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Clostridium Chauvoei Vaccine

General Notices

Blackleg Vaccine

(Clostridium Chauvoei Vaccine for Veterinary Use, Ph. Eur. monograph 0361)

Ph Eur

1 DEFINITION

Clostridium chauvoei vaccine for veterinary use is prepared from liquid cultures of one or more suitable strains of *Clostridium chauvoei*. The whole culture is inactivated to eliminate its toxicity while maintaining adequate immunogenic properties. This monograph applies to vaccines intended for active immunisation of animals against disease caused by *C. chauvoei*.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

C. chauvoei Used for production is grown in an appropriate liquid medium. Inactivated cultures may be treated with a suitable adjuvant.

2-2 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 animals for which it is intended.

The following test for safety (section 2-2-1) may be used during the demonstration of safety.

2-2-1 Safety

Carry out the tests for each route and method of administration to be recommended for vaccination and where applicable, in animals of each category for which the vaccine is intended, using in each case animals 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 animals that do not have antibodies against *C. chauvoei*. Administer to each animal 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 animals at least daily until 14 days after the last administration.

The vaccine complies with the test if no animal shows abnormal local or systemic reactions or dies from causes attributable to the vaccine.

3 BATCH TESTS

3-1 Identification

The vaccine protects susceptible animals against infection with *C. chauvoei*. The potency test may also serve for identification.

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

Use for the test not fewer than 10 healthy guinea-pigs, each weighing 350-450 g. Administer to each guinea-pig by the subcutaneous route a quantity of the vaccine not greater than the minimum dose stated on the label as the 1st dose. After 28 days, administer to the same animals a quantity of the vaccine not greater than the minimum dose stated on the label as the 2nd dose. 14 days after the 2nd vaccination, inoculate by the intramuscular route each of the vaccinated guinea-pigs and each of 5 control animals with a suitable quantity of a virulent culture, or of a spore suspension, of *C. chauvoei*, activated if necessary with an activating agent such as calcium chloride.

The vaccine complies with the test if not more than 10 per cent of the vaccinated guinea-pigs die from *C. chauvoei* infection within 5 days and all the control animals die from *C. chauvoei* infection within 48 h of challenge or within 72 h if a spore suspension was used for the challenge. If more than 10 per cent but not more than 20 per cent of the vaccinated animals die, repeat the test. The vaccine complies with the test if not more than 10 per cent of the 2nd group of vaccinated animals die within 5 days and all of the 2nd group of control animals die within 48 h of challenge or within 72 h if a spore suspension was used for the challenge. To avoid unnecessary suffering following virulent challenge, moribund animals are euthanised and are then considered to have died from *C. chauvoei* infection.