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Feline Chlamydiosis Vaccine (Inactivated)

General Notices

(Ph. Eur. monograph 2324)

Ph Eur

1 DEFINITION

Feline chlamydiosis vaccine (inactivated) is a preparation of one or more suitable strains of *Chlamydophila felis*, which have been inactivated by a suitable method. This monograph applies to vaccines intended for administration to cats for active immunisation.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The seed material is cultured in embryonated hens' eggs from a healthy flock (*5.2.13*) or in suitable cell cultures (*5.2.4*). If the vaccine contains more than one strain of bacterium, the different strains are grown and harvested separately. The bacterial harvests are inactivated using suitable and validated methods. The suspensions may be treated to fragment the micro-organisms and the fragments may be purified and concentrated. The vaccine may contain adjuvants.

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*) in 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.

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 *C. felis*. 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.

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.

2-2-2 Immunogenicity

Carry out the test for each route and method of administration to be recommended for vaccination, using in each case cats not older than the minimum age to be recommended for vaccination. The vaccine to be administered to each cat is of minimum potency.

Vaccinate 10 cats that are free from antibodies against *C. felis* and keep 10 cats as controls. Not later than 4 weeks after the last administration of vaccine, administer by a suitable route to each cat a quantity of a virulent strain of *C. felis* sufficient to produce in susceptible cats typical signs of disease such as conjunctivitis and nasal discharge. Observe the cats for 28 days. Where reduction of chlamydophila excretion is to be claimed, collect nasal washings and/or conjunctival swabs on days 7, 14, 17, 21, 24 and 28 after challenge to test for chlamydophila excretion. The duration of excretion for the vaccinated animals is significantly lower than for the controls. Note daily the body temperature and signs of disease using a suitable scoring system. The vaccine complies with the test if the score for the vaccinated cats is significantly lower than that for the controls.

2-3 MANUFACTURER'S TESTS

2-3-1 Residual live chlamydophila

A validated test for residual live chlamydophila is carried out. The vaccine complies with the test if no live chlamydophila is detected.

2-3-2 Batch potency test

It is not necessary to carry out the potency test (section 3-4) for each batch of the vaccine if it has been carried out using a batch of vaccine with a minimum potency. Where the test is not carried out on a batch, 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 potency test (section 3-4). The following test may be used.

Inject a suitable dose by a suitable route into each of 5 seronegative cats or another suitable species. Where the schedule stated on the label requires a booster injection to be given, a booster vaccination may also be given in this test provided it has been demonstrated that this will still provide a suitably sensitive test system. Before the vaccination and at a given interval usually within the range of 14-21 days after the last injection, collect blood from each animal and prepare serum samples. Determine individually for each serum the titre of antibodies against each strain stated on the label, using a suitable test such as enzyme-linked immunosorbent assay (*2.7.1*). The vaccine complies with the test if the antibody levels are not significantly lower than those obtained for a batch that has given satisfactory results in the potency test (section 3-4).

2-3-3 Bacterial endotoxins

A test for bacterial endotoxins (*2.6.14*) is carried out on the final lot or, where the nature of the adjuvant prevents performance of a satisfactory test, on the bulk antigen or the mixture of bulk antigens immediately before addition of the adjuvant. The maximum acceptable amount of bacterial endotoxins is that found for a batch of vaccine that has been shown to be satisfactory in the safety test (section 2-2-1). The method chosen for determining the maximum acceptable amount of bacterial endotoxins is subsequently used for the testing of each batch.

3 BATCH TESTS

3-1 Identification

The vaccine contains the antigen or antigens stated under Definition.

3-2 Residual live chlamydophila

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

Carry out a validated test for residual live chlamydophila to confirm inactivation of *C. felis*. The vaccine complies with the test if no live chlamydophila is detected.

3-3 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)*.

3-4 Potency

The vaccine complies with the test for immunogenicity (section 2-2-2).
