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Infectious Chicken Anaemia Vaccine (Live)

General Notices

(Ph. Eur. monograph 2038)

Ph Eur

1 DEFINITION

Infectious chicken anaemia vaccine (live) is a preparation of a suitable strain of chicken anaemia virus. This monograph applies to vaccines intended for administration to breeder chickens for active immunisation, to prevent excretion of the virus, to prevent or reduce transmission of the virus via the egg and to protect passively their future progeny.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in embryonated hens' eggs or in cell cultures.

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 is shown to be satisfactory with respect to safety (*5.2.6*) and efficacy (*5.2.7*) for the chickens 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 in chickens not older than the minimum age to be recommended for vaccination and from an SPF flock (5.2.2). Use vaccine virus at the least attenuated passage level that will be present in a batch of the vaccine.

2-3-1-1 General safety. For each test, use not fewer than 8 chickens. Administer to each chicken 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. 14 days after vaccination, collect blood samples from half of the chickens and determine the haematocrit value. Euthanise these chickens and carry out post-mortem examination. Note any pathological changes attributable to chicken anaemia virus, such as thymic atrophy and specific bone-marrow lesions. Observe the remaining chickens at least daily, for at least 21 days after vaccination.

The test is not valid if non-specific mortality occurs.

The vaccine virus complies with the test if during the observation period no chicken shows abnormal signs of disease or dies from causes attributable to the vaccine virus.

2-3-1-2 Safety for young chickens. Use not fewer than twenty 1-day-old chickens from an SPF flock (5.2.2). Administer to each chicken by the oculonasal route a quantity of the vaccine virus equivalent to not less than the maximum titre likely to be contained in 1 dose of the vaccine. Observe the chickens at least daily. Record the incidence of any signs attributable to the vaccine virus, such as depression, and any deaths. 14 days after vaccination, collect blood samples from half of the chickens and determine the haematocrit value. Euthanise these chickens and carry out post-mortem examination. Note any pathological changes attributable to chicken anaemia virus, such as thymic atrophy and specific bone marrow lesions. Observe the remaining chickens at least daily, for at least 21 days after vaccination. Assess the extent to which the vaccine strain is pathogenic for 1-day-old susceptible chickens from the results of the clinical observations and mortality rates and the proportion of chickens examined at 14 days that show anaemia (haematocrit value less than 27 per cent) and signs of infectious chicken anaemia on post-mortem examination. The results are used to formulate the label statement on safety for young chickens.

2-3-2 Increase in virulence

Carry out the test according to general chapter 5.2.6 using 1-day-old chickens from an SPF flock (5.2.2). 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 chicken of the 1st group by the intramuscular route a quantity of the vaccine virus that will allow recovery of virus for the passages described below. Prepare 7-9 days after administration a suspension from the liver of each chicken and pool these samples. Depending on the tropism of the virus, other tissues such as spleen or bone marrow may be used. Administer 0.1 mL of the pooled samples by the intramuscular route to each chicken 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 chickens.

If the 5th group of chickens 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 chickens 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 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 chickens and a subsequent repeat passage in 10 chickens, 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 chickens not older than the minimum age to be recommended for vaccination and from an SPF flock (5.2.2). The test for prevention of virus excretion is intended to demonstrate reduction of virus transmission to the egg through viraemia and virus excretion in the faeces. The quantity of the vaccine virus to be administered to each chicken 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.

2-3-3-1 Passive immunisation of chickens. Vaccinate according to the schedule to be recommended not fewer than 10 breeder chickens not older than the minimum age to be recommended for vaccination and from an SPF flock (5.2.2); keep not fewer than 10 unvaccinated breeder chickens of the same origin and from an SPF flock (5.2.2) as controls that have no contact with the vaccinated chickens. At a suitable time, after excretion of vaccine virus has ceased, collect fertilised eggs from the vaccinated and control breeder chickens and incubate them. Challenge at least 30 1-day-old chickens from each of the vaccinated and control groups by intramuscular administration of a sufficient quantity of virulent chicken anaemia virus. Observe the chickens at least daily for 14 days after challenge. Record the deaths and the surviving

chickens that show signs of disease. At the end of the observation period determine the haematocrit value of each surviving chicken. Euthanise these chickens and carry out post-mortem examination. Note any pathological signs attributable to chicken anaemia virus, such as thymic atrophy and specific bone-marrow lesions.

The test is not valid if:

— the laying rate in the vaccinated and control breeder chickens is significantly different;

— during the observation period after challenge fewer than 90 per cent of the chickens of the control breeder chickens die or show severe signs of infectious chicken anaemia, including haematocrit value under 27 per cent, and/or notable macroscopic lesions of the bone marrow and thymus;

— and/or during the period between vaccination and egg collection more than 10 per cent of vaccinated or control breeder chickens show notable signs of disease or die from causes not attributable to the vaccine.

The vaccine complies with the test if during the observation period after challenge not fewer than 90 per cent of the chickens of the vaccinated breeder chickens survive and show no notable signs of disease and/or macroscopic lesions of the bone marrow and thymus.

2-3-3-2 Prevention of virus excretion. Vaccinate, according to the schedule to be recommended, not fewer than 10 chickens not older than the minimum age to be recommended for vaccination and from an SPF flock (*5.2.2*). Maintain not fewer than 10 chickens of the same age and origin as controls that have no contact with the vaccinated chickens. At a suitable time after excretion of vaccine virus has ceased, challenge all the chickens by intramuscular administration of a sufficient quantity of virulent chicken anaemia virus. Collect blood samples from the chickens on days 3, 5 and 7 after challenge and faecal samples from the chickens on days 7, 14 and 21 after challenge and carry out a test for presence of virus to determine whether or not the chickens are viraemic and are excreting the virus.

The test is not valid if:

— fewer than 70 per cent of the control chickens are viraemic and excrete the virus at one or more times of sampling;

— and/or during the period between vaccination and challenge more than 10 per cent of control or vaccinated chickens show abnormal clinical signs or die from causes not attributable to the vaccine.

The vaccine complies with the test if not fewer than 90 per cent of the vaccinated chickens do not develop viraemia or excrete the virus.

3 BATCH TESTING

3-1 Identification

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

3-2 Bacteria and fungi

Vaccines intended for administration by injection comply with the test for sterility prescribed in the general monograph *Vaccines for veterinary use (0062)*.

Any diluent supplied for reconstitution of the vaccine 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 suitable cell cultures (*5.2.4*) or eggs from an SPF flock (*5.2.2*). 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 requirements of the tests prescribed under Immunogenicity (sections 2-3-3-1 and 2-3-3-2) 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.

4 LABELLING

The label states to which extent the vaccine virus causes disease if it spreads to susceptible young chickens.