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Canine Adenovirus Vaccine, Inactivated

General Notices

(Canine Adenovirus Vaccine (Inactivated), Ph. Eur. monograph 1298)

Ph Eur

1 DEFINITION

Canine adenovirus vaccine (inactivated) is a preparation of one or more suitable strains of canine adenovirus 1 (canine contagious hepatitis virus) and/or canine adenovirus 2, inactivated while maintaining adequate immunogenic properties. This monograph applies to vaccines intended for the active immunisation of dogs against canine contagious hepatitis and/or respiratory disease caused by canine adenovirus.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in cell cultures. The virus harvest is inactivated. 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 dogs 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 dogs of the minimum age to be recommended and that do not have antibodies against canine adenovirus 1 or 2. Administer to each dog 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 dogs at least daily for at least 14 days after the last administration.

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

2-3-2 Immunogenicity

For vaccines intended to protect against hepatitis, the test described below is suitable for demonstration of immunogenicity. If the vaccine is indicated for protection against respiratory signs, a further test to demonstrate immunogenicity for this indication is also necessary.

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 vaccine administered to each dog is of minimum potency.

Use for the test not fewer than 7 dogs that do not have antibodies against canine adenovirus. Vaccinate not fewer than 5 dogs, according to the schedule to be recommended. Maintain not fewer than 2 dogs as controls. Challenge each dog after 20-22 days by the intravenous route with a sufficient quantity of a suspension of pathogenic canine adenovirus. Observe the dogs at least daily for 21 days after challenge. Dogs displaying typical signs of serious infection with canine adenovirus are euthanised to avoid unnecessary suffering.

The test is not valid if, during the observation period after challenge, fewer than 100 per cent of the control dogs die from or show typical signs of serious infection with canine adenovirus. The vaccine complies with the test if, during the observation period, all the vaccinated dogs survive and show no signs of disease.

2-4 MANUFACTURER'S TESTS

2-4-1 Residual live virus

The test for residual live virus is carried out using a quantity of inactivated virus harvest equivalent to at least 10 doses of vaccine with 2 passages in cell cultures of the same type as those used for production 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

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.

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 canine adenovirus using 10 doses of vaccine by inoculation into sensitive cell cultures; make a passage after 6-8 days and maintain the cultures for 14 days. The vaccine complies with the test if no live virus is detected. If the vaccine contains an adjuvant, 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 mentioned under Immunogenicity (section 2-3-2) when administered by a recommended route and method.

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