



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Huvepharma, Inc.
USDA Vet Biologics Establishment Number	605
Product Code	1U11.R1
True Name	Clostridium Perfringens Type A Vaccine, Live Salmonella Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Avert NE - No distributor specified
Date of Compilation Summary	May 03, 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.

Study Type	Efficacy																														
Pertaining to	<i>Clostridium perfringens</i> type A																														
Study Purpose	Efficacy against necrotic enteritis due to <i>Clostridium perfringens</i> Type A																														
Product Administration	One dose administered by coarse spray at day of age (Study Day 1)																														
Study Animals	Group 1: Non-vaccinated, non-challenged sentinel control Group 2: Non-vaccinated, <i>Eimeria maxima</i> treated control Group 3: Placebo vaccinated, <i>Eimeria</i> treated and <i>Clostridium</i> challenge Group 4: Product vaccinated (Vaccine), <i>Eimeria</i> treated and <i>Clostridium</i> challenge																														
Challenge Description	Chickens were treated with <i>Eimeria maxima</i> on Study Day 14 and challenged with <i>Clostridium perfringens</i> on Study Day 19																														
Interval observed after challenge	Observed twice daily for 10 days after challenge. Birds that succumbed during the observation period were evaluated for intestinal lesions. Remaining birds were humanely euthanized on Study Day 28.																														
Results	<p style="text-align: center;">Mortality after Challenge due to Necrotic Enteritis</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Treatment Group</th> <th>Number Chickens</th> <th>Vaccine</th> <th><i>Eimeria</i> inoculation</th> <th><i>C. perfringens</i> challenge</th> <th>Results</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>16</td> <td>None</td> <td>-</td> <td>-</td> <td>0/14</td> </tr> <tr> <td>2</td> <td>80</td> <td>None</td> <td>+</td> <td>-</td> <td>0/73</td> </tr> <tr> <td>3</td> <td>192</td> <td>Placebo</td> <td>+</td> <td>+</td> <td>62/182*</td> </tr> <tr> <td>4</td> <td>192</td> <td>Vaccine</td> <td>+</td> <td>+</td> <td>33/178*</td> </tr> </tbody> </table> <p>* Death due to necrotic enteritis (confirmed by necropsy) per total birds challenged</p>	Treatment Group	Number Chickens	Vaccine	<i>Eimeria</i> inoculation	<i>C. perfringens</i> challenge	Results	1	16	None	-	-	0/14	2	80	None	+	-	0/73	3	192	Placebo	+	+	62/182*	4	192	Vaccine	+	+	33/178*
Treatment Group	Number Chickens	Vaccine	<i>Eimeria</i> inoculation	<i>C. perfringens</i> challenge	Results																										
1	16	None	-	-	0/14																										
2	80	None	+	-	0/73																										
3	192	Placebo	+	+	62/182*																										
4	192	Vaccine	+	+	33/178*																										
USDA Approval Date	October 16, 2019																														

Treatment Group	Chickens Challenged	Mortality Due to Necrotic Enteritis by Day After Challenge									
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
3	182	0	15	41	5	1	0	0	0	0	0
4	178	0	4	28	1	0	0	0	0	0	0

Study Type	Safety					
Pertaining to	All					
Study Purpose	To demonstrate safety under field conditions					
Product Administration	Administered by coarse spray at day of age					
Study Animals	Commercial broiler chickens day of age					
Challenge Description	N/A					
Interval observed after challenge	Chickens were observed daily for 21 days after vaccination					
Results	Total Mortality for Vaccinates and Controls ¹					
		Site	Treatment	Number of Chickens	Mortality	Percent Mortality
		1	Vaccinates	37,200	2461	6.62 ²
			Controls	38,320	1500	3.91
		2	Vaccinates	206,400	3539	1.71
			Controls	209,560	5073	2.42
		3				
		Farm 1	Vaccinates	64,800	1311	2.02
			Controls	65,480	1854	2.83
		Farm 2	Vaccinates	81,100	1169	1.44
			Controls	83,480	2450	2.93
		¹ Mortality of controls at each site is the average mortality of five previous flocks at the same site. ² Mortality was due to flock-specific factors and was not product related as affirmed by licensee. No product related adverse events were observed during this trial.				
	USDA Approval Date	April 26, 2021				