



ASEAN STANDARD REQUIREMENTS FOR PORCINE PARVOVIRUS VACCINE, INACTIVATED

I. SEED AND PRODUCTION SUBSTRATE REQUIREMENTS

1. SEED VIRUS

Master and working seed viruses are produced in suitable cell cultures in a seed lot system. The seed viruses must satisfy sterility, purity, safety and potency tests before they are used for vaccine production. The seed viruses are preserved and stored under suitable validated systems, such as the lyophilized seed viruses should be kept at 2 to 8°C. The liquid form of seed virus should be stored at -70 °C or lower.

2. PRODUCTION SUBSTRATE

Primary cell culture or cell lines used throughout production of the vaccine should be free from cytopathogenic and haemadsorbing agents.

II. QUALITY CONTROL REQUIREMENTS

1. STERILITY TEST

Final container samples should be tested for absence of bacteria, fungi and Mycoplasma by the methods that appear as Appendix 2. However, tests for Mycoplasma may be carried out on bulk samples.

2. PURITY TEST

Seed lot/bulk production samples should be tested for absence of cytopathogenic and haemadsorbing agents.

3. INACTIVATION TEST

Final product is tested for residual infectious porcine parvovirus. This test may be omitted by the manufacturer if a test for inactivation has been carried out on the bulk vaccine, immediately before the addition of the adjuvant, where applicable. 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 or otherwise interfere with detection of live virus. 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. No live virus is detected.

4. SAFETY TEST

Final product should be tested as follows:

Use two pigs 6 weeks to 6 months old and having no antibodies against porcine parvovirus or against a fraction of the virus. Inject 2 doses of the vaccine by one of the recommended routes. Observe the animals for 14 days and then inject a single dose of vaccine by the same route into each pig. Observe the animals for a further 14 days. No abnormal local or systemic reaction occurs during the 28 days of the test.

5. POTENCY TEST

Bulk or final container samples should be tested using one of the following methods:

a) Vaccinate according to the recommended schedule not less than seven gilts, 5 to 6 months old, which do not have antibodies against porcine parvovirus or against a fraction of the virus. The interval between vaccination and service is that stated on the label. Mate the gilts on two consecutive days immediately following signs of oestrus. Keep not less than five unvaccinated mated gilts of the same age as controls. At about the 40th day of gestation, challenge all gilts using a suitable strain of porcine parvovirus. Slaughter 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 vaccine complies with the test if not fewer than 80 percent of the total number of piglets from vaccinated gilts are protected from infection. The test is not valid unless: not fewer than seven vaccinated gilts and five control gilts are challenged; not fewer than 90 percent of piglets from the control gilts are infected; and the average number of piglets per litter for the vaccinated gilts is not less than six.

b) Vaccinate subcutaneously not fewer than five guinea-pigs, 5 to 7 weeks old, according to the vaccination scheme stated on the label using one-fourth 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 antibody titres are not less than those obtained with a batch of vaccine shown to be satisfactory in a validated protection test in pigs.

III. OTHER REQUIREMENTS

The vaccine should comply with the General Requirements for Veterinary Vaccines that appear as *Appendix 4*.

