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Feline Infectious Enteritis Vaccine, Living

General Notices

Feline Panleucopenia Vaccine, Living

(Feline Infectious Enteritis (Feline Panleucopenia) Vaccine (Live), Ph. Eur. monograph 0251)

Ph Eur

1 DEFINITION

Feline infectious enteritis (feline panleucopenia) vaccine (live) is a preparation of a suitable strain of feline panleucopenia virus. This monograph applies to vaccines intended for the active immunisation of cats against feline infectious enteritis (feline panleucopenia).

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, including safety for pregnant queens if the vaccine may be used in such queens. If the virus is excreted in the faeces, the effect in pregnant queens must be documented.

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.

2-3-1-1 General safety. For each test, use not fewer than 5 cats of the minimum age to be recommended for vaccination and that do not have antibodies against feline panleucopenia virus and canine parvovirus. Make counts of leucocytes in

circulating blood on days 8 and 4 before injection of the vaccine virus and calculate the mean of the 2 counts to serve as the initial value. 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. Make leucocyte counts on the 4th, 6th, 8th and 10th days after inoculation.

The vaccine virus complies with the test if no cat shows abnormal local or systemic reactions, signs of disease or dies from causes attributable to the vaccine virus and if, for each cat and each blood count, the number of leucocytes is not less than 50 per cent of the initial value.

2-3-1-2 Safety in pregnant queens. If the vaccine is intended for use or may be used in pregnant queens, use not fewer than 5 queens per group, at the stage of pregnancy to be recommended or at a range of stages of pregnancy according to the schedule to be recommended. Administer to each queen a quantity of vaccine virus at least equivalent to the maximum virus titre likely to be contained in 1 dose of the vaccine. Observe the queens at least daily until 1 day after parturition and observe their kittens until at least the age of 3 weeks.

The vaccine virus complies with the test if no queen shows abnormal local or systemic reactions, signs of disease or dies from causes attributable to the vaccine virus and if no adverse effects on the pregnancy or the offspring, such as foetal resorption or ataxia in the kittens, are noted.

2-3-2 Increase in virulence

Carry out the test according to general chapter *5.2.6* using cats of the minimum age to be recommended for vaccination and that do not have antibodies against feline panleucopenia virus and canine parvovirus. 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. Collect the faeces from each cat from the 2nd to the 10th day after administration of the virus, check them for the presence of the virus and pool the faeces containing virus. Administer 1 mL of the suspension of pooled faeces by either the oral or the intranasal route to each cat of the next group. Carry out this passage operation not fewer than 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 (count of white blood cells, results of histological examination of the thymus and titre of excreted virus) in a group of at least 8 cats receiving the material used for the 1st passage and another similar group receiving the virus at the final passage level.

The vaccine virus complies with the test if no cat dies or shows signs attributable to the vaccine virus and no indication of increasing virulence of the virus recovered for the final passage compared with the material used for the 1st passage is observed. Account is taken, notably, of the count of white blood cells, of results of histological examination of the thymus and of the titre of excreted virus. 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 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 10 cats, 8-12 weeks old, that do not have antibodies against feline panleucopenia virus and canine parvovirus. Vaccinate not fewer than 5 cats, according to the schedule to be recommended. Maintain not fewer than 5 cats as controls. Carry out leucocyte counts 8 days and 4 days before challenge and calculate the mean of the 2 counts to serve as the initial value. Challenge each cat after 20-22 days by the intraperitoneal route with a sufficient quantity of a suspension of virulent feline panleucopenia virus. Observe the cats at least daily for 14 days after challenge. Carry out leucocyte counts on the 4th, 6th, 8th and 10th days after challenge.

The test is not valid if during the observation period after challenge, fewer than 100 per cent of the control cats show, on fewer than one occasion, a diminution in the number of leucocytes of at least 75 per cent of the initial value or die from feline panleucopenia. The vaccine virus complies with the test if during the observation period after challenge, all the vaccinated cats survive and show no signs of disease nor leucopenia; that is to say, the diminution in the number of leucocytes does not exceed, in any of the 4 counts, 50 per cent of the initial value.

3 BATCH TESTS

3-1 Identification

The vaccine virus is identified and differentiated from canine parvovirus using a suitable method, for example, an immunofluorescence or an immunostaining test in susceptible cell cultures using specific monoclonal antibodies.

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. 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.