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Lungworm (Dictyocaulus Viviparus) Oral Vaccine, Living

General Notices

DEFINITION

Lungworm (Dictyocaulus Viviparus) Oral Vaccine, Living is an aqueous preparation containing approximately 1000 modified *Dictyocaulus viviparus* larvae per dose.

PRODUCTION

The vaccinal organisms are produced in calves. The calves used for production are obtained from a known, defined source that is monitored for freedom from certain diseases, as agreed with the competent authority. The calves are healthy, have not been exposed previously to *Dictyocaulus viviparus* and have been shown to be free from a range of infectious diseases, as agreed with the competent authority.

The third stage larvae are harvested from the faeces, purified, partially inactivated by ionising radiation, then diluted as necessary.

Choice of vaccine strain

The suspension of irradiated vaccinal organisms is shown to be satisfactory with respect to safety and immunogenicity for the animals for which the vaccine is intended. The following tests may be used during the demonstration of safety, Appendix XV K(Vet)1 and immunogenicity, Appendix XV K(Vet)2.

Safety

Carry out a test in at least five calves of the minimum age to be recommended for vaccination that do not have antibodies to *Dictyocaulus viviparus*. Administer orally, to each calf, a quantity of irradiated vaccinal organisms corresponding to twice the maximum number of organisms likely to be included in a dose of the vaccine. If the schedule to be recommended requires a single dose or primary vaccination series followed by booster vaccination, the primary vaccination regimen plus an additional dose should be used with an interval of 14 days between doses. Observe the calves for 6 weeks after the last administration. They remain in good health and show no more than transient respiratory signs approximately one week after vaccination. Collect faecal samples from each calf 4, 5 and 6 weeks after vaccination and examine separately for the presence of *D. viviparus* larvae. No larvae are detected.

Immunogenicity

The test described under Potency is suitable to demonstrate immunogenicity when carried out using the minimum number of organisms likely to be included in a dose of the vaccine.

Batch testing

If Identification test B and the test for Potency have been carried out with satisfactory results on a representative batch of vaccine, these tests may be omitted as a routine control on other batches of vaccine subject to the agreement of the competent authority.

Extraneous bacteria

For each batch, the number of non-pathogenic organisms per dose is shown to be within the limits set for the product and shown to be safe.

The vaccine complies with the requirements stated under Veterinary Vaccines with the following modifications.

IDENTIFICATION

A. Produces petechial haemorrhages in the lungs of guinea-pigs within 48 hours of oral administration. Adult worms do not develop.
B. Protects calves against *D. viviparus* infection and does not cause parasitic bronchitis.

TESTS

Extraneous bacteria and fungi

The vaccine is shown by appropriate methods to be free from pathogenic organisms including *Brucella*, *Mycobacteria* and *Salmonella* species.

Extraneous viruses

Appendix XV J (Vet) 2. Management of Extraneous Agents in Immunological Veterinary Medicinal Products. The vaccine complies with the test if it does not contain extraneous viruses.

Viable larvae

The number of viable larvae is not less than 1000 per dose determined by microscopic examination.

POTENCY

Use calves of the minimum age for vaccination recommended on the label and that do not have antibodies to *D. viviparus*. Vaccinate at least ten calves as recommended on the label. Maintain at least five calves as unvaccinated controls. Seven weeks after vaccination challenge by oral administration of a sufficient quantity of stage 3 larvae. Observe the calves for 40 days and monitor and score the calves for signs of respiratory disease (e.g. increased respiratory rate, coughing). Carry out post-mortem examination of the lungs of any animal that dies during the observation period. At the end of the observation period, kill the surviving calves and examine the lungs. The test is not valid unless the control calves show typical signs of respiratory disease due to lungworm infection and, at post-mortem examination, there are noticeable, typical lesions in the lungs (e.g. areas of consolidation) and in calves submitted to post-mortem examination in the later stages, adult worms are present.

The vaccine complies with the test if the vaccinated calves show no more than very mild respiratory signs after challenge and, at post-mortem examination, there are no or only very limited lesions in the lungs (e.g. areas of consolidation) and no or very few adult worms are present.