Edition: BP 2025 (Ph. Eur. 11.6 update)

Feline Viral Rhinotracheitis Vaccine, Inactivated

General Notices

(Feline Viral Rhinotracheitis Vaccine (Inactivated), Ph. Eur. monograph 1207)

Ph Eur

1 DEFINITION

Feline viral rhinotracheitis vaccine (inactivated) is a preparation of a suitable strain of feline rhinotracheitis virus (feline herpesvirus 1), inactivated while maintaining adequate immunogenic properties, or of an inactivated fraction of the virus having adequate immunogenic properties. This monograph applies to vaccines intended for the active immunisation of cats against feline viral rhinotracheitis.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in cell cultures. The virus harvest is inactivated; the virus may be disrupted and the fractions purified and concentrated. The vaccine may be adjuvanted.

2-2 SUBSTRATE FOR VIRUS PROPAGATION

2-2-1 Cell cultures

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

2-3 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 2-3-1) and immunogenicity (section 2-3-2) 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 a batch of vaccine containing not less than the maximum potency that may be expected in a batch of 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 herpesvirus 1 or against a fraction of the virus. Administer to each cat 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 after the last administration. Observe the cats at least daily for at least 14 days after the last administration.

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

2-3-2 Immunogenicity

A test is carried out for each route and method of administration to be recommended for vaccination, using in each case cats 8-12 weeks old. The vaccine administered to each cat is of minimum potency.

Use for the test not fewer than 20 cats that do not have antibodies against feline herpesvirus 1 or against a fraction of the virus. 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 quantity of a suspension of virulent feline herpesvirus 1 sufficient to produce typical signs of the disease such as fever, nasal discharge and cough in a cat that does not have antibodies against feline herpesvirus 1 or a fraction of the virus. Observe the cats at least daily for 14 days after challenge. Collect nasal washings daily on days 2 to 14 after challenge to test for virus excretion. Note daily the body temperature and signs of disease using the scoring system shown below.

The vaccine complies with the test if the score for the vaccinated cats is significantly lower than that for the controls.

Sign	Score
Death	10
Depressed state	2
Temperature:	
39.5 °C - 40.0 °C	1
≥ 40.0 °C	2
≤ 37.0 °C	3
Glossitis	3
Nasal discharge, slight	1
Nasal discharge, copious	2
Cough	2
Sneezing	1
Sneezing, paroxysmal	2
Ocular discharge, slight	1
Ocular discharge, serious	2
Conjunctivitis	2
Weight loss ≥ 5.0 per cent	5
Virus excretion (total number of days):	
≤ 4 days	1
5-7 days	2
> 7 days	3

2-4 MANUFACTURER'S TESTS

2-4-1 Residual live virus

The test for residual live virus is carried out using 2 passages in cell cultures of the same type as those used for preparation of the vaccine or in cell cultures shown to be at least as sensitive; the quantity of inactivated virus harvest used in the test is equivalent to not less than 25 doses of vaccine. 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. The following test may be used.

Use for the test a group of 15 seronegative mice. Administer to each mouse half a dose of the vaccine and, 7 days later, repeat the administration. 21 days after the first injection, take blood samples and determine the level of antibodies against feline herpesvirus 1 by a suitable immunochemical method (*2.7.1*), such as an immunofluorescence technique using pools of serum from groups of 3 mice. The vaccine complies with the test if the antibody levels are not significantly lower than those obtained with a batch of vaccine that has given satisfactory results in the test described under Potency.

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).

Carry out a test for residual live feline herpesvirus 1 using 10 doses of vaccine and 2 passages in cell cultures of the same type as those used for preparation of the vaccine, or in other suitably sensitive cell cultures. The vaccine complies with the test if no live virus is detected. If the vaccine contains an adjuvant that interferes with the test, where 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 2-3-2) when administered by a recommended route and method.