



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	7890.00
True Name	Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco Salud Animal, S.A. de C.V. - Elanco US Inc. Elanco US Inc. Pili Shield Porcino + C - Elanco Animal Health - Elanco US Inc. Pili Shield Porcino + C - Elanco US Inc. Porcine Pili Shield + C - Elanco US Inc. Porcine Pili Shield + C - Eli Lilly Philippines, Inc. - Elanco US Inc.
Date of Compilation Summary	April 06, 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.

Study Type	Efficacy																						
Pertaining to	Clostridium Perfringens Type C																						
Study Purpose	To demonstrate passive immunity against Clostridium Perfringens Type C in progeny																						
Product Administration	Pregnant gilts were vaccinated twice approximately 4 and 2 weeks prior to farrow.																						
Study Animals	Thirty (30) 7-day old piglets born from 10 vaccinated gilts. Three piglets per litter were used for study analysis.																						
Challenge Description	Not Applicable																						
Interval observed after challenge	Serum was collected from baby pigs at 7 days of age and was tested for antitoxin titers to C. perfringens Type C (CPTC) beta toxin. Serum from each litter was pooled prior to testing.																						
Results	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Litter</th> <th>C Perf Type C Antitoxin Titer*</th> </tr> </thead> <tbody> <tr><td>1</td><td>100</td></tr> <tr><td>2</td><td>40</td></tr> <tr><td>3</td><td>60</td></tr> <tr><td>4</td><td>40</td></tr> <tr><td>5</td><td>40</td></tr> <tr><td>6</td><td>10</td></tr> <tr><td>7</td><td>10</td></tr> <tr><td>8</td><td>10</td></tr> <tr><td>9</td><td>40</td></tr> <tr><td>10</td><td>20</td></tr> </tbody> </table> <p>*Geometric mean antibody titers of piglets to CPTC. A titer ≥ 2 units/mL is considered positive.</p>	Litter	C Perf Type C Antitoxin Titer*	1	100	2	40	3	60	4	40	5	40	6	10	7	10	8	10	9	40	10	20
Litter	C Perf Type C Antitoxin Titer*																						
1	100																						
2	40																						
3	60																						
4	40																						
5	40																						
6	10																						
7	10																						
8	10																						
9	40																						
10	20																						
USDA Approval Date	October 1, 1984																						

Study Type	Efficacy
Pertaining to	Escherichia Coli
Study Purpose	To demonstrate effectiveness against Escherichia Coli Bacterin Type 987p
Product Administration	
Study Animals	Porcine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
USDA Approval Date	04/28/1995

Study Type	Efficacy
Pertaining to	Escherichia Coli
Study Purpose	To demonstrate effectiveness against Escherichia Coli Bacterin Type F41
Product Administration	
Study Animals	Porcine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
USDA Approval Date	04/28/1995

Study Type	Efficacy
Pertaining to	Escherichia Coli
Study Purpose	To demonstrate effectiveness against Escherichia Coli Bacterin Type K88
Product Administration	
Study Animals	Porcine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
USDA Approval Date	04/28/1995

Study Type	Efficacy
Pertaining to	Escherichia Coli
Study Purpose	To demonstrate effectiveness against Escherichia Coli Bacterin Type K99
Product Administration	
Study Animals	Porcine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
USDA Approval Date	04/28/1995

Study Type	Safety																		
Pertaining to	All																		
Study Purpose	To demonstrate safety under typical field conditions																		
Product Administration	Two doses administered at 5 weeks and 2 weeks prior to farrow																		
Study Animals	Pregnant gilts and sows																		
Challenge Description	NA																		
Interval observed after challenge	Animals were observed on the day of each vaccination, the following day, and approximately seven days post vaccination.																		
Results	<p>Frequency of events:</p> <table border="1"> <thead> <tr> <th></th> <th># Gilts/Sows receiving 2 doses</th> <th>No Reaction</th> <th>Injection site reaction</th> </tr> </thead> <tbody> <tr> <td>Site 1</td> <td>153</td> <td>149</td> <td>4</td> </tr> <tr> <td>Site 2</td> <td>184</td> <td>184</td> <td>0</td> </tr> <tr> <td>Site 3</td> <td>168</td> <td>168</td> <td>0</td> </tr> </tbody> </table> <p>No other adverse reactions were observed.</p>				# Gilts/Sows receiving 2 doses	No Reaction	Injection site reaction	Site 1	153	149	4	Site 2	184	184	0	Site 3	168	168	0
	# Gilts/Sows receiving 2 doses	No Reaction	Injection site reaction																
Site 1	153	149	4																
Site 2	184	184	0																
Site 3	168	168	0																
USDA Approval Date	February 13, 1995																		