

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1231.20
True Name	Bronchitis Vaccine, Ark Type, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro IB ARK - Lohmann Animal Health International AviPro IB ARK - No distributor specified Lohmann Animal Health International
Date of Compilation Summary	January 24, 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.

196 1231.20 Page 1 of 4

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus, Ark. type
Study Purpose	To demonstrate immunogenicity of Infectious Bronchitis Virus,
_	Arkansas type, ARK 3168 strain
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	March 18, 1988

196 1231.20 Page 2 of 4

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus, Ark. type
Study Purpose	To demonstrate immunogenicity of Infectious bronchitis virus,
	Arkansas type, ARK 3168 strain
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	June 20, 1984

196 1231.20 Page 3 of 4

Study Type	Safety
Pertaining to	Infectious bronchitis virus, Arkansas type
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	Coarse spray, 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	January 15, 1985

196 1231.20 Page 4 of 4