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Avian Paramyxovirus 3 Vaccine for Turkeys, Inactivated

General Notices

(Avian Paramyxovirus 3 Vaccine (Inactivated) for Turkeys, Ph. Eur. monograph 1392)

Ph Eur

1 DEFINITION

Avian paramyxovirus 3 vaccine (inactivated) for turkeys is a preparation of a suitable strain of avian paramyxovirus 3, inactivated while maintaining adequate immunogenic properties. This monograph applies to vaccines intended for protection of turkeys against a drop in egg production and loss of egg quality.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in embryonated eggs or in cell cultures. The vaccine may be adjuvanted.

2-2 SUBSTRATE FOR VIRUS PROPAGATION

2-2-1 Embryonated eggs

If the vaccine virus is grown in embryonated 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 each category of turkeys 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 turkeys not older than the minimum age to be recommended for vaccination, that have not been vaccinated and that do not have antibodies against avian paramyxovirus 3. Administer by a recommended route and method to each turkey 1 dose of the vaccine. If the schedule to be recommended requires a 2nd dose, administer 1 dose to each turkey after an interval of at least 14 days. Observe the turkeys at least daily for at least 14 days after the last administration of the vaccine.

The test is not valid if non-specific mortality occurs. The vaccine complies with the test if no turkey 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 turkeys of the minimum age to be recommended for vaccination. The vaccine administered to each turkey is of minimum potency.

Use for the test 2 groups, each of not fewer than 20 turkeys of the same origin and of the same age, that do not have antibodies against avian paramyxovirus 3. Vaccinate one group in accordance with the recommendations stated on the label. Maintain the other group as controls.

The test is not valid if serological tests carried out on serum samples obtained at the time of first vaccination show the presence of antibodies against avian paramyxovirus 3 in either vaccinates or controls or if tests carried out at the time of challenge show such antibodies in controls.

At the egg-production peak, challenge the 2 groups by the oculonasal route with a sufficient quantity of a virulent strain of avian paramyxovirus 3. For not less than 6 weeks after challenge, record the number of eggs laid weekly for each group, distinguishing between normal and abnormal eggs. The vaccine complies with the test if egg production and quality are significantly better in the vaccinated group than in the control group.

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 eggs, 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 of the vaccine 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 the cultures show no 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 each of not fewer than 10 embryonated hen eggs 9-11 days old, from flocks free from specified pathogens (SPF) (*5.2.2*) and incubate. Observe for 6 days and pool separately the allantoic fluid from eggs containing live embryos, and that from eggs containing dead embryos, excluding those dying within 24 h of the injection. Examine embryos that die within 24 h of injection for the presence of avian paramyxovirus 3.

The inactivated virus harvest does not comply with the test if avian paramyxovirus 3 is found.

Inject into the allantoic cavity of each of not fewer than ten 9- to 11-day-old fertilised hen eggs from an SPF flock (*5.2.2*), 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 fluid from the dead embryos, and incubate for 5-6 days. Test the allantoic fluid from each egg for the presence of haemagglutinins using chicken erythrocytes.

The inactivated virus harvest complies with the test if there is no evidence of haemagglutinating activity and if not more than 20 per cent of the embryos die at either stage. If more than 20 per cent of the embryos die at one of the stages, repeat that stage; the vaccine complies with the test if there is no evidence of haemagglutinating activity and not more than 20 per cent of the embryos die at that stage.

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.

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.