

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1271.02
True Name	Bursal Disease Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro VIBURSA CE - Lohmann Animal Health International AviPro VIBURSA CE - No distributor specified Lohmann Animal Health International
Date of Compilation Summary	August 20, 2019

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	Infectious bursal disease virus (IBDV), CE strain
Study Purpose	To demonstrate efficacy against IBDV
Product Administration	Drinking water
Study Animals	Chicken
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 requires publication of data submitted after that date.
USDA Approval Date	May 1, 1991

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Study Type	Efficacy
Pertaining to	Infectious bursal disease virus (IBDV), CE strain
Study Purpose	To demonstrate efficacy against IBDV
Product Administration	Drinking water
Study Animals	Chicken
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 requires publication of data submitted after that date.
USDA Approval Date	February 6, 1995

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Study Type	Safety
Pertaining to	Infectious bursal disease virus, CE strain
Study Purpose	To demonstrate safety under field conditions
Product Administration	
Study Animals	Chicken
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 requires publication of data submitted after that date.
USDA Approval Date	September 23, 1991

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