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Ovine Enzootic Abortion Vaccine, Inactivated

General Notices

DEFINITION

Ovine Enzootic Abortion Vaccine, Inactivated is a suspension of one or more strains of the chlamydia organisms of ovine enzootic abortion which have been inactivated in such a manner that the immunogenic activity is retained.

PRODUCTION

The *Chlamydia psittaci* organisms are grown in either suitable cell cultures, Appendix XV J(Vet)1, or in the yolk sacs of embryonated eggs derived from healthy chicken flocks. The organisms are harvested and inactivated. A validated, suitably sensitive test for residual chlamydia is carried out in tissue cultures, on each batch of antigen immediately after inactivation.

The vaccine contains an adjuvant.

Choice of vaccine composition

The 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 K(Vet)1, and immunogenicity, Appendix XV K(Vet)2.

Safety

Carry out a test in each category 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 *Chlamydia psittaci*. 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 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 (e.g. protection from abortion) reflect the type of data generated.

Batch testing

Inactivation

Carry out a suitable validated test in tissue cultures for residual *Chlamydia psittaci* on the bulk antigen blend immediately before the addition of the adjuvant. No live organisms are detected.

CAUTION *Accidental injection of oil emulsion vaccines 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*.

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 antibodies against *Chlamydia psittaci*.

TESTS

Extraneous bacteria and fungi

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

POTENCY

Inject each of five healthy susceptible sheep according to the recommendations stated on the label. Maintain two unvaccinated sheep from the same source as the unvaccinated controls. Bleed all of the animals before vaccination and again not less than 28 days later. Using an appropriate serological test (complement-fixation or immunofluorescence is suitable) the serum of each sheep before vaccination is negative at a 2-fold dilution and, not less than 28 days after vaccination, the serum of no fewer than four of the vaccinated sheep gives a positive reaction at an 8-fold or greater dilution. The test is not valid if there is an increase in antibody levels in the controls.