



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1271.00
True Name	Bursal Disease Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health Univax-BD - Abdulrehman Algosabi GTC (Saudi Arabia) Univax-BD - Egyptian Trading and supply - Merck Sharpe and Dohme (MSD) Univax-BD - Intervet South Africa (Pty) Ltd. Univax-BD - Intervet Veterinaria Chile Ltda Univax-BD - MSD Salud Animal Columbia S.A.S. Univax-BD - Merck Animal Health Univax-BD - No distributor specified
Date of Compilation Summary	October 21, 2021

**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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bursal Disease (IBD), Standard Strain
<b>Study Purpose</b>	To demonstrate effectiveness against IBD, standard strain.
<b>Product Administration</b>	Subcutaneous
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	February 25, 1992

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bursal Disease (IBD), Standard Strain
<b>Study Purpose</b>	To demonstrate effectiveness against IBD, standard strain.
<b>Product Administration</b>	<i>In Ovo</i>
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	May 9, 1995

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bursal Disease (IBD), Standard Strain
<b>Study Purpose</b>	To demonstrate effectiveness against IBD, standard strain.
<b>Product Administration</b>	Drinking Water
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	May 9, 1995

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To demonstrate safety of product under typical field conditions
<b>Product Administration</b>	<i>In Ovo</i> , Drinking Water
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	1997

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To demonstrate safety of product under typical field conditions
<b>Product Administration</b>	Subcutaneous
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	1992