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Duck Plague Vaccine (Live)

General Notices

(Ph. Eur. monograph 1938)

Ph Eur

1 DEFINITION

Duck plague vaccine (live) is a preparation of a suitable strain of duck plague virus (anatid herpesvirus 1). This monograph applies to vaccines intended for the active immunisation of ducks.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in embryonated hens' eggs or in cell cultures. The vaccine may be freeze-dried.

2-2 SUBSTRATE FOR VIRUS PROPAGATION

2-2-1 Embryonated hens' eggs

If the vaccine virus is grown in embryonated hens' eggs, they are obtained from flocks free from specified pathogens (SPF) (*5.2.2*).

2-2-2 Cell cultures

If the vaccine virus is grown in cell cultures, they 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 shall be shown to be satisfactory with respect to safety (*5.2.6*) and efficacy (*5.2.7*) for the ducks for which the vaccine 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 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, using in each case ducks from a species considered to be the most susceptible among the species to be recommended for vaccination, not older than the minimum age to be recommended for vaccination and that do not have antibodies against duck plague virus. Use vaccine virus at the least attenuated passage level that will be present in a batch of the vaccine.

For each test performed in ducks younger than 3 weeks of age, use not fewer than 10 susceptible ducks. For each test performed in ducks older than 3 weeks of age, use not fewer than 8 susceptible ducks. Administer to each duck a quantity of 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 ducks at least daily for at least 14 days.

The test is not valid if more than 10 per cent of the ducks younger than 3 weeks of age show abnormal signs of disease or die from causes not attributable to the vaccine. For ducks older than 3 weeks of age, the test is not valid if non-specific mortality occurs.

The vaccine virus complies with the test if no duck shows abnormal 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 domestic ducks that do not have antibodies against duck plague virus and of an age suitable for the multiplication of the virus. 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 duck of the 1st group by a route to be recommended a quantity of the vaccine virus that will allow recovery of virus for the passages described below. 2 to 4 days later, take samples of liver and spleen from each duck and pool all samples. Administer 0.1 mL of the pooled suspension by the oro-nasal or a parenteral route to each duck 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 ducks.

If the 5th group of ducks 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 10 ducks 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 an increase in virulence of the virus at the final passage level compared with the material used for the 1st passage is observed. If virus is not recovered after an initial passage in 5 ducks and a subsequent repeat passage in 10 ducks, 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 domestic ducks not older than the minimum age to be recommended for vaccination. The quantity of the vaccine virus administered to each duck 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 the vaccine. For each test, use not fewer than 30 ducks of the same origin and that do not have antibodies against duck plague virus. Vaccinate by a route to be recommended not fewer than 20 ducks. Maintain not fewer than 10 ducks as controls. After 5 days, challenge each duck by a suitable route with a sufficient quantity of virulent duck plague virus. Observe the ducks at least daily for 14 days after challenge. Record the deaths and the number of surviving ducks that show clinical signs of disease.

The test is not valid if during the observation period after challenge fewer than 80 per cent of the control ducks die or show typical signs of duck plague and/or if during the period between the vaccination and challenge more than 10 per cent of control or vaccinated ducks show abnormal clinical signs of disease or die from causes not attributable to the vaccine.

The vaccine virus complies with the test if during the observation period after challenge not fewer than 80 per cent of the vaccinated ducks survive and show no notable clinical signs of duck plague.

3 BATCH TESTS

3-1 Identification

The vaccine, diluted if necessary, is identified using a suitable method. For example, when mixed with a monospecific duck plague virus antiserum, it is no longer able to infect embryonated hens' eggs from an SPF flock (*5.2.2*) or susceptible cell cultures (*5.2.4*) into which it is inoculated.

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 by inoculation into embryonated hens' eggs from an SPF flock (*5.2.2*) or into suitable cell cultures (*5.2.4*). The vaccine complies with the test if 1 dose contains not less than the minimum virus titre stated on the label.

3-6 Potency

The vaccine complies with 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.