



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1761.17
True Name	Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Conn Types, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro ND-IB Polybanco - EURL Provast - Lohmann Animal Health International AviPro ND-IB Polybanco - Elanco Animal Health - Lohmann Animal Health International AviPro ND-IB Polybanco - Eli Lilly, Inc. AviPro ND-IB Polybanco - International Science Solution Co. LTD. - Lohmann Animal Health International AviPro ND-IB Polybanco - Laboratories Bimex SRL AviPro ND-IB Polybanco - Lohmann Animal Health International AviPro ND-IB Polybanco - No distributor specified Lohmann Animal Health International
Date of Compilation Summary	February 14, 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, Conn. type
Study Purpose	To demonstrate immunogenicity of Infectious Bronchitis Virus, Conn. 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 22, 1976

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	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	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	August 27, 1990

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. Study data, however, are no longer available.
USDA Approval Date	February 1, 1977