2	102.4	103.2
		9DPC 10	102.4	1014	102.3	102.6	102.0	102.5	1016	1014	102.6	102.4	102.0	1018	102.4	1016	102.3	102.2	102.1	1016	102.2	1016		9DPC 10	102.6	102.3	101.7	102.2	1014	102.4	1016	102.2	$\overline{}$	103.8
		8DPC 9	102.6	102.0	102.0	102.4	102.4	1016	102.6	1016	102.0	1014	1016	1016	102.4	1018	102.2	1016	102.8	1014	1018	101.1		8DPC 9	102.0	102.6	102.4	1018	1014	1018	102.2	102.4	$\rightarrow$	1014
		7DPC 8	1016	1016	1018	102.2	102.0	1016	102.4	1016	102.6	102.2	1018	102.8	103.2	102.2	1014	102.0	102.8	102.6	102.6	1014		7DPC 8	102.0	102.4	102.8	1014	1018	102.4	1018	1018	$\rightarrow$	103.4
		6DPC 7	102.4	102.2	102.0	102.4	102.6	102.0	102.8	101.6	102.8	102.6	101.8	101.8	102.6	102.4	102.0	102.2	102.4	102.6	102.4	102.0		6DPC 7	102.6	102.4	102.2	102.2	101.6	103.0	102.2	$\overline{}$	$\overline{}$	103.8
		5DPC 61	102.6	101.4	102.6	102.6	101.6	102.6	102.6	101.8	103.0	102.7	102.2	101.4	103.0	101.4	101.4	101.8	102.5	101.8	102.4	101.6		50PC 61	102.4	101.8	103.0	101.6	102.0	102.4	103.0	103.2 11		103.6
		4DPC 50	103.8 10	102.6	102.6 10	103.4 10	102.0	103.6 10	103.6	102.6	103.6 10	103.8 10	103.0 10	103.0	103.6 10	102.6	102.4	102.6	103.2 10	103.8	103.0 10	103.0		4DPC 50	102.4 10	102.0	103.6 10	103.0	102.4 10	102.4 10	103.6 10	103.4 10		104.4
		3DPC 40	102.8 10	101.9	102.5 10	103.2 10	102.3 10	102.4 10	103.2 10	103.2 10	103.5 10	102.7 10	101.8	103.0 10	103.4 10	103.0 10	102.8 10	102.6 10	103.1 10	102.5 10	103.1	102.2 10		3DPC 40	102.5 10	102.7 10	103.5 10	102.8 10	102.1 10	103.5 10	103.1 10	103.0 10	$\overline{}$	104.2 10
		2DPC 3D	102.2 10	104:0	102.4 10	102.6 10	103.0 10	103.2 10	103.0	101.6	104.0	102.8 10	104.0	102.8 10	103.0 10	102.8 10	103.2 10	102.5 10	102.4 10	101.6 10	103.9 10	102.2 10		2DPC 3D	102.4 10	102.8 10	103.2 10	102.8 10	102.6 10	102.4 10	102.6 10	103.0 10	$\rightarrow$	104.0 10
		1DPC 2D	101.8	101.9	101.4 10.	101.4 10.	101.4 10:	101.8	101.8	101.4	102.0	101.8	101.4	-	101.8 10.	102.2 10;	├	-	102.6 10.	$\vdash$	102.6 10	101.8		1DPC 2D	101.8 10;	103.0 103	102.4 10:	101.4 10.	101.5 10.	103.0 103	102.4 103	101.4	$\rightarrow$	101.4
		-	10t	10t M	10t M	10t M	101 M	101	10 10	10t	M 102	101	SC	SC 1022	SC 101	SC 102	SC 102.4	SC 1022	SC 102	SC 101.6	SC 102	SC		Route 1D6	ē	100	100	ũ	ũ	100	10;	ē	ű	ē
		Cat ID Route	-	2	3	4	2	9	1 L	8	6	10	11 S	12 S	13 S	14 S	15 S	16	17 S	18	19	20 S		Cat ID Rou	Ļ	2	3	4	2	9	7		6	10
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Daily Clinical Signs Following FCP Challenge

		_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_		
	28DPC	M2	M		ΜŽ	₹		M2	W	EI/W3	EI/W3	M2	EI/M2	ΝŽ	EI/W3	₹	EI/M2	E(M3	ΜŽ	EI/M2	M2		
	27DPC	M2	25		≅	ž		EIMI	Z	EIMI	EIME	EUMB	EIMS	EIME	EUMB	22	EUNZ	EUNZ	EUMB	EUNZ	₹		
	26DPC	M	M2		ELMI	Ξ		æ	W2	EIMS	EIMS	£	W2	EIMB	EIMS	W	M2	EIMS	æ	W3	Ξ		
	25DPC	W	W W		ē.	Ē		W W	Ø.	EI/W3	EI/W2	EI/M3	M2	EI W3	EW	ĕ.	W W	EI/M2	g	EI/M3	ž.		
	240PC	W.	27	≅	EMS	≅	27	EIMS	EUNE	EUMD	2	Elwa	EUNZ	EUMD	EIJM	걸	27	EUND	EIMB	EUMD	≅		
	23DPC 2	M2	M2		₹	≅	≅	M2	₹	OLM2	2W	2	EIMS	DIEIJMS	EIMS	EIMS	W5	M3	EIMB	M3	2		
	ZZDbc	M2	M2		EM	Ξ	ī	W.	ī	ELM2	¥	EIW3	W.	ELM3	ELM2	ELM2	ELM2	ELM2	EIW3	ELM3	ž.		
	210PC 2	EUNZ	W.		¥	¥	M2	EINE	¥	DIETNE	EUNZ	EUMD	EUMD	DIETME	EUNE	EUNE	DIETMS	EUMD	DZEIMB	DIENNE	EUNE		
	20DPC 21	EIWS E	25	₹	₹	₹	₹	EI/WB E	ELMI	EIJW2 OI	SW SW	BEWN	EIWS E	Eljvis Or	EIME	EIJW2 B	EIWS OI	Eljyts E	DQELM3 D2	EI/WB CI	E	ļ	
	9DPC 20	M3	Æ	Æ	Æ	Æ	M	EI/M3	E	EUMI	EUM2	ELM3 B,	ELM2 E	ELM2 E	ELM2 E	W 2	EUMI	D(ELM3 E	DLELM3 C2	EI/M3	ELM2		
	18DPC 19	SW.	EIMD				DIEIMI	EUMD	Z.	W S	W W	EI/W2	aw aw	a a	EUM2 E	W.	W.	EUMD DI	ELMO DI	E2JM3 E	EUM2 E		
	17DPC 18	awia	34	≅	2	≅	ELMI	DQM3	≅	EIMS	EIMS	EI/WB E	EIMB	B/WS	EIWE	왕	ELJMI	Elwis E	E EMETO	DZ,EZ,MD E	EI/WB E		
	16DPC 17	EI/M3 E	EIJM3	E	EIMI	EUMI	D(EI)M2	DQ E2JVIB C	EtMI	E	2	CEIMB	DIEZMD E	EI M2	EIWIS	EI/W2	B IMI	SW.	EI MIS DI	EI,GI,MI3 D2	EIJW2 E		
tes	15DPC 16	ELM3 E	EI/M3	豆	2	W Zw	ELM2 DI	DZEZM3 DZ	EtM2	5	ELM3	EIM3 C	DZEUM3 DI,	W W	EIM3	ELM2	<u> </u>	EIM2	EI/M2	OZEZM3 EI,	W W		Controls
Vaccinates	14DPC 15	DZEZMO E	DQEIJM3 E	₹	₹	EIMS	ω	DQE2,M3 02,	ш	₹	EZ JWG	EZ MIS E	DQE2M3 D2	DIEUNE	DIEIMB E	OI M2	≅	OIEWE E	EIME E	DQEI,M2 02,	ElM2		Non-Vaccinated Controls
	13DPC 14	DZETM3 DZJ	DZJMB DQ.	₹		DOM: E	DIMI	DZETMO DUB	DUM		EI MIS	DIMI E	DZETMO DUB	DIM2 DIJ	EIJW2 OIJ	D IMID	W2	OZETM2 OU	DIM2 E	DUM DE	DLEIJM2 E		Non-
	12DPC 13I	ELM3 028	DIETM3 02	_		DUETIM2 DO	8	DZEIMB OZE	2		M2 EI	_	D2,M20 02,8		ELM2 EI	i Mio	B,MI	108	IM IM ID	6	M DUE		
	11DPC 12I	EIMB EI	BJETM2 DUE			품		D2,E2,M3 D2,6	_		- W		EI JWI DO		E	-	B/MI B	≅	E E	Б	ž		
	10DPC 11	EI MIS EI	DIM3 BE	M				DQE2JNB D2B					<u> </u>	E		BJMI	B/M B	₹	IM.				
	9DPC 10	ELM3 EI	ELM3 D	. IM	5			DIETM3 DQ5		₽				- 5		B ≅	B ₩	M	- W		E E		
	30PC 9E	EUN2 EI	EUMD EI					970 8W		<u></u>	×	₹			×	<u> </u>	×		<u> </u>	×			
	7DPC 80	Elwis El	DIEDMS EL	M	M			oteljus n		_	_				_	_	M	M	DIEDVE	_	¥		
	6DPC 7D	EUM2 EU	M2 DUE	_	_			EUM2 DUE						E		E	MI IM	M M	M DIE		_		
	Н	EIMI EI	EIMI N		B/M			EIMI EI						_		×	_	W W	_				
	30 SDPC	Ē	區		88			亩								_		_					
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	Route TOPC 2DPC 3DPC 4DPC	H																					
	PC 21	$\vdash$	$\vdash$	_		$\vdash$	$\vdash$	$\vdash$	$\vdash$	$\vdash$	$\vdash$		$\vdash$	$\vdash$	$\vdash$	$\vdash$		$\vdash$					
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	Cat ID Ro	Ē		_	-	2	9	_	-	6	9	- 8	12 S	13	14 S	15 S	16 S	17 S	S S	19	$\vdash$		
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280PC	₹	EI/M2	MD	EI/M2	EI/M2		EI/M2	ELMS	ELM3	ELM3				
27DPC	EIMS	EINS	EIMS	EIMS	E2 JVI2	ElMS	EUMB	EUMB	EUMB	EUMB				
26DPC	EIMI	EIWS	W5	EIJMB	EIMS	EIJVIS	EIWS	W.	EIMB	EIMB				
250PC	₹	₹	M	Et/M2	æ	EI/M2	EI/W3	ELM3	EIM3	EI/M2				
24DPC	EUNE	EIM	EIMI	EUNE	EUNE	ž	EUNE	EUMD	M2	EUMD				
23DPC	₹	<u>~</u>	M2	EIJVS	EIMI	W2	EIMS	EIMB	EIJVS	æ				
220PC		Ξ	M	EUM2	EZMZ	Ø	EIWS	EUM2	ELM3	EIM3				
21DPC			EIMS	EINE	EIMS	旦	EIMB	EIMB	EUMD	EIMB				
20DPC	≅	-	EIWS	EUMB	≅	EIWS	EUMD	EIMB	EUMB	EIMB	E	tion		
190PC	Ξ	×	EUM2	EUM2	EIMI	EI/M3	EZMO	EI/M3	ELM3	EI/WS	I-Depression	k-dehydration		
180PC		Z	EUM2	EIMD		EIMD	EIMD	EUMD	EUMD	DIEUMO				
17DPC	≅		EIWD	E2M3	≅	EIMB	EIMB	D2,E2,M0	BEUMD	EIMB	.10	tivitis	itis	
16DPC			EUMI	EIMB		DÍM	BEIM	DLEUM3	EIMB	EIMB	M1-Slight Conjunctivitis	M2 - moderate Conjunctivitis	M3-Severe Conjunctivitis	
150PC	₹		02E2M3	E(M2	≅	EI/M2	DIETIMS	DLE2JVB	DZEIMB	EZMB	M1-Slight (	M2-moder	M3-Severe	
14DPC	EIWI		D2,E2,M0	₹	₹	D2,E2,M0	24	EUNZ	D2,E2,M0	D2,E3,M0				
13DPC	₹		DQE2JMB	M		DQ E2JMB	ž	M	DQE2MB D2E2MD	DQE23MB	charge	rdischarge	scharge	
120PC	₹		DIETMO	ω		EZMZ	₹	IM10	DZEIMB	DQE1JM3	E1 - slight mucopurulent ocular discharge	E2 - Moderate mucopurulent ocular discharge	B - Severe mucopurulent ocular discharge	
11DPC			EUNE			ž	₹	ž	DIETMB	DQ.E1JM3	ucopurulen	te mucopur	nucopurule	
100PC				₹		ElMI	Ξ	BMI	DLEIMB	DREUM3	El-slightm	E2 - Modera	B-Severe	
90FC	₹		M				₹	¥	BEIMB	DZETMB				
3DPC				×			≅	Σ	EUMD	DIENNS			ar discharge	ar discharg
7DPC	₹			₹			₹	₹	EIMB	EIMB			erous ocula	serous ocul
OH09			M	IM			Ξ	Ξ	EUM2	DIEZMO	B-sneezing	C-Cough	D 1 - Slight serous ocular discharge	D2 - Severe serous ocular discharge
SOPC							≅		EUNZ	E2/M3				
9							₹			₹				
200										₹				
36				$\vdash$										
22	$\vdash$	$\vdash$	$\vdash$	$\vdash$	$\vdash$		$\vdash$	$\vdash$		$\vdash$				
Cat ID Route 10PC 20PC 30PC 40PC														
8	<u> </u>			_						_				
3	-	2	60	4	S	9	7	00	6	2				

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Study Type	Safety				=								
Pertaining to	All												
Study Purpose	Demostrate safety of product under typical use conditions												
Product	A total of 416 cats of various ages and breeds were administered 1 dose of												
Administratio	vaccine. In addition, 308 of the 416 animals were given a second dose 2-3												
n	weeks later.												
Study Animals	Client-owned cats presenting to a veterinary clinic.												
Challenge													
Description	NA												
Interval													
observed after	Followed for 4-7 days after each vaccination.												
challenge													
Results	Frequency of Adverse Events:												
	Total number of Doses Administered = 724												
		1st Dose	2nd Dose	Total	Percent per #								
		100 2 000	2.10.2000		of Doses								
	No Adverse Events	370	298	668	92.27%								
	Look at injection site	4	1	5	0.69%								
	Turn in Circles	1	0	1	0.14%								
	Scratch at site	2	0	2	0.28%								
	Chew at site	1.24%											
	Vocalize as in pain	12	1	13	1.80%								
	Lethargy	24*	9*	33	4.56%								
	Anorexia	1	0	1	0.14%								
	Soreness	3	2	5	0.69%								
	Swelling or Nodule	0	0	0	0.00%								
	Other	4	1	5	0.69%								
	* It was noted that a large r one (31) came from the san commented that these cats vaccination, which were no	ne site locati were observ	on. Upon conv ed to be temp	versation with the porarily tired or m	veterinarian, he ellow after								
USDA	September 14, 1990												
<b>Approval Date</b>	September 14, 1990												

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