



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	48B5.10
True Name	Newcastle-Bronchitis Vaccine, Mass Type, Killed Virus, Mycoplasma Gallisepticum Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro 304 ND-IB-MG - EURL Provast - Lohmann Animal Health International AviPro 304 ND-IB-MG - Elanco Colombia SAS - Lohmann Animal Health International AviPro 304 ND-IB-MG - Elanco Salud Animal, S.A. de C.V. AviPro 304 ND-IB-MG - Lohmann Animal Health International AviPro 304 ND-IB-MG - No distributor specified
Date of Compilation Summary	February 19, 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	Infectious bronchitis virus (IBV)
Study Purpose	To demonstrate effectiveness against IBV (Mass. type, Holland 52 strain)
Product Administration	Subcutaneous injection
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	June 27, 2000

Study Type	Efficacy
Pertaining to	Newcastle disease virus, infectious bronchitis virus, and <i>Mycoplasma gallisepticum</i>
Study Purpose	To demonstrate effectiveness against Newcastle disease virus (B1 type, LaSota strain), infectious bronchitis virus (Mass. type, Holland 52 strain), and <i>Mycoplasma gallisepticum</i>
Product Administration	Subcutaneous injection
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	October 13, 1988

Study Type	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
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 20, 2003

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
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	October 13, 1988