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Fowl Cholera Vaccine (Inactivated)

General Notices

(Ph. Eur. monograph 1945)

Ph Eur

1 DEFINITION

Fowl cholera vaccine (inactivated) is a preparation of one or more suitable strains of one or more serovars of *Pasteurella multocida*, inactivated while maintaining adequate immunogenic properties. This monograph applies to vaccines intended for the active immunisation of chickens, turkeys, ducks and geese against acute fowl cholera.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The seed material is cultured in a suitable medium. If the vaccine contains more than one strain of bacterium, the different strains are grown and harvested separately. The bacterial harvests are inactivated. The vaccine may be adjuvanted.

2-2 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 species for which it is intended.

The following tests for safety (section 2-2-1) and immunogenicity (section 2-2-2) may be used during the demonstration of safety and efficacy.

2-2-1 Safety

The test is carried out for each route of administration to be recommended for vaccination and for each avian species for which the vaccine is intended. Use a batch of vaccine containing not less than the maximum potency that may be expected in a batch of vaccine.

For each test performed in birds younger than 3 weeks of age, use not fewer than 10 birds not older than the minimum age to be recommended for vaccination. For each test performed in birds older than 3 weeks of age, use not fewer than 8 birds not older than the minimum age to be recommended for vaccination. In the case of chickens, use chickens from a flock free from specified pathogens (SPF) (*5.2.2*) and in the case of turkeys, ducks or geese, use birds that have not been vaccinated and that do not have antibodies against *P. multocida*. Administer by a route and method to be recommended to each bird 1 dose of vaccine. If the schedule to be recommended requires a 2nd dose, administer 1 dose to each bird after an interval of at least 14 days. Observe the birds at least daily for at least 14 days for the last administration of the vaccine.

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

The vaccine complies with the test if no bird shows abnormal signs of disease or dies from causes attributable to the vaccine.

2-2-2 Immunogenicity

The test is carried out for each route and method of administration to be recommended for vaccination, for each avian species for which the vaccine is intended and for each serovar of *P. multocida* against which protection is claimed. Use for each test not fewer than 30 birds not older than the minimum age to be recommended for vaccination. Use birds that have not been vaccinated and that are free from antibodies against *P. multocida*. For each test, administer to each of not fewer than 20 birds a quantity of the vaccine not greater than 1 dose. If re-vaccination is recommended, repeat this operation after the recommended interval. Maintain not fewer than 10 birds as controls. Challenge each of the birds of both groups 21 days after the last administration by the intramuscular route with a sufficient quantity of virulent *P. multocida*. Observe the birds for 14 days after challenge. Birds displaying severe clinical signs of fowl cholera are euthanised to avoid unnecessary suffering.

The test is not valid if during the observation period after challenge, fewer than 70 per cent of the control birds die or show signs of infection (such as either clinical signs or bacterial re-isolation in organs) or if during the period before challenge, more than 10 per cent of the birds from the control group or from the vaccinated group show abnormal signs of disease or die from causes not attributable to the vaccine.

The vaccine complies with the test if, at the end of the observation period after challenge, not fewer than 70 per cent of the birds from the vaccinated group survive and show no signs of disease. Mild signs that do not persist beyond the observation period may be tolerated.

2-3 MANUFACTURER'S TESTS

2-3-1 Batch potency test

It is not necessary to carry out the potency test (section 3-3) for each batch of vaccine if it has been carried out using a batch of vaccine with 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. The following test may be used.

Use not fewer than 13 SPF chickens (*5.2.2*), 3-4 weeks old. Collect serum samples from each vaccinated and control chicken just before vaccination and check for the absence of antibodies against each serovar of *P. multocida* in the vaccine. Administer to each of 10 chickens 1 dose of the vaccine by the subcutaneous route. Maintain not fewer than 3 chickens as controls. Collect serum samples 5 weeks after vaccination from each vaccinated and control chicken. Measure the titres of serum antibodies against each serovar of *P. multocida* stated on the label using a suitable validated serological method. Calculate the mean titres for the group of vaccinates.

The test is not valid if specific *P. multocida* antibodies are found: before vaccination in 1 or more sera from chickens to be vaccinated or from controls; in 1 or more sera from control chickens 5 weeks after the time of administration of the vaccine.

The vaccine complies with the test if the mean antibody titres of the group of vaccinates are equal to or greater than the titres obtained with a batch that has given satisfactory results in the test described under Potency.

2-3-2 Bacterial endotoxins

A test for bacterial endotoxins (*2.6.14*) is carried out on the final lot or, where the nature of the adjuvant prevents performance of a satisfactory test, on the bulk antigen or the mixture of bulk antigens immediately before addition of the adjuvant. The maximum acceptable amount of bacterial endotoxins is that found for a batch of vaccine that has been shown satisfactory in safety test (section 2-2-1). The method chosen for determining the maximum acceptable amount of bacterial endotoxins is used subsequently for testing each batch.

3 BATCH TESTS

3-1 Identification

The vaccine contains the antigen or antigenic component(s) of *P. multocida* 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 Potency

The vaccine complies with the requirements of the test mentioned under Immunogenicity (section 2-2-2) when administered by a recommended route and method.

LABELLING

The label states:

— the serovar(s) used to prepare the vaccine;

— the serovar(s) against which protection is claimed.