



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	48D7.11
True Name	Newcastle Disease-Bronchitis Vaccine, Mass & Ark Types, Killed Virus, Salmonella Enteritidis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro 329 ND-IB2-SE4 - No distributor specified AviPro 329 ND-IB2-SE4 Conc - Elanco Salud Animal, S.A. de C.V. - Lohmann Animal Health International AviPro 329 ND-IB2-SE4 Conc - Lohmann Animal Health International AviPro 329 ND-IB2-SE4 Conc - No distributor specified
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
Study Purpose	To demonstrate effectiveness against infectious bronchitis virus (Mass and Ark Types)
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	August 1, 2001

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus
Study Purpose	To demonstrate effectiveness against infectious bronchitis virus (Mass and Ark Types)
Product Administration	Intramuscular 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	March 30, 2001

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	To demonstrate effectiveness against Newcastle disease virus
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	August 1, 2001

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	To demonstrate effectiveness against Newcastle disease virus
Product Administration	Intramuscular 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	March 30, 2001

Study Type	Efficacy
Pertaining to	<i>Salmonella enteritidis</i>
Study Purpose	To demonstrate effectiveness against <i>Salmonella enteritidis</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	August 1, 2001

Study Type	Efficacy
Pertaining to	<i>Salmonella enteritidis</i>
Study Purpose	To demonstrate effectiveness against <i>Salmonella enteritidis</i> ,
Product Administration	Intramuscular 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	March 30, 2001

Study Type	Safety
Pertaining to	All fractions
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	August 1, 2001