

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	13D1.21
True Name	Canine Distemper-Adenovirus Type 2-Parainfluenza- Parvovirus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Canine Imuno-Vax 5 - Aspen Veterinary Resources Ltd. Canine Spectra 5 - Peak Marketing Solo-Jec 5 - No distributor specified Solo-Jec 5 Plus - No distributor specified Univac 5 - ProLabs Ltd
Date of Compilation Summary	September 04, 2019

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.

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Study Type	Efficacy
Pertaining to	Canine adenovirus (CAV)
<b>Study Purpose</b>	Demonstration of efficacy against CAV Type 1 by CAV Type 2
<b>Product Administration</b>	
Study Animals	Canine
<b>Challenge Description</b>	
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.
<b>USDA Approval Date</b>	September 14, 2006

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Study Type	Efficacy
Pertaining to	Canine adenovirus (CAV)
<b>Study Purpose</b>	Demonstration of efficacy against CAV Type 2 by CAV Type 2
<b>Product Administration</b>	
Study Animals	Canine
<b>Challenge Description</b>	
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.
<b>USDA Approval Date</b>	September 5, 2006

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Study Type	Efficacy
Pertaining to	Canine parainfluenza (CPI)
Study Purpose	Demonstration of efficacy against CPI
<b>Product Administration</b>	
Study Animals	Canine
<b>Challenge Description</b>	
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.
<b>USDA Approval Date</b>	October 26, 1990

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Study Type	Efficacy
Pertaining to	Canine distemper virus (CDV)
Study Purpose	Demonstration of efficacy against CDV
<b>Product Administration</b>	Intramuscular
Study Animals	Canine
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.
<b>USDA Approval Date</b>	March 12, 1975

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Study Type	Efficacy
Pertaining to	Canine distemper virus (CDV)
Study Purpose	Demonstration of efficacy against CDV
<b>Product Administration</b>	Subcutaneous
Study Animals	Canine
<b>Challenge Description</b>	
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.
<b>USDA Approval Date</b>	June 3, 1980

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Study Type	Efficacy
Pertaining to	Canine parvovirus (CPV)
Study Purpose	Demonstration of efficacy against CPV
<b>Product Administration</b>	
Study Animals	Canine
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.
<b>USDA Approval Date</b>	September 12, 2006

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Study Type	Safety
Pertaining to	Canine Adenovirus Type-2 (CAV-2)
Study Purpose	Development of corneal opacity is not associated with the use of
, ,	this product
<b>Product Administration</b>	
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	Study data are not available.

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
<b>Product Administration</b>	
Study Animals	Canine
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.
<b>USDA Approval Date</b>	May 3, 2007

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