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Feline Leukaemia Vaccine, Inactivated

General Notices

(Feline Leukaemia Vaccine (Inactivated), Ph. Eur. monograph 1321)

Ph Eur

1 DEFINITION

Feline leukaemia vaccine (inactivated) is a preparation of immunogens from a suitable strain of feline leukaemia virus. This monograph applies to vaccines intended for the active immunisation of cats against feline leukaemia.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The immunogens consist either of a suitable strain of feline leukaemia virus inactivated while maintaining adequate immunogenic properties or of a fraction of the virus with adequate immunogenic properties; the immunogenic fraction may be produced by recombinant DNA technology. The vaccine may be adjuvanted.

2-2 CHOICE OF VACCINE COMPOSITION

The vaccine 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 2-2-1) and immunogenicity (section 2-2-2) may be used during the demonstration of safety and efficacy.

2-2-1 Safety

Carry out the test for each route and method of administration to be recommended for vaccination. Use a batch of vaccine containing not less than the maximum potency that may be expected in a batch of vaccine.

2-2-1-1 General safety and immunosuppression. Use for the test not fewer than 15 cats of the minimum age to be recommended and that do not have antibodies against gp 70 antigen of feline leukaemia virus nor display viraemia or antigenaemia at the time of the test; absence of antibodies and antigen is demonstrated by enzyme-linked immunosorbent assay (*2.7.1*). Administer to each of not fewer than 10 cats 1 dose of the vaccine. If the schedule to be recommended requires a 2nd dose, administer 1 dose after an interval of at least 14 days. Maintain not fewer than 5 cats as controls. Record the body temperature of each cat on the day before each vaccination, at the time of vaccination, 4 h and 8 h later, and once per day during the 4 following days. Observe the cats at least daily for not less than 4 weeks after the last vaccination. 1, 2 and 4 weeks after the last vaccination, submit the cats to suitable tests for evidence of an immunosuppressive effect.

The vaccine complies with the test if no cat shows abnormal local or systemic reactions or dies from causes attributable to the vaccine and if no significant difference is observed in vaccinated cats compared with controls regarding

immunosuppressive effect.

2-2-2 Immunogenicity

A test is carried out for each route and method of administration to be recommended, using in each case cats of the minimum age to be recommended for vaccination. The vaccine administered to each cat is of minimum potency.

Use for the test not fewer than 25 cats that do not have antibodies against the antigens of feline leukaemia virus and against the feline oncogene membrane antigen (anti-FOCMA antibodies), and showing no viraemia or antigenaemia at the time of the test. Vaccinate not fewer than 15 cats according to the schedule to be recommended. Maintain not fewer than 10 cats as controls. Challenge each cat after 14 days by the peritoneal or oronasal route, on one or several occasions, with a sufficient quantity of suspension of an epidemiologically relevant virulent strain of feline leukaemia virus, consisting predominantly of type A virus. Observe the cats at least daily for 15 weeks and, from the 3rd week onwards, test each week for viraemia or antigenaemia (p27 protein) by suitable methods such as immunofluorescence on circulating leucocytes or enzyme-linked immunosorbent assay. A cat is considered persistently infected if it shows positive viraemia or antigenaemia for 3 consecutive weeks or on 5 occasions, consecutively or not, between the 3rd and the 15th week.

The test is not valid if during the observation period after challenge, fewer than 80 per cent of the control cats show persistant viraemia or antigenaemia. The vaccine complies with the test if during the observation period after challenge, not fewer than 80 per cent of the vaccinated cats show no persistent infection.

2-3 IN-PROCESS CONTROL TESTS

During production, suitable immunochemical tests are carried out for the evaluation of the quality and purity of the viral antigens included in the vaccine composition. The values found are within the limits approved for the particular vaccine.

2-4 MANUFACTURER'S TESTS

2-4-1 Residual live virus

Where applicable, the test for residual live virus is carried out using a quantity of inactivated virus harvest equivalent to not less than 25 doses of vaccine and 2 passages in the same type of cell cultures as used for the production of the vaccine or in cell cultures shown to be at least as sensitive. The inactivated virus harvest complies with the test if no live virus is detected.

2-4-2 Batch potency test

It is not necessary to carry out the Potency test (section 3-4) for each batch of vaccine if it has been carried out using a batch of vaccine with a minimum potency. Where the test is not carried out, an alternative validated method is used, the criteria for acceptance being set with reference to a batch of vaccine that has given satisfactory results in the test described under Potency.

2-4-3 Bacterial endotoxins

For vaccines produced by recombinant DNA technology with a bacterial host cell such as *Escherichia coli*, a test for bacterial endotoxins (*2.6.14*) is carried out on each final lot or, where the nature of the adjuvant prevents performance of a satisfactory test, on the antigen immediately before addition of the adjuvant. The value found is within the limit approved for the particular vaccine and which has been shown to be safe for cats.

3 BATCH TESTS

3-1 Identification

The vaccine contains the antigen or antigens stated under Definition.

3-2 Bacteria and fungi

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

3-3 Residual live virus

This test may be omitted for batch release, as stated in the monograph Vaccines for veterinary use (0062).

If the vaccine contains inactivated virus, carry out a test for residual live feline leukaemia virus by making 2 passages on susceptible cell cultures. The vaccine complies with the test if no virus is detected. If the vaccine contains an adjuvant, if possible separate the adjuvant from the liquid phase by a method that does not inactivate the virus or otherwise interfere with the detection of live viruses.

3-4 Potency

The vaccine complies with the requirements of the test prescribed under Immunogenicity (section 2-2-2) when administered by a recommended route and method.
