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Swine Erysipelas Vaccine, Inactivated

General Notices

(Swine Erysipelas Vaccine (Inactivated), Ph. Eur. monograph 0064)

Ph Eur

1 DEFINITION

Swine erysipelas vaccine (inactivated) is a preparation of one or more suitable strains of *Erysipelothrix rhusiopathiae*, inactivated while maintaining adequate immunogenic properties. This monograph applies to vaccines intended for the active immunisation of pigs against swine erysipelas.

2 PRODUCTION

The vaccine may be adjuvanted.

2-1 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 pigs for which it is intended.

The following tests for safety (section 2-1-1) and immunogenicity (section 2-1-2) may be used during the demonstration of safety and efficacy.

2-1-1 Safety

Carry out the test for each route and method of administration to be recommended for vaccination and where applicable, in pigs of each category for which the vaccine is intended, using in each case pigs not older than the minimum age 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 pigs that do not have antibodies against swine erysipelas. Administer to each pig 1 dose of the vaccine. If the schedule to be recommended requires a 2nd dose, administer another dose after an interval of at least 14 days. Observe the pigs at least daily until at least 14 days after the last administration. Record body temperatures the day before each vaccination, at vaccination, 2 h, 4 h and 6 h later and daily for 4 days; note the maximum temperature increase for each pig.

The vaccine complies with the test if no pig shows abnormal local or systemic reactions or signs of disease, or dies from causes attributable to the vaccine, if the average body temperature increase for all pigs does not exceed 1.5 °C, and if no pig shows a rise greater than 2.0 °C.

2-1-2 Immunogenicity

The test described below is suitable to demonstrate immunogenicity of the vaccine with respect to *E. rhusiopathiae* serotypes 1 and 2. If claims are made concerning another serotype, then a further test to demonstrate immunogenicity against this serotype is necessary.

If the vaccine contains more than 1 serotype, a test for 2 serotypes may be carried out on a single group by injecting each challenge serotype on different flanks of the pigs. Validation and acceptance criteria are applied separately to the respective injection sites. If the vaccine contains more than 1 serotype, the immunogenicity test may also be carried out using a separate group for each serotype.

A test is carried out for each route and method of administration to be recommended, using in each case pigs not less than 12 weeks old and weighing not less than 20 kg. The vaccine administered to each pig is of minimum potency.

For each test, use not fewer than 15 pigs that do not have antibodies against swine erysipelas. Divide the pigs into 2 groups. Vaccinate a group of not fewer than 10 pigs according to the schedule to be recommended. Maintain a group of not fewer than 5 pigs as controls. Challenge each pig 3 weeks after vaccination by the intradermal route by separate injections of 0.1 mL of a virulent strain of each of serotype 1 and serotype 2 of *E. rhusiopathiae*. Observe the pigs at least daily for 7 days.

The test is not valid if fewer than 80 per cent of control pigs show typical signs of disease, i.e. diamond skin lesions at the injection sites. The vaccine complies with the test if not fewer than 90 per cent of the vaccinated pigs remain free from diamond skin lesions at the injection site.

Swine erysipelas bacteria serotype 1 BRP and *swine erysipelas bacteria serotype 2 BRP* are suitable for use as challenge strains.

2-2 MANUFACTURER'S TESTS

2-2-1 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.

Use 10 mice of a suitable strain (for example, NMRI) weighing 17-20 g, from a uniform stock and that do not have antibodies against swine erysipelas. Vaccinate each mouse by the subcutaneous route with a suitable dose (usually 1/10 of the pig dose). At a given interval (for example, 21-28 days), depending on the vaccine to be examined, bleed the mice under anaesthesia. Pool the sera, using an equal volume from each mouse. Determine the level of antibodies by a suitable immunochemical method (*2.7.1*), for example, enzyme-linked immunosorbent assay with *erysipelas ELISA coating antigen BRP*. The vaccine complies with the test if the antibody level is not significantly less than that obtained with a batch 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 monograph *Vaccines for veterinary use (0062)*.

3-3 Potency

The vaccine complies with the requirements of the tests mentioned under Immunogenicity (section 2-1-2) when administered by a recommended route and method.