Edition: BP 2025 (Ph. Eur. 11.6 update)

Newcastle Disease and Avian Infectious Bronchitis Vaccine, Living

General Notices

DEFINITION

Newcastle Disease and Avian Infectious Bronchitis Vaccine, Living is a mixed preparation derived from separate groups of eggs infected with suitable strains of Newcastle disease virus and of avian infectious bronchitis virus. The Newcastle disease virus seed is either a modified strain, such as Hitchner B1 or La Sota, or a naturally occurring strain of low pathogenicity. The avian infectious bronchitis virus seed is an IB strain and it may be used at various levels of attenuation. The vaccine is prepared immediately before use by reconstitution from the dried vaccine with a suitable liquid.

PRODUCTION

For vaccine production the virus is propagated in embryonated eggs derived from chicken flocks free from specified pathogens. The final product is freeze dried.

Provided that the test for potency described below has been performed with satisfactory results on a representative batch of vaccine it may be omitted by the manufacturer as a routine control on other batches of vaccine prepared from the same seed lot, subject to the agreement of the competent authority.

Virus titre

For the Newcastle disease component Neutralise the vaccine with monospecific avian infectious bronchitis virus antiserum. Inoculate serial dilutions of neutralised vaccine into the allantoic cavity of 10- to 11-day-old embryonated eggs derived from chicken flocks free from specified pathogens. Incubate the eggs for 3 days at 37° and then examine the embryos for evidence of virus infection, which is shown by the presence of chick red cell haemagglutinins. The vaccine contains not less than $10^{6.0}$ EID_{50} of virus per bird dose.

For the avian infectious bronchitis component Neutralise the vaccine with monospecific Newcastle disease virus antiserum. Inoculate serial dilutions of neutralised vaccine into the allantoic cavity of 10- to 11-day-old embryonated eggs derived from chicken flocks free from specified pathogens. Incubate the eggs at 37° for 7 days and then examine the embryos for lesions typical of avian infectious bronchitis. The vaccine contains not less than $10^{3.5}$ EID_{50} of virus per bird dose.

The vaccine, reconstituted with a suitable liquid to provide a concentration appropriate to the particular test, complies with the requirements stated under Veterinary Vaccines with the following modifications.

IDENTIFICATION

Newcastle disease

The vaccine, diluted if necessary, is identified using a suitable method. For example, when mixed with a monospecific Newcastle disease virus antiserum, it is no longer able to provoke haemagglutination of chicken red blood cells, or to infect embryonated hens' eggs from an SPF flock into which it is inoculated (Appendix XV H (Vet). Chicken Flocks Free from Specified Pathogens for the Production and Quality Control of Vaccines) or susceptible cell cultures (Appendix XV J (Vet) 1. Cell Cultures for the Production of Vaccines for Veterinary Use) may be suitable).

Avian infectious bronchitis

The vaccine, diluted if necessary, is identified using a suitable method. For example, when mixed with avian infectious bronchitis virus antiserum specific for the virus type, it is no longer able to infect embryonated hens' eggs from an SPF flock into which it is inoculated (Appendix XV H (Vet). Chicken Flocks Free from Specified Pathogens for the Production and Quality Control of Vaccines) or susceptible cell cultures (Appendix XV J (Vet) 1. Cell Cultures for the Production of Vaccines for Veterinary Use) may be suitable.

TESTS

Mycoplasmas

Complies with the *test for absence of mycoplasmas*, Appendix XVI B(Vet)3.

Sterility

Carry out the test described under Veterinary Vaccines using solid media in place of liquid media. The vaccine contains no pathogenic organisms and not more than one organism of a non-pathogenic species per bird dose.

Absence of extraneous pathogens

Appendix XV J (Vet) 2. Management of Extraneous Agents in Immunological Veterinary Medicinal Products. The vaccine is free from extraneous agents

POTENCY

For the Newcastle disease component

Vaccinate each of twenty-five 5- to 10-day-old chicks from flocks free from specified pathogens, by the nasal instillation of one dose of vaccine. Twenty-one days later challenge the vaccinated chicks as well as 10 control birds by the intramuscular inoculation of at least $10^{6.0}$ EID_{50} of Herts (Weybridge 33/56) strain of Newcastle disease virus and observe for 10 days. All the control birds die within 6 days and no fewer than 23 of the vaccinated birds survive the observation period without showing signs of Newcastle disease.

For the avian infectious bronchitis component

Vaccinate each of 10 healthy 3- to 4-week-old chickens from flocks free from specified pathogens, by nasal or ocular instillation such that each chicken receives one dose of vaccine. Twenty-one to twenty-eight days later challenge the vaccinated chickens, as well as 10 control birds that are kept separate from the vaccinated birds, by nasal or ocular instillation of $10^{3.0}$ to $10^{3.5}$. EID_{50} of the Massachusetts 41 strain of virulent infectious bronchitis virus.

Between the 4th and 7th day after challenge, take a tracheal swab from each bird. Place each swab in a test tube containing 3 mL of broth to which suitable antibiotics have been added to inhibit the growth of bacterial contaminants and test for the presence of infectious bronchitis virus by the inoculation of 0.2 mL of inoculum into the allantoic cavity of 9- to 11-day-old embryonated eggs using at least five eggs for each swab. A tracheal swab is positive if 20% or more of the embryos inoculated from it show lesions typical of infectious bronchitis virus. If more than one embryo but fewer than 20% of those inoculated from any one swab show lesions similar to those of infectious bronchitis, inoculate at least five additional embryonated eggs with allantoic fluid from each of the suspect embryos. The swab is positive if 20% or more of these additional embryos show lesions typical of infectious bronchitis virus.

Not less than 80% of the control birds give positive tracheal swabs, and no more than 20% of the vaccinated chickens give positive tracheal swabs.

LABELLING

The label states the names of the strains of virus used in the vaccine.