



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1935.20
True Name	Bovine Rotavirus-Coronavirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Scour Bos 4 - Elanco Canada Limited - Elanco US Inc. Scour Bos 4 - Elanco US Inc.
Date of Compilation Summary	February 27, 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	Bovine Coronavirus
Study Purpose	To demonstrate passive immunity against Bovine Coronavirus in calves
Product Administration	Intramuscular to pregnant heifers
Study Animals	Calves
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	November 18, 1999

Study Type	Efficacy
Pertaining to	Bovine Rotavirus
Study Purpose	To demonstrate passive immunity against Bovine Rotavirus in calves
Product Administration	Intramuscular to pregnant cattle
Study Animals	Cattle
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	November 18, 1999

Study Type	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	
Study Animals	Bovine
Challenge Description	NA
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	November 22, 1999