



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19E1.21
True Name	Porcine Rotavirus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	ProSystem Rota - Merck Animal Health ProSystem Rota - Merck Sharpe and Dohme (MSD) ProSystem Rota - No distributor specified
Date of Compilation Summary	October 25, 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>Rotavirus</i>
Study Purpose	To determine efficacy of Rotavirus
Product Administration	IM and Oral
Study Animals	Swine
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	December 27, 1993

Study Type	Efficacy
Pertaining to	<i>Rotavirus</i>
Study Purpose	To determine efficacy against Rotavirus
Product Administration	
Study Animals	Swine
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	December 27, 1993

Study Type	Safety
Pertaining to	<i>Rotavirus</i>
Study Purpose	Demonstrate safety
Product Administration	Oral
Study Animals	Young pigs
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	April 4, 1984

Study Type	Safety
Pertaining to	<i>Rotavirus</i>
Study Purpose	Establish safety of vaccine under typical field conditions
Product Administration	One dose by both the intramuscular and oral route
Study Animals	Preweaning pigs
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.
USDA Approval Date	1985