



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2648.53
True Name	Escherichia Coli Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc. Porcine Pili Shield - Elanco Canada Limited - Elanco US Inc. Porcine Pili Shield - Elanco Chile SpA. Porcine Pili Shield - Elanco US Inc. Porcine Pili Shield - Elanco Vietnam Company Limited - Elanco US Inc. Porcine Pili Shield - No distributor specified
Date of Compilation Summary	June 07, 2023

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	Escherichia Coli Bacterin Type 987p
Study Purpose	To demonstrate effectiveness against Escherichia Coli Bacterin Type 987p in piglets
Product Administration	Pregnant gilts
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. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
USDA Approval Date	August 31, 1984

Study Type	Efficacy
Pertaining to	Escherichia Coli Bacterin Type F41
Study Purpose	To demonstrate effectiveness against Escherichia Coli Bacterin Type F41 in piglets
Product Administration	Pregnant gilts
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. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
USDA Approval Date	October 13, 1987

Study Type	Efficacy
Pertaining to	Escherichia Coli Bacterin Type K88
Study Purpose	To demonstrate effectiveness against Escherichia Coli Bacterin Type K88 in piglets
Product Administration	Pregnant gilts
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. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
USDA Approval Date	June 5, 1984

Study Type	Efficacy
Pertaining to	Escherichia Coli Bacterin Type K99
Study Purpose	To demonstrate effectiveness against Escherichia Coli Bacterin Type K99 in piglets
Product Administration	Pregnant gilts
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. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
USDA Approval Date	April 17, 1984

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Safety by intramuscular route in swine
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.