

Summary of Studies Supporting USDA Product Licensure

| Establishment Name | Elanco US Inc. |
|---|---|
| USDA Vet Biologics Establishment Number | 196 |
| Product Code | 16D5.20 |
| True Name | Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Elanco US Inc. Fel-O-Vax PCT - No distributor specified Fel-O-Vax PCT - Zoetis (Shanghai) Animal Health - Elanco US Inc. Fel-O-Vax PCT - Zoetis Inc Elanco US Inc. |
| Date of Compilation Summary | February 14, 2022 |

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 | Feline Calicivirus |
| Study Purpose | To demonstrate effectiveness against respiratory disease due to |
| | feline calicivirus |
| Product Administration | |
| Study Animals | |
| 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 | June 1, 1979 (license received) |

| Study Type | Efficacy |
|-------------------------|---|
| | Feline Rhinotracheitis (FVR) |
| Pertaining to | |
| Study Purpose | To demonstrate effectiveness against Feline Rhinotracheitis |
| Product Administration | |
| Study Animals | |
| 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 | June 1, 1979 (license received) |

| Study Type | Efficacy |
|-------------------------|---|
| Pertaining to | Feline Panleukopenia Virus |
| Study Purpose | To demonstrate effectiveness against Feline Panleukopenia Virus |
| Product Administration | |
| Study Animals | |
| 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 | June 1, 1979 (license received) |

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|-------------------------|---|
| Study Type | Safety |
| Pertaining to | All |
| Study Purpose | Demonstrate Safety of product under typical use conditions |
| Product Administration | |
| Study Animals | |
| Challenge Description | NA |
| 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. |
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