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Porcine Parvovirus Vaccine, Inactivated

General Notices

(Porcine Parvovirosis Vaccine (Inactivated), Ph. Eur. monograph 0965)

Ph Eur

1 DEFINITION

Porcine parvovirosis vaccine (inactivated) is a preparation of a suitable strain of porcine parvovirus, inactivated while maintaining adequate immunogenic properties, or of a non infectious fraction of the virus. This monograph applies to vaccines intended for the active immunisation of sows and gilts for protection of their progeny against transplacental infection.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The vaccine virus is grown in cell cultures. The viral suspension is harvested; the virus is inactivated by a suitable method and may be fragmented (inactivation may be by fragmentation); the virus or viral fragments may be purified and concentrated at a suitable stage of the process. The vaccine may be adjuvanted.

2-2 SUBSTRATE FOR VIRUS PROPAGATION

2-2-1 Cell cultures

The cell cultures comply with the requirements for cell cultures for the production of vaccines for veterinary use (*5.2.4*).

2-3 CHOICE OF VACCINE COMPOSITION

The vaccine is shown to be satisfactory with respect to safety (*5.2.6*) (including absence of adverse effects on fertility, gestation, farrowing or offspring) and efficacy (*5.2.7*) for the pigs for which it is intended.

The following tests for safety (section 2-3-1) and immunogenicity (section 2-3-2) may be used during the demonstration of safety and efficacy.

2-3-1 Safety

2-3-1-1 Laboratory tests. Carry out the tests 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.

2-3-1-1-1 General safety. For each test, use not fewer than 8 pigs that do not have antibodies against porcine parvovirus or against a fraction of the virus. 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 14 days after the last administration.

The vaccine complies with the test if no pig shows notable signs of disease or dies from causes attributable to the vaccine during the test.

2-3-1-1-2 Safety in pregnant sows. If the vaccine is intended for use in pregnant sows, use for the test not fewer than 8 pregnant sows at the stage or at different stages of pregnancy according to the recommended schedule. Administer to each sow 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 sows at least daily until farrowing.

The vaccine complies with the test if no sow shows abnormal local or systemic reactions or dies from causes attributable to the vaccine and if no adverse effects on gestation or the offspring are noted.

2-3-1-1-3 Safety in the pigs used in test 2-3-2 for immunogenicity. The pigs used in the test for immunogenicity are also used to evaluate safety. Measure the body temperature of each vaccinated pig at the time of vaccination 24 h and 48 h later. Examine the injection site after vaccination and at slaughter for local reactions.

The vaccine complies with the test if no pig shows:

— abnormal body temperature;

— other systemic reactions (for example, anorexia);

— abnormal local reactions attributable to the vaccine.

2-3-1-2 Field studies. The pigs used for field trials are also used to evaluate safety. Carry out a test in each category of pigs for which the vaccine is intended (sows, gilts). Use not fewer than 3 groups each of not fewer than 20 pigs with corresponding groups of not fewer than 10 controls. Measure the body temperature of each vaccinated pig at the time of vaccination, 24 h and 48 h later. Examine the injection site after vaccination and at slaughter for local reactions.

The vaccine complies with the test if no pig shows:

— abnormal body temperature;

— abnormal local reactions attributable to the vaccine.

2-3-2 Immunogenicity

A test is carried out for each route and method of administration to be recommended, using in each case gilts of 5-6 months old. The vaccine administered to each gilt is of minimum potency.

Use for the test not fewer than 12 gilts that do not have antibodies against porcine parvovirus or against a fraction of the virus. Vaccinate not fewer than 7 gilts according to the schedule to be recommended. Maintain not less than 5 unvaccinated gilts of the same age as controls. The interval between vaccination and service is that to be recommended. Mate all the gilts on 2 consecutive days immediately following signs of oestrus. At about the 40th day of gestation, challenge each gilt with a suitable quantity of a virulent strain of porcine parvovirus. Euthanise the gilts at about the 90th day of gestation and examine their foetuses for infection with porcine parvovirus as demonstrated by the presence of either virus or antibodies.

The test is not valid if:

— fewer than 7 vaccinated gilts and 5 control gilts are challenged;

— fewer than 90 per cent of piglets from the control gilts are infected;

— and the average number of piglets per litter for the vaccinated gilts is fewer than 6.

The vaccine complies with the test if not fewer than 80 per cent of the total number of piglets from vaccinated gilts are protected from infection.

2-4 MANUFACTURER'S TESTS

2-4-1 Residual live virus

A test for residual live virus is carried out on each batch of antigen immediately after inactivation. The quantity of inactivated virus harvest used in the test is equivalent to not less than 100 doses of the vaccine. The bulk harvest is inoculated into suitable non-confluent cells; after incubation for 7 days, a subculture is made using trypsinised cells. After incubation for a further 7 days, the cultures are examined for residual live parvovirus by an immunofluorescence test. The inactivated virus harvest complies with the test if no live virus is detected.

2-4-2 Batch potency test

It is not necessary to carry out the potency test (section 3-4) for each batch of the 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 not fewer than 5 guinea-pigs, 5-7 weeks old and that do not have antibodies against porcine parvovirus or against a fraction of the virus. Vaccinate each guinea-pig by the subcutaneous route with a quarter of the prescribed dose volume. Take blood samples after the period corresponding to maximum antibody production and carry out tests on the serum for specific antibodies by a haemagglutination-inhibition test or other suitable test. The vaccine complies with the test if the level of antibodies is not lower than that found for a batch of vaccine 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 general monograph *Vaccines for veterinary use (0062)*.

3-3 Residual live virus

This test may be omitted for batch release, as stated in the general monograph Vaccines for veterinary use (0062).

Use a quantity of vaccine equivalent to 10 doses. If the vaccine contains an oily adjuvant, break the emulsion and separate the phases. If the vaccine contains a mineral adjuvant, carry out an elution to liberate the virus. Concentrate the viral suspension 100 times by ultrafiltration or ultracentrifugation. None of the above procedures must be such as to inactivate the virus or otherwise interfere with the detection of live viruses. Carry out a test for residual live virus in suitable non-confluent cells; after incubation for 7 days, make a subculture using trypsinised cells. After incubation for a further 7 days, examine the cultures for residual live parvovirus by an immunofluorescence test. The vaccine complies with the test if no live virus is detected.

3-4 Potency

The vaccine complies with the requirements of the test prescribed under Immunogenicity (section 2-3-2) when administered by a recommended route and method.