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Turkey Infectious Rhinotracheitis Vaccine (Live)

General Notices

(Ph. Eur. monograph 2461)

Ph Eur

1 DEFINITION

Turkey infectious rhinotracheitis vaccine (live) is a preparation of a suitable strain of turkey rhinotracheitis virus. This monograph applies to vaccines intended for administration to turkeys for active immunisation against turkey infectious rhinotracheitis.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in cell cultures.

2-2 SUBSTRATE FOR VIRUS PROPAGATION

2-2-1 Cell cultures

The vaccine virus is grown in cell cultures that 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 turkeys 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 the demonstration of safety and efficacy.

2-3-1 Safety

Safety for the respiratory tract Carry out the test using turkeys not older than the minimum age to be recommended for vaccination and free from antibodies against turkey rhinotracheitis virus. Use vaccine virus at the least attenuated passage level that will be present in a batch of vaccine.

For each test performed in turkeys younger than 3 weeks of age, use not fewer than 10 turkeys. For each test performed in turkeys older than 3 weeks of age, use not fewer than 8 turkeys. Administer to each turkey, by the oculonasal route, 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 turkeys at least daily for at least 14 days and monitor clinical signs individually by a suitable scoring system. Mortality should be taken into account when calculating clinical scores. Record the death of any turkey and check for lesions of the respiratory tract.

The test is not valid if more than 10 per cent of the turkeys younger than 3 weeks of age show abnormal signs of disease or die from causes not attributable to the vaccine virus. For turkeys 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 vaccinated turkey shows notable signs of disease or dies from causes attributable to the vaccine virus.

The clinical scores are used in the test described under 2-3-2.

2-3-2 Increase in virulence

Carry out the test according to general chapter *5.2.6* using turkeys younger than 3 weeks of age and free from antibodies against turkey rhinotracheitis virus. 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 turkey of the 1st group, by the oculonasal route, a quantity of the vaccine virus that will allow recovery of virus for the passages described below. 2-6 days after administration of the vaccine virus, prepare a suspension from the mucosa of the turbinates or the upper trachea, or from an oropharyngeal or tracheal swab from not less than 5 inoculated turkeys and pool these samples. Administer 0.1 mL of the pooled samples by the oculonasal route to each turkey 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 turkeys.

If the 5th group of turkeys shows no evidence of an increase in virulence during the observation period, further testing is not required. Otherwise, carry out an additional safety test for the respiratory tract and compare the clinical signs and any relevant parameters in a group of at least 10 turkeys 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 an increased virulence of the virus at the final passage level compared with the material used for the 1st passage is observed or a slight increase in virulence of the virus at the final passage level may be observed for a vaccine which complies with the safety test (section 2-3-1). If virus is not recovered after an initial passage in 5 turkeys and a subsequent repeat passage in 10 turkeys, 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 turkeys not older than the minimum age to be recommended for vaccination and that are free from antibodies against turkey rhinotracheitis virus. The quantity of vaccine virus to be administered to each turkey 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.

Clinical protection against virulent challenge Use not fewer than 30 turkeys of the same origin and free from antibodies against turkey rhinotracheitis virus. Vaccinate by a route to be recommended not fewer than 20 turkeys according to the schedule to be recommended. Maintain not fewer than 10 turkeys as controls. Challenge each turkey after 21 days by the oculonasal route with a sufficient quantity of a suitable strain of virulent turkey rhinotracheitis virus. Observe the turkeys at least daily for 10 days and monitor clinical signs individually. Record the death of any turkey and check for lesions of the respiratory tract.

The test is not valid if one or more of the following applies:

— fewer than 80 per cent of the unvaccinated turkeys show typical signs of respiratory disease following challenge with the virulent turkey rhinotracheitis virus;

— during the period between vaccination and challenge, more than 10 per cent of vaccinated or control turkeys 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 fewer than 90 per cent of the vaccinated turkeys survive and show no typical clinical signs or lesions of an infection with turkey rhinotracheitis virus.

3 BATCH TESTS

3-1 Identification

The vaccine, diluted if necessary, is identified using a suitable method. For example, when mixed with turkey rhinotracheitis virus antiserum specific for the virus subgroup, it is no longer able to infect susceptible cell cultures (*5.2.4*) into which it is inoculated. The vaccine may also be identified using appropriate molecular biology techniques (for example RT-PCR).

3-2 Bacteria and fungi

Vaccines intended for administration by injection 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 suitable cell cultures (*5.2.4*). The vaccine complies with the test if 1 dose contains not less than the minimum titre of vaccine virus 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.