



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1761.12
True Name	Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass Type, Live Virus
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	<p>AviPro ND-IB Vibanco - EURL Provast - Lohmann Animal Health International</p> <p>AviPro ND-IB Vibanco - Elanco Animal Health - Lohmann Animal Health International</p> <p>AviPro ND-IB Vibanco - Elanco Colombia SAS - Lohmann Animal Health International</p> <p>AviPro ND-IB Vibanco - Eli Lilly Interamerica Inc. y Cia. Ltda. - Lohmann Animal Health International</p> <p>AviPro ND-IB Vibanco - Ilender Bolivia S.A.</p> <p>AviPro ND-IB Vibanco - J. Orbe Asesores S.A.C. - Lohmann Animal Health International</p> <p>AviPro ND-IB Vibanco - Lohmann Animal Health International</p> <p>AviPro ND-IB Vibanco - No distributor specified</p> <p>Lohmann Animal Health International</p>
Date of Compilation Summary	July 10, 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), Mass. type, M-48 strain
Study Purpose	To demonstrate efficacy against IBV, Mass. type
Product Administration	Drinking water, intraocular
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 15, 1976

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus (IBV), Mass. type, M-48 strain
Study Purpose	To demonstrate efficacy against IBV, Mass. type
Product Administration	Coarse spray
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 15, 1976

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus, Mass. type, M-48 strain
Study Purpose	To demonstrate efficacy against infectious bronchitis virus, Mass. type
Product Administration	Intranasal
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. Study data, however, are no longer available.
USDA Approval Date	June 25, 1975

Study Type	Efficacy
Pertaining to	Newcastle disease virus, B1 type, B1 strain
Study Purpose	To demonstrate efficacy against Newcastle disease virus, B1 type, B1 strain
Product Administration	Intraocular, 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 9, 1994

Study Type	Efficacy
Pertaining to	Newcastle disease virus, B1 type, B1 strain
Study Purpose	To demonstrate efficacy against Newcastle disease virus, B1 type, B1 strain
Product Administration	Intraocular, drinking water, coarse spray
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 9, 1994

Study Type	Efficacy
Pertaining to	Newcastle disease virus, B1 type, B1 strain
Study Purpose	To demonstrate efficacy against Newcastle disease virus
Product Administration	Intranasal
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. Study data, however, are no longer available.
USDA Approval Date	June 25, 1975

Study Type	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under typical field conditions
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	November 20, 1989

Study Type	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	Intraocular, intranasal, coarse spray (aerosol)
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. Study data, however, are no longer available.
USDA Approval Date	June 25, 1975