Edition: BP 2025 (Ph. Eur. 11.6 update)

Fowl Pox Vaccine, Living

General Notices

(Fowl-pox Vaccine (Live), Ph. Eur. monograph 0649)

Ph Eur

1 DEFINITION

Fowl-pox vaccine (live) is a preparation of a suitable strain of avian pox virus. This monograph applies to vaccines intended for administration to chickens for active immunisation.

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 shall be 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 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 chickens not older than the minimum age to be recommended for vaccination 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.

For each test performed in chickens younger than 3 weeks of age, use not fewer than 10 chickens. For each test performed in chickens older than 3 weeks of age, 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. Observe the chickens at least daily for at least 14 days.

The test is not valid if more than 10 per cent of the chickens younger than 3 weeks of age show abnormal signs of disease or die from causes not attributable to the vaccine. For chickens 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 chicken 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 chickens not older than the minimum age to be recommended for vaccination and 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 a suitable route a quantity of the vaccine virus that will allow recovery of virus for the passages described below. Prepare 4-7 days after administration a suspension from the induced skin lesions of each chicken and pool these samples. Administer 0.2 mL of the pooled samples by cutaneous scarification of the comb or other unfeathered part of the body, or by another suitable method 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 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 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 using in each case chickens not older than the minimum age to be recommended for vaccination. The quantity of the vaccine virus 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 the vaccine. Use for the test not fewer than 30 chickens of the same origin and from an SPF flock (5.2.2). Vaccinate by a route to be recommended not fewer than 20 chickens. Maintain not fewer than 10 chickens as controls. Challenge each chicken after 21 days by the feather-follicle route with a sufficient quantity of virulent fowl-pox virus. Observe the chickens at least daily for 21 days after challenge. Record the deaths and the number of surviving chickens that show clinical signs of disease. Examine each surviving chicken for macroscopic lesions: cutaneous lesions of the comb, wattle and other unfeathered areas of the skin and diphtherical lesions of the mucous membranes of the oropharyngeal area.

The test is not valid if:

— during the observation period after challenge fewer than 90 per cent of the control chickens die or show severe clinical signs of fowl pox, including notable macroscopical lesions of the skin or mucous membranes of the oropharyngeal area;

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

The vaccine virus complies with the test if during the observation period after challenge not less than 90 per cent of the vaccinated chickens survive and show no notable clinical signs of disease, including macroscopical lesions of the skin and mucous membranes of the oropharyngeal area.

3 BATCH TESTS

3-1 Identification

The vaccine virus is identified using a suitable method, for example an immunostaining test in susceptible cell cultures using monoclonal antibodies, to demonstrate the presence of the vaccine virus stated on the label. For egg adapted strains, inoculate the vaccine into eggs and notice the characteristic lesions.

3-2 Bacteria and fungi

Vaccines intended for administration by injection, scarification or wing web piercing 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 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 requirements of the test prescribed under Immunogenicity (section 2-3-3) when administered according to the recommended schedule 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.