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Canine Parainfluenza Virus Vaccine (Live)

General Notices

(Ph. Eur. monograph 1955)

Ph Eur

1 DEFINITION

Canine parainfluenza virus vaccine (live) is a preparation of a suitable strain of parainfluenza virus of canine origin. This monograph applies to vaccines intended for the active immunisation of dogs against respiratory signs of infection with parainfluenza virus of canine origin.

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 dogs 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 5 dogs of the minimum age to be recommended for vaccination and that do not have antibodies against parainfluenza virus of canine origin. Administer to each dog 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 dogs at least daily for at least 14 days.

The vaccine virus complies with the test if no dog shows abnormal local or systemic reactions, signs of disease 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 dogs 5-7 weeks old, that do not have antibodies against parainfluenza virus of canine origin. 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 dog of the 1st group by the intranasal route and 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 to virulence. After 3-10 days, prepare a suspension from nasal swabs of each dog. Administer 1 mL of the suspension from the swabs that contain the maximum amount of virus by the intranasal route to each dog 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 dogs.

If the 5th group of dogs 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 dogs 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 indication of increased virulence of the virus recovered for the final passage compared with the material used for the 1st passage is observed. If virus is not recovered after an initial passage in 2 dogs and a subsequent repeat passage in 10 dogs, 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, using in each case dogs of the minimum age to be recommended. The quantity of vaccine virus to be administered to each dog 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 15 dogs that do not have antibodies against parainfluenza virus of canine origin. Vaccinate not fewer than 10 dogs according to the schedule to be recommended. Maintain not fewer than 5 dogs as controls. Challenge each dog after not less than 20-22 days by the intratracheal or intranasal route with a sufficient quantity of a suspension of virulent parainfluenza virus of canine origin. Observe the dogs at least daily for 14 days after challenge. Collect nasal swabs or washings from each dog daily from day 2 to 10 after challenge and test these samples for the presence of excreted virus. Use a scoring system to record the incidence of coughing in each dog.

The test is not valid if more than 1 of the control dogs shows neither coughing nor the excretion of the challenge virus.

The vaccine complies with the test if the scores for coughing or virus excretion for the vaccinated dogs are significantly lower than in the controls.

3 BATCH TESTS

3-1 Identification

The vaccine is identified using a suitable method, for example, an immunofluorescence test in susceptible cell cultures using a monospecific antiserum.

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.
