



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	12M5.44
True Name	Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard & Variant, Mass Type, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 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.

Study Type	Efficacy
Pertaining to	Infectious bursal disease, standard and variant E
Study Purpose	Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against infectious bursal disease, standard and variant E
Product Administration	Intramuscularly (IM)
Study Animals	Chickens
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, 1992

Study Type	Efficacy
Pertaining to	Infectious bursal disease, standard and variant E
Study Purpose	Demonstrate efficacy against bursal disease, standard and variant E
Product Administration	Intramuscularly (IM)
Study Animals	Chickens
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 21, 2005

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus, Massachusetts type
Study Purpose	Demonstrate efficacy against infectious bronchitis virus, Massachusetts type
Product Administration	Intramuscularly (IM)
Study Animals	Chickens
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 21, 2005

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus, Massachusetts type
Study Purpose	Demonstrate efficacy against infectious bronchitis virus, Massachusetts type vaccine
Product Administration	One dose intramuscularly (IM) on study Day 21
Study Animals	Twelve-week-old SPF chicks; 24-25 per group; Group 9 was primed at 9 weeks of age on study Day 0 with a live IBV Mass vaccine. Group 7: No priming; No vaccine; IBV Mass challenge Group 9: Primed; Vaccinated; IBV Mass challenge Group 13: No priming; No vaccine; no challenge
Challenge Description	Infectious bronchitis, Mass type on study Day 42
Interval observed after challenge	Five days post challenge, the tracheas were harvested for tracheal ring evaluation and virus re-isolation of the strains used for the challenge.
Results	<u>Tracheal ring scores:</u> A bird was considered affected if less than 50% of a tracheal ring section had discernible ciliary activity in any of three samples (representing the upper third, middle third, and lower third of the trachea). Each bird received a score from 0-3 depending on how many sections were affected. Number of affected birds: Group 7: 25/25 (unvaccinated control) Group 9: 0/25 Group 13: 0/25 (non-challenged control) <u>Virus Isolation:</u> A bird was considered affected if any embryos died after each tracheal swab was used to inoculate 5 embryonated eggs. Each bird received a score from 0-5 based on the number of embryos that died. Number of affected birds: Group 7: 25/25 (unvaccinated control) Group 9: 3/25 Group 13: 0/25 (non-challenged control) Raw data on attached page.
USDA Approval Date	June 3, 2008

Tracheal Ring Scores – Raw data

Tracheal Score, individual Results

Three 2 mm wide tracheal rings representing the upper third, middle third and lower third of the trachea of each bird were examined for ciliary activity. Tracheal ring sections were considered positive if less than 50% of the ring had discernible ciliary activity. Each bird received a score of 0, 1, 2, or 3 depending on how many sections were positive. A score of zero indicated that all sections were negative. A score of three indicated that all sections were positive. A score ≥ 1 is considered affected.

Group	vaccine	challenge	Unit	ID	Score
7	None	MASS	7	381	3
				382	3
				383	3
				384	3
				385	3
				386	3
				387	3
				388	3
				389	3
				390	3
				391	3
				392	3
				393	3
			8	394	3
				395	3
				396	3
				397	3
				398	3
				399	3
				400	3
				401	3
				402	3
				403	3
				404	3
				405	3
9	Vaccine	MASS	3	331	0
				332	0
				333	0
				334	0
				335	0
				336	0
				337	0
				338	0
				339	0
				340	0

Group	vaccine	challenge	Unit	ID	Score
				341	0
				342	0
				343	0
			4	344	0
				345	0
				346	0
				347	0
				348	0
				349	0
				350	0
				351	0
				352	0
				353	0
				354	0
				355	0
13	None	N/A	1	306	0
				307	0
				308	0
				309	0
				310	0
				311	0
				312	0
				313	0
				314	0
				315	0
			2	316	0
				317	0
				318	0
				319	0
				320	0
				321	0
				322	0
				323	0
				324	0
				325	0
				326	0
				327	0
				328	0
				329	0
				330	0

MASS = Infectious bronchitis virus, Massachusetts type
N/A = Not applicable

Virus Isolation (VI) – Raw data

VI Score, individual results

Each tracheal swab was used to inoculate 5 embryonated eggs. Each bird received a score of 0, 1, 2, 3, 4 or 5 depending on how many embryos died. A score of zero indicated that none of the embryos died and a score of 5 indicated that all five of the embryos died. A score ≥ 1 is considered affected.

Group	vaccine	challenge	Unit	ID	Score
7	None	MASS	7	381	5
				382	4
				383	5
				384	5
				385	5
				386	4
				387	3
				388	3
				389	5
				390	4
				391	3
				392	3
				393	3
			8	394	5
				395	5
				396	2
				397	5
				398	4
				399	4
				400	4
				401	5
				402	4
				403	5
				404	5
				405	5
9	Vaccine	MASS	3	331	4
				332	0
				333	0
				334	2
				335	0
				336	0
				337	0
				338	0
				339	0
				340	0
				341	0

Group	vaccine	challenge	Unit	ID	Score
				342	0
				343	0
			4	344	0
				345	0
				346	0
				347	0
				348	0
				349	3
				350	0
				351	0
				352	0
				353	0
				354	0
				355	0
				507	0
				508	0
				509	0
				510	0
				511	0
				512	0
				513	0
				514	0
				515	0
				516	0
				518	0
			24	519	0
				520	0
				521	0
				522	0
				523	0
				524	0
				525	0
				526	0
				527	0
				528	0
				529	0
				530	0
13	None	N / A	1	306	0
				307	0
				308	0
				309	0
				310	0
				311	0
				312	0
				313	0
				314	0
				315	0
				316	0

Group	vaccine	challenge	Unit	ID	Score
				317	0
				318	0
			2	319	0
				320	0
				321	0
				322	0
				323	0
				324	0
				325	0
				326	0
				327	0
				328	0
				329	0
				330	0

MASS = Infectious bronchitis virus, Massachusetts type
N/A = Not applicable

Study Type	Efficacy
Pertaining to	Newcastle disease
Study Purpose	Demonstrate efficacy against Newcastle disease
Product Administration	Intramuscularly (IM)
Study Animals	Chickens
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 21, 2005

Study Type	Efficacy
Pertaining to	Avian reovirus
Study Purpose	Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against reovirus
Product Administration	Intramuscularly (IM)
Study Animals	Chickens
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 21, 2005

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Intramuscularly (IM)
Study Animals	Chickens
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	February 14, 2005