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# Louping-ill Vaccine

General Notices

## DEFINITION

Louping-ill Vaccine is a preparation of a suitable strain of louping-ill virus which has been inactivated in such a manner that immunogenic activity is retained.

## PRODUCTION

The virus strain is grown in suitable cell cultures, Appendix XV J(Vet)1. The viral suspension is harvested and inactivated. A test for residual infectious louping-ill virus is carried out on each batch of antigen immediately after inactivation. A mouse inoculation test may provide a suitably sensitive test if there is no suitably sensitive *in vitro* test for the strain.

The vaccine contains an adjuvant.

**Choice of vaccine composition**

This vaccine is shown to be satisfactory with respect to safety and immunogenicity for the animals for which the vaccine is intended. The following tests may be used during the demonstration of safety, Appendix XV J(Vet)1 and immunogenicity, Appendix XV J(Vet)2.

**Safety**

Carry out a test in each category of each species of animal for which the vaccine is to be recommended and by each recommended route of administration. Vaccinate at least five animals that do not have antibodies to louping-ill virus. Use for the test a batch of vaccine with the maximum potency likely to be included in a dose of the vaccine. Administer a single dose of vaccine to each animal and observe them for two weeks. If the schedule to be recommended requires a single dose or primary vaccination series followed by booster vaccination, the primary vaccination regimen plus an additional dose should be used with an interval of 14 days between doses. No abnormal local or systemic reactions occur.

**Immunogenicity**

The tests to demonstrate immunogenicity are carried out in each category of each species of animal for which the vaccine is to be recommended and by each recommended route of administration and using a batch or batches with the minimum potency likely to be included in a dose of the vaccine. The efficacy claims made on the label reflect the type of data generated.

**Batch testing**

**Inactivation**

Carry out a suitable validated test for residual louping-ill virus on the bulk antigen blend immediately before the addition of the adjuvant. No live virus is detected.

*The vaccine complies with the requirements stated under Veterinary Vaccines with the following modifications.*

## IDENTIFICATION

When injected into healthy seronegative animals, the vaccine stimulates the production of specific haemagglutinating antibodies against louping-ill virus.

## TESTS

**Extraneous bacteria and fungi**

The vaccine complies with the test for sterility described under Veterinary Vaccines.

## POTENCY

Inject subcutaneously each of no fewer than six healthy sheep, free from louping-ill haemagglutination-inhibiting (HI) antibodies, with the dose stated on the label and administer a second dose 4 weeks later. Between 7 and 14 days after the second injection the serum of at least five of the sheep contains HI antibodies with a mean antibody titre of at least 16.7.