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Anthrax Vaccine, Living

General Notices

(Anthrax Spore Vaccine (Live) for Veterinary Use, Ph. Eur. monograph 0441)

Ph Eur

1 DEFINITION

Anthrax spore vaccine (live) for veterinary use is a preparation of live spores of a suitable attenuated, non-capsulated strain of *Bacillus anthracis*. This monograph applies to vaccines intended for the active immunisation of animals against disease caused by *B. anthracis*.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

B. anthracis Is grown in an appropriate medium. At the end of growth the spores are suspended in a stabilising solution and counted. The vaccine may be adjuvanted.

2-2 CHOICE OF VACCINE STRAIN

The strain used is:

— not lethal to the guinea-pig or the mouse,

— or lethal to the guinea-pig but not to the rabbit,

— or lethal to some rabbits.

The vaccine strain 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.

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

2-2-1 Immunogenicity

For a strain of *B. anthracis* which is not lethal to the guinea-pig or the mouse, the test may be carried out in guinea-pigs. For a strain which is lethal to the guinea-pig but not to the rabbit, the test may be carried out in rabbits. For a strain which is lethal to some rabbits, carry out the test in sheep.

If the test is carried out in guinea-pigs or in rabbits, use not fewer than 13 healthy animals (group a). Inject by the subcutaneous or the intradermal route into each of not fewer than 10 animals 1/10th of the smallest dose to be recommended for sheep. Maintain not fewer than 3 animals of the same species and the same origin as controls. Observe the animals at least daily for 21 days. If more than 2 animals die from non-specific causes, repeat the test.

If the test is carried out in sheep, use not fewer than 8 healthy sheep (group b). Vaccinate by the subcutaneous or the intradermal route each of not fewer than 5 sheep 1/10 of the smallest dose of the vaccine stated on the label for sheep. Maintain not fewer than 3 sheep of the same origin as controls. Observe the sheep at least daily for 21 days.

Challenge each vaccinated animal of group (a) or group (b) by a subcutaneous route with at least 100 MLD, and challenge each control animal by a subcutaneous route with at least 10 MLD of a strain of *B. anthracis* pathogenic for the species of animal used in the test. Observe all the animals at least daily for 10 days after challenge.

The vaccine complies with the test if during the observation period after challenge, all the vaccinated animals survive and all the controls die from anthrax. If a vaccinated animal dies after the challenge, repeat the test. If in the second test a vaccinated animal dies, the vaccine fails the test.

3 BATCH TESTS

3-1 Identification

B. anthracis present in the vaccine is identified by means of morphological and serological tests, culture and biochemical tests.

3-2 Bacteria and fungi

Carry out the test by microscopic examination and by inoculation of suitable media. The vaccine, including where applicable, the diluent supplied for reconstitution, does not contain contaminating bacteria and fungi.

3-3 Live spores

Make a count of live spores by plate count. The vaccine complies with the test if the number of live spores is not less than 80 per cent of that stated on the label.

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3-4 Potency

The vaccine complies with the requirements of the test prescribed under Immunogenicity (section 2-2-1). It is not necessary to carry out the potency test for each batch of the vaccine if it has been carried out on a representative batch using a vaccinating dose containing not more than the minimum number of live spores stated on the label.

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