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Avian Infectious Bronchitis Vaccine (Inactivated)

General Notices

Infectious Bronchitis Vaccine, Inactivated

(Ph. Eur. monograph 0959)

CAUTION Accidental injection of oily vaccine can cause serious local reactions in man. Expert medical advice should be sought immediately and the doctor should be informed that the vaccine is an oil emulsion.

Ph Eur

1 DEFINITION

Avian infectious bronchitis vaccine (inactivated) is a preparation of one or more suitable strains of one or more serotypes of avian infectious bronchitis virus, inactivated while maintaining adequate immunogenic properties. This monograph applies to vaccines intended to protect birds against a drop in egg production or quality; for vaccines also intended for protection against respiratory signs, a demonstration of efficacy additional to that described under Potency is required.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in fertilised hens' eggs or in cell cultures. The vaccine may be adjuvanted.

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 healthy flocks (*5.2.13*).

2-2-2 Cell cultures

If the vaccine 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 COMPOSITION

The vaccine is shown to be satisfactory with respect to safety (*5.2.6*) and efficacy (*5.2.7*) for the birds 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

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, 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 if the vaccine is used for species other than chickens, they have not been vaccinated and do not have antibodies against avian infectious bronchitis virus. Administer by a route to be recommended and method to each bird 1 dose of the vaccine. Observe the birds for at least daily for at least 14 days after the administration of the vaccine.

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.

2-3-2 Immunogenicity

A test is carried out for each route and method of administration to be recommended, using in each case chickens from an SPF flock (5.2.2) and for each serotype in the vaccine. The vaccine administered to each chicken is of minimum potency.

Use for the test 4 groups, each of not fewer than 30 chickens treated as follows:

— group A: unvaccinated controls;

— group B: vaccinated with inactivated avian infectious bronchitis vaccine;

— group C: vaccinated with live avian infectious bronchitis vaccine and inactivated avian infectious bronchitis vaccine according to the schedule to be recommended;

— group D: vaccinated with live avian infectious bronchitis vaccine.

Monitor egg production and quality in all chickens from point of lay until at least 4 weeks after challenge. At the peak of lay, challenge all groups with a quantity of virulent avian infectious bronchitis virus sufficient to cause a drop in egg production or quality over 3 consecutive weeks during the 4 weeks following challenge. The test is invalid unless there is a drop in egg production in group A compared to the normal level noted before challenge of at least 35 per cent where challenge has been made with a Massachusetts-type strain; where it is necessary to carry out a challenge with a strain of another serotype for which there is documented evidence that the strain will not cause a 35 per cent drop in egg production, the challenge must produce a drop in egg production commensurate with the documented evidence and in any case not less than 15 per cent. The vaccine complies with the test if egg production or quality is significantly better in group C than in group D and significantly better in group B than in group A.

2-4 MANUFACTURER'S TESTS

2-4-1 Residual live virus

An amplification test for residual live avian infectious bronchitis virus is carried out on each batch of antigen immediately after inactivation; the test is carried out in suitable cell cultures or in embryonated hen eggs from SPF flocks (5.2.2), whichever is the most sensitive for the vaccine strain. The quantity of inactivated virus harvest used in the test is equivalent to not less than 10 doses of vaccine.

A. For vaccine prepared with cell-culture-adapted strains of virus, inoculate an amount equivalent to not less than 10 doses into suitable cell cultures. Incubate at 38 ± 1 °C for 7 days. Make a passage on another set of cell cultures and incubate at 38 ± 1 °C for 7 days.

The inactivated virus harvest complies with the test if none of the cultures show signs of infection.

B. For vaccine prepared with embryo-adapted strains of virus, inject 0.2 mL of inactivated virus harvest into the allantoic cavity of ten 9- to 11-day-old embryonated hens' eggs from an SPF flock (5.2.2) and incubate. Observe for 5-6 days and pool separately the allantoic liquid from eggs containing live embryos and that from eggs containing dead embryos, excluding those that die within the first 24 h after injection. Examine for abnormalities all embryos which die after 24 h of injection or which survive 5-6 days. The inactivated virus harvest complies with the test if no death or abnormality attributable to the vaccine virus occurs. Inject into the allantoic cavity of each of ten 9- to 11-day-old embryonated hens' eggs from an SPF flock (5.2.2) 0.2 mL of the pooled allantoic liquid from the live embryos and into each of 10 similar eggs 0.2 mL of the pooled liquid from the dead embryos and incubate for 5-6 days. Examine for abnormalities all embryos which die after 24 h of injection or which survive 5-6 days. If more than 20 per cent of the embryos die at either stage repeat the test from that stage.

The inactivated virus harvest complies with the test if there is no death or abnormality attributable to the vaccine virus.

2-4-2 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 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. The following test may be used.

Administer 1 dose of vaccine by the intramuscular route to each of not fewer than 10 chickens, between 2 weeks of age and the minimum age stated for vaccination and from an SPF flock (*5.2.2*), and maintain not fewer than 3 hatch mates as unvaccinated controls. Collect serum samples from each chicken just before administration of the vaccine and after the period defined when testing the reference vaccine; determine the antibody titre of each serum, for each serotype in the vaccine, by a suitable serological method, for example, serum neutralisation. The test is invalid unless the sera collected from the unvaccinated controls and from the chickens just before the administration of the vaccine are free from detectable specific antibody. The vaccine complies with the test if the antibody levels are not significantly less than those obtained with a batch 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 general monograph *Vaccines for veterinary use (0062)*.

3-3 Potency

The vaccine complies with the requirements of the test prescribed under Immunogenicity (section 2-3-2) when administered by a recommended route and method.

4 LABELLING

The label states whether the strain in the vaccine is embryo-adapted or cell-culture-adapted.