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Egg Drop Syndrome 76 (Adenovirus) Vaccine

General Notices

(Egg Drop Syndrome '76 Vaccine (Inactivated), Ph. Eur. monograph 1202)

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

Egg drop syndrome '76 vaccine (inactivated) is a preparation of a suitable strain of egg drop syndrome '76 virus (haemagglutinating avian adenovirus), inactivated while maintaining adequate immunogenic properties. This monograph applies to vaccines intended for protection of laying birds against a drop in egg production and/or for prevention of loss of egg quality.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine strain is grown in embryonated hens' or ducks' eggs or in cell cultures. The vaccine may be adjuvanted.

2-2 SUBSTRATE FOR VIRUS PROPAGATION

2-2-1 Embryonated hens' or ducks' eggs

If the vaccine virus is grown in embryonated hens' or ducks' eggs, they are obtained from healthy flocks (*5.2.13*).

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 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. 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 hens not older than the minimum age to be recommended for vaccination and from a flock free from specified pathogens (SPF) (5.2.2). Administer by a route and method to be recommended to each hen 1 dose of the vaccine. Observe the hens 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 hen 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 hens from an SPF flock (5.2.2) and of the age at which vaccination is recommended. The vaccine administered to each hen is of minimum potency.

Vaccinate each of 2 groups of 30 hens. Maintain 2 control groups, one of 10 hens and the other of 30 hens, of the same age and from the same source as the vaccinates. Maintain egg production records from point of lay until 4 weeks after challenge. At 30 weeks of age, challenge each hen from 1 group of 30 vaccinates and the group of 10 control hens with a quantity of egg drop syndrome '76 virus sufficient to cause a well marked drop in egg production and/or quality. The test is invalid unless there is a well marked drop in egg production and/or quality in the control hens. The vaccine complies with the test if the vaccinated hens show no marked drop in egg production and/or quality.

When the second group of vaccinated hens and the group of 30 control hens are nearing the end of lay, challenge these hens, as before. The test is invalid unless there is a well marked drop in egg production and/or quality in the control hens. The vaccine complies with the test if the vaccinated hens show no marked drop in egg production and/or quality.

Carry out serological tests on serum samples obtained at the time of vaccination, 4 weeks later and just prior to challenge. The test is not valid if antibodies against egg drop syndrome '76 virus are detected in any sample from control hens.

2-4 MANUFACTURER'S TESTS

2-4-1 Residual live virus

The test for residual live virus is carried out in suitable cell cultures, or in embryonated ducks' eggs from a flock free from egg drop syndrome '76 virus infection, or in embryonated hens' eggs from an SPF flock (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 the vaccine.

A. For a vaccine adapted to growth in cell cultures, inoculate an amount equivalent to not less than 10 doses into suitable cell cultures. Incubate the cultures 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. Examine the cultures regularly and at the end of the incubation period examine the supernatant for the presence of haemagglutinating activity. The inactivated virus harvest complies with the test if the cell cultures show no sign of infection and if there is no haemagglutinating activity in the supernatant.
B. For a vaccine prepared in eggs, carry out the test in embryonated ducks' eggs from a flock free from egg drop syndrome '76 virus infection or, if it is known to provide a more sensitive test system, in hens' eggs from an SPF flock (5.2.2). Inject 0.2 mL of inactivated virus harvest into the allantoic cavity of each of ten 10- to 14-day-old embryonated eggs that are free from parental antibodies to egg drop syndrome '76 virus. Incubate the eggs and observe for 8 days. Pool separately the allantoic fluid from eggs containing live embryos, and that from eggs containing dead embryos, excluding those that die from non-specific causes within 24 h of the injection. Inject into the allantoic cavity of each of ten 10- to 14-day-old embryonated eggs that do not have parental antibodies to egg drop syndrome '76 virus, 0.2 mL of the pooled allantoic fluid from the live embryos and into each of 10 similar eggs, 0.2 mL of the pooled allantoic fluid from the dead embryos and incubate for 8 days. Examine the allantoic fluid from each egg for the presence of haemagglutinating activity using chicken erythrocytes. If more than 20 per cent of the embryos die at either stage, repeat that stage. The inactivated virus harvest complies with the test if there is no evidence of haemagglutinating activity and if, in any repeat test, not more than 20 per cent of the embryos die from non-specific causes.

Antibiotics may be used in the test to control extraneous bacterial infection.

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.

Vaccinate not fewer than ten 14- to 28-day-old chickens from an SPF flock (*5.2.2*) with 1 dose of vaccine by one of the recommended routes. 4 weeks later, collect serum samples from each bird and from not fewer than 3 unvaccinated control birds of the same age and from the same source. Measure the antibody response in a haemagglutination (HA) inhibition test on each serum using 4 HA units of antigen and chicken erythrocytes. The test is not valid if there are specific antibodies in the sera of the unvaccinated birds. The vaccine complies with the test if the mean titre of the vaccinated group is not less than that found previously for a batch of vaccine 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 duck- or hen-embryo-adapted or cell-culture-adapted.