SWINE ERYSIPELAS VACCINE (INACTIVATED)

Vaccinum erysipelatis suillae inactivatum

**DEFINITION**
Swine erysipelas vaccine (inactivated) is a preparation of one or more suitable strains of *Erysipelothrix rhusiopathiae* (*E. insidiosae*) inactivated by a suitable method. This monograph applies to vaccines intended to protect pigs against swine erysipelas.

**PRODUCTION**
The vaccine may contain an adjuvant.

**CHOICE OF VACCINE COMPOSITION**
The vaccine is shown to be satisfactory with respect to safety (5.2.6) and efficacy (5.2.7).

**Immunogenicity.** The test described under Potency 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.

**BATCH TESTING**

**Batch potency test.** The test described under Potency is not carried out for routine testing of batches of vaccine. It is carried out, for a given vaccine, on one or more occasions, as decided by or with the agreement of the competent authority. Where the test is not carried out, a suitable validated alternative test is carried out, 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 after a satisfactory correlation with the test described under Potency has been established.

Use 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. Administer the vaccine to be examined to a group of 10 mice. Inject a suitable dose (usually 1/10 of the pig dose) subcutaneously into each mouse. At a given interval (for example, 21-28 days), depending on the vaccine to be examined, bleed the animals 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 antibody level is not significantly less than that obtained with a batch that has given satisfactory results in the test described under Potency.

**IDENTIFICATION**
Injected into animals that do not have antibodies against *E. rhusiopathiae*, it stimulates the production of such antibodies.

**TESTS**

**Safety.** Use pigs of the minimum age recommended for vaccination and preferably having no antibodies against swine erysipelas or, where justified, use pigs with a low level of such antibodies as long as they have not been vaccinated against Swine erysipelas and administration of the vaccine does not cause an anamnestic response. Administer a double dose of vaccine by a recommended route to each of 2 pigs. Observe the animals for 14 days. No abnormal local or systemic reaction occurs.

**POTENCY**
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 animals. Validation and acceptance criteria are applied separately to the respective injection sites. If the vaccine contains more than 1 serotype, the potency test may also be carried out using a separate group for each serotype.

Use not fewer than 15 pigs not less than 12 weeks old, weighing not less than 20 kg and that do not have antibodies against swine erysipelas. Divide the animals into 2 groups. Vaccinate a group of not fewer than 10 pigs according to the recommended schedule. Maintain a group of not fewer than 5 pigs as unvaccinated controls. 3 weeks after vaccination, challenge the vaccinated animals and the control group by separate intradermal injections of 0.1 ml of a virulent strain of each of serotype 1 and serotype 2 of *E. rhusiopathiae*. Observe the animals for 7 days. The vaccine complies with the test if not fewer than 90 per cent of the vaccinated animals remain free from diamond skin lesions at the injection site. The test is invalid if fewer than 80 per cent of control animals show typical signs of disease, i.e. diamond skin lesions at the injection sites.

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

**LABELLING**
The label states the serotypes of *E. rhusiopathiae* included in the vaccine.

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**SWINE-FEVER VACCINE (LIVE), CLASSICAL, FREEZE-DRIED**

Vaccinum pestis classicae suillae vivum cryodesiccatum

**DEFINITION**
Freeze-dried classical swine-fever vaccine (live) is a preparation obtained from a strain of classical swine-fever virus which has lost its pathogenicity for the pig by adaptation either to cell cultures or to the rabbit.

**PRODUCTION**
For vaccine prepared in rabbits, the seed-lot (or the vaccine) is made from the homogenised organs and/or blood of rabbits from healthy colonies, sacrificed at the peak of the temperature rise following intravenous inoculation of the virus. The vaccine is freeze-dried.

**CHOICE OF VACCINE STRAIN**
Only a virus strain shown to be satisfactory with respect to the following characteristics may be used in the preparation of the vaccine: safety; non-transmissibility; irreversibility of attenuation; and immunogenic properties. The following tests may be used during demonstration of safety (5.2.6) and efficacy (5.2.7).

The dose of vaccine used throughout the following tests is determined by the manufacturer on the basis of prior experiments.

**Tests in pigs**

**Selection of animals.** The piglets are 6 to 7 weeks old. The sows are primiparous. All animals are healthy and must
A. For vaccines prepared in rabbits and lapinised vaccines

**IDENTIFICATION**

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See the information section on general monographs (cover pages)

have had no contact with swine-fever virus and serologically
must be free from swine-fever and bovine viral diarrhoea
antibodies. They must have a week in which to adapt
themselves to the new quarters where the tests are to be
conducted.

**Safety**

(a) Each of five piglets receives intramuscularly as a single
injection ten doses of vaccine (group a).

(b) Five piglets are immunodepressed by the daily injection
of 2 mg of prednisolone per kilogram of body mass for five
consecutive days and on the third day they receive one dose
of vaccine (group b).

The animals of groups (a) and (b) are observed for 21 days.
They must remain in good health. The temperature curve
and the weight curve must not differ significantly from those
of control animals.

(c) Ten non-immune pregnant sows each receive two doses
of vaccine intramuscularly as a single injection between
the twenty-fifth and thirty-fifth days of gestation. Ten
non-immune pregnant sows of the same age and of the
same origin receive instead of the two doses of vaccine an
equal volume of a 0.9 g/l solution of sodium chloride R.
The vaccinal virus does not cause abnormalities in the gestation
or in the piglets.

**Non-transmissibility.** Twelve piglets of the same age are
kept together. Six are vaccinated in the normal way and the
six others are kept as contact controls. After 40 days,
all the pigs are challenged by intramuscular inoculation of
a sufficient quantity of the challenge virus (see Potency)
to kill an unvaccinated piglet in 7 days. The vaccinated piglets
resist challenge whereas the contact piglets must display the
typical signs of swine fever.

**Irreversibility of attenuation.** Each of two piglets receives
one dose of vaccine intramuscularly. Seven days later, 5 ml
of blood is taken from each of the piglets and the samples are
pooled. 5 ml of the pooled blood is injected intramuscularly
into each of two other piglets. This operation is repeated
twice. The animals must not display any sign of swine
fever and must show normal growth.

**Immunogenic properties.** The immunogenic properties
may be demonstrated by the method described for the
determination of potency. The quantity of the vaccinal virus
reconstituted as stated on the label into one dose of vaccine contains at least
100 PD50.

B. For non-lapinised vaccines prepared in cell cultures, the
serum of pigs immunised with the vaccine neutralises the
virus used in the preparation of the vaccine.

**TESTS**

**Safety.** Use three piglets complying with the requirements
prescribed for the selection of animals under Choice of
Vaccine Strain. Inject intramuscularly into each piglet
ten doses of the reconstituted vaccine as a single injection.
Observe the animals for 21 days. The temperature curve
remains normal and the animals remain in apparent good
health and display normal growth.

**Extraneous viruses.** Mix the vaccine with a monospecific
antisemur and inoculate into susceptible cell cultures. No
cytopathic effect is produced.

Carry out a haemagglutination test using chicken red blood
cells and the supernatant liquid of the cell cultures. The
test is negative. Carry out a haemadsorption test on the cell
cultures. The test is negative.

Use ten mice each weighing 11 g to 15 g. Inject intracerebrally
into each mouse 0.03 ml of the vaccine reconstituted so that
1 ml contains 1 dose. Observe the animals for 21 days. If
more than two mice die within the first 48 h, repeat the test.
From the third to the twenty-first day after the injection, the
mice show no abnormalities attributable to the vaccine.

**Bacterial and fungal contamination.** The vaccine to be
examined complies with the test for sterility prescribed in
the monograph on Vaccines for veterinary use (0062).

**Mycoplasmas (2.6.7).** The vaccine complies with the test
for mycoplasmas.

**POTENCY**

The potency is expressed as the number of 50 per cent
protective doses (PD50) for pigs contained in the dose
indicated on the label. The vaccine contains at least 100 PD50
per dose.

Use piglets complying with the requirements for selection of
animals described under Choice of Vaccine Strain. To two
groups of five piglets inject intramuscularly:

- 1/40 of a dose of the vaccine to be examined into each
piglet of the first group,

- 1/160 of a dose of the vaccine to be examined into each
piglet of the second group.

Use two piglets as controls.

Prepare the dilutions using buffered salt solution pH 7.2 R.
On the fourteenth day after the injection, inoculate
intramuscularly into each vaccinated and control animal a
sufficient quantity of challenge virus to kill an unvaccinated
piglet in 7 days. The challenge virus preparation consists
of blood of pigs infected experimentally by virus that has
not been submitted to passage in cell cultures. The control
animals die within the seven days of inoculation. Observe
the vaccinated animals for 14 days. From the number of
animals which survive without showing any sign of swine
fever, calculate the number of PD50 contained in the vaccine
using the usual statistical methods.

**LABELLING**

The label states that the vaccine has been prepared in cell
cultures or in rabbits as appropriate.