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Feline Calicivirus Vaccine, Living

General Notices

(Feline Calicivirosis Vaccine (Live), Ph. Eur. monograph 1102)

Ph Eur

1 DEFINITION

Feline calicivirosis vaccine (live) is a preparation of one or more suitable strains of feline calicivirus. This monograph applies to vaccines intended for the active immunisation of cats against feline calicivirosis.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in cell cultures.

2-2 SUBSTRATE FOR VIRUS PROPAGATION

2-2-1 Cell cultures

The cell cultures comply with the requirements for cell cultures for the production of vaccines for veterinary use (*5.2.4*).

2-3 CHOICE OF VACCINE VIRUS

The vaccine virus is shown to be satisfactory with respect to safety (*5.2.6*) and efficacy (*5.2.7*) for the cats for which it is intended.

The following tests for safety (section 2-3-1), increase in virulence (section 2-3-2) and immunogenicity (section 2-3-3) may be used during the demonstration of safety and efficacy.

2-3-1 Safety

Carry out the test for each route and method of administration to be recommended for vaccination. Use vaccine virus at the least attenuated passage level that will be present in a batch of the vaccine.

For each test, use not fewer than 8 cats of the minimum age to be recommended for vaccination and that do not have antibodies against feline calicivirus. Administer to each cat a quantity of the vaccine virus equivalent to not less than 10 times the maximum virus titre likely to be contained in 1 dose of the vaccine. Observe the cats at least daily for at least 14 days.

The vaccine virus complies with the test if no cat shows abnormal local or systemic reactions, or dies from causes attributable to the vaccine virus.

2-3-2 Increase in virulence

Carry out the test according to general chapter *5.2.6* using cats that do not have antibodies against feline calicivirus. If the properties of the vaccine virus allow sequential passage through 5 groups via natural spreading, this method may be used, otherwise passage as described below is carried out.

Administer to each cat of the 1st group by a route to be recommended a quantity of the vaccine virus that will allow recovery of virus for the passages described below. Administer the virus by the route to be recommended for vaccination most likely to lead to reversion of virulence. After 5 days, remove the nasal mucus, tonsils and trachea of each cat. Mix, homogenise in 10 mL of buffered saline and allow the solids to settle. Administer the supernatant by the intranasal route to each cat of the next group. Carry out this passage operation 4 times; verify the presence of the virus at each passage. If the virus is not found at a passage level, repeat the passage by administration to a group of 10 cats.

If the 5th group of cats shows no evidence of an increase in virulence indicative of reversion during the observation period, further testing is not required. Otherwise, carry out an additional safety test and compare the clinical signs and any relevant parameters in a group of at least 8 cats receiving the material used for the first passage and another similar group receiving the virus at the final passage level.

The vaccine virus complies with the test if no indication of increased virulence of the virus recovered for the final passage compared with the material used for the first passage is observed. If virus is not recovered after an initial passage in 2 cats and a subsequent repeat passage in 10 cats, the vaccine virus also complies with the test.

2-3-3 Immunogenicity

A test is carried out for each strain of feline calicivirus in the vaccine, for each route and method of administration to be recommended for vaccination. The quantity of vaccine virus to be administered to each cat is not greater than the minimum virus titre to be stated on the label and the virus is at the most attenuated passage level that will be present in a batch of vaccine.

Use for the test not fewer than 20 cats, 8-12 weeks old, that do not have antibodies against feline calicivirus. Vaccinate not fewer than 10 cats, according to the schedule to be recommended. Maintain not fewer than 10 cats as controls. Challenge each cat after 4 weeks by the intranasal route with a sufficient quantity of a suspension of virulent feline calicivirus virus. Observe the cats at least daily for 14 days after challenge. Collect nasal washings daily on days 2 to 14 to test for virus excretion. Note daily the body temperature and signs of disease using the scoring system shown below.

The test is not valid if during the observation period after challenge, fewer than 80 per cent of the control cats show notable signs of feline calicivirosis (hyperthermia, buccal ulcers, respiratory signs).

The vaccine virus complies with the test if during the observation period after challenge, the score for the vaccinated cats is significantly lower than that for the controls.

Observed signs	**Score**
Death	10
Depressed state	2
Temperature ≥ 39.5 °C	1
Temperature ≤ 37 °C	2
Ulcer (nasal or oral)	
— small and few in number	1
— large and numerous	3
Nasal discharge	
— slight	1
— copious	2
Ocular discharge	1

Observed signs	Score
Weight loss	2
Virus excretion (total number of days):	
≤ 4 days	1
5-7 days	2
> 7 days	3

3 BATCH TESTS

3-1 Identification

The vaccine is identified using a suitable method. For example, when neutralised by 1 or more monospecific antisera, it is no longer able to infect susceptible cell cultures into which it is inoculated.

3-2 Bacteria and fungi

The vaccine, including where applicable the diluent supplied for reconstitution, complies with the test for sterility prescribed in the general monograph *Vaccines for veterinary use (0062)*.

3-3 Mycoplasmas (*2.6.7*)

The vaccine complies with the test for mycoplasmas.

3-4 Extraneous agents (*5.2.5*)

The vaccine is free from extraneous agents.

3-5 Virus titre

Titrate the vaccine virus in suitable cell cultures at a temperature favourable to replication of the virus. The vaccine complies with the test if one dose contains not less than the minimum virus titre stated on the label.

3-6 Potency

The vaccine complies with the requirements of the test prescribed under Immunogenicity (section 2-3-3) when administered by a recommended route and method. It is not necessary to carry out the potency test for each batch of the vaccine if it has been carried out on a representative batch using a vaccinating dose containing not more than the minimum virus titre stated on the label.