



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Merial, Inc.
USDA Vet Biologics Establishment Number	298
Product Code	1901.R4
True Name	Rabies Vaccine, Live Canarypox Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	PureVax Feline Rabies 3 YR - Merial Canada, Inc. PureVax Feline Rabies 3 YR - No distributor specified
Date of Compilation Summary	May 01, 2018

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	Rabies
Study Purpose	To evaluate efficacy against rabies thirty-six months post-vaccination to establish a 3 year revaccination interval.
Product Administration	One dose subcutaneously
Study Animals	A total of 63 cats, 61 to 69 days of age at time of vaccination Vaccinates: 32 Controls: 31
Challenge Description	Challenged 1106 days after vaccination with virulent rabies virus
Interval observed after challenge	Cats were observed for 90 days post-challenge
Results	Efficacy was based on clinical signs of rabies (mortality) as confirmed by positive fluorescent antibody (FA) testing for rabies per 9 CFR 113.209 Raw data shown on attached pages.
USDA Approval Date	May 6, 2013

CONTROLS

Mortality and Presence of Rabies Antigen in Brain Tissue

ID	Mortality Days PC*	Rabies Antigen (FA)
GDR1	10	+
GDR4	10	+
GDS1	19	+
GDS2	-	-
GDU1	10	+
GDU2	16	+
GDU3	-	-
NID4	12	+
NIF1	12	+
NIF2	13	+
NIG2	15	+
NII2	17	+
NIJ1	16	+
NIJ3	-	-
NIK1	10	+
NIK4	11	+
NIK5	11	+
NIK7	12	+
NIL3	15	+
NIM1	17	+
NIM3	12	+
NIN2	12	+
NIN3	10	+
NIN5	11	+
VEJ3	26	+
VEK1	9	+
VEK3	10	+
VEK5	10	+
VEL2	-	-
VEM4	8	+
VEM5	11	+

*Animals that did not succumb to rabies infection were euthanatized 91 days post-challenge (PC).

+ is positive for rabies virus infection.

- is negative for rabies virus infection.

VACCINATES

Mortality and Presence of Rabies Antigen in Brain Tissue

ID	Mortality Days PC*	Rabies Antigen (FA)
GDR2	-	-
GDR3	-	-
GDS3	-	-
GDU4	-	-
GDU5	-	-
GDU6	-	-
GDV6	9	+
GDW4	-	-
GDX1	-	-
NIF3	-	-
NIF6	-	-
NIG1	-	-
NIG3	-	-
NII1	-	-
NIJ2	-	-
NIK2	-	-
NIK3	-	+
NIK6	-	-
NIL2	13	+
NIM2	-	-
NIM4	-	-
NIM5	-	-
NIN1	-	-
NIN4	-	-
VEI2	-	-
VEJ1	-	-
VEJ2	-	-
VEK2	-	-
VEK6	-	-
VEL1	-	-
VEM2	-	-
VEM3	-	-

*Animals that did not succumb to rabies infection were euthanatized 91 days post-challenge (PC).

+ is positive for rabies virus infection.

- is negative for rabies virus infection.

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Subcutaneously (SQ)
Study Animals	Cats
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 4, 1998