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Salmonella Typhimurium Vaccine (Inactivated) for Chickens

General Notices

(Ph. Eur. monograph 2361)

Ph Eur

1 DEFINITION

Salmonella Typhimurium vaccine (inactivated) for chickens is a preparation of a suitable strain or strains of *Salmonella enterica* Typhimurium, inactivated while maintaining adequate immunogenic properties. This monograph applies to vaccines intended for administration to chickens for reducing *S. enterica* Typhimurium colonisation and faecal excretion of *S. enterica* Typhimurium.

2 PRODUCTION

2-1 PREPARATION OF THE VACCINE

The seed material is cultured in a suitable medium; each strain is cultivated separately. During production, various parameters such as growth rate are monitored by suitable methods; the values are within the limits approved for the particular vaccine. Purity of the cultures and identity are verified on the harvest using suitable methods. After cultivation, the bacterial harvests are collected separately, inactivated by a suitable method, and blended. The vaccine may contain adjuvants.

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 birds for which it is intended.

The following tests for safety (section 2-2-1) and immunogenicity (section 2-2-2) may be used during the demonstration of safety and efficacy.

2-2-1 Safety

The test is carried out for each route of administration to be recommended for vaccination, using in each case chickens not older than the minimum age to be recommended for vaccination and from a flock free from specified pathogens (SPF) (5.2.2). Use a batch of vaccine containing not less than the maximum potency that may be expected in a batch of vaccine.

For each test performed in chickens younger than 3 weeks of age, use not fewer than 10 chickens. For each test performed in chickens older than 3 weeks of age, use not fewer than 8 chickens. Administer by a route and method to be recommended to each chicken 1 dose of the vaccine. If the schedule to be recommended requires a 2nd dose, administer 1 dose to each chicken after an interval of at least 14 days. Observe the chickens at least daily for at least 14 days after the last administration of the vaccine.

The test is not valid if more than 10 per cent of the chickens younger than 3 weeks of age show abnormal signs of disease or die from causes not attributable to the vaccine. For chickens older than 3 weeks of age, the test is not valid if non-specific mortality occurs.

The vaccine complies with the test if no chicken shows abnormal signs of disease or dies from causes attributable to the vaccine.

2-2-2 Immunogenicity

A test is carried out for each route and method of administration to be recommended for vaccination. The vaccine administered to each animal is of minimum potency.

Use for the test not fewer than 60 SPF chickens (*5.2.2*) not older than the minimum age to be recommended for vaccination. Vaccinate not fewer than 30 chickens with no more than the minimum number of doses of vaccine to be recommended. Maintain not fewer than 30 chickens as controls for each group of vaccinates. Challenge both groups, 4 weeks after the last administration of vaccine, by oral administration to each chicken of a sufficient quantity of a strain of *S. enterica* Typhimurium that is able to colonise chickens. Take blood samples from control chickens on the day before challenge. Observe the chickens at least daily for 4 weeks. Take individual fresh faeces samples on day 1 after challenge and at least twice weekly (including day 7) until 14 days after challenge. Test the fresh faeces samples for the presence of *S. enterica* Typhimurium by direct plating. Euthanise all surviving chickens at the end of the observation period, take samples of liver and spleen and test for the presence of *S. enterica* Typhimurium by an appropriate method.

The test is not valid if antibodies against *S. enterica* Typhimurium are found in any control chicken before challenge.

The vaccine complies with the test if:

— the number of *S. enterica* Typhimurium in fresh faeces samples from vaccinated chickens after challenge at the different days of sampling is significantly lower in vaccinates than in controls and remains lower until the end of the test;

— the number of positive samples of liver and spleen is significantly lower in vaccinates than in controls.

2-3 MANUFACTURER'S TEST

2-3-1 Batch potency test

It is not necessary to carry out the potency test (section 3-3) for each batch of the vaccine if it has been carried out using a batch of vaccine with a minimum potency. Where the test is not carried out, an alternative validated method is used, the criteria for acceptance being set with reference to a batch of vaccine that has given satisfactory results in the test described under Potency. The following test may be used.

Use not fewer than 13 SPF chickens (*5.2.2*). Maintain not fewer than 3 SPF chickens as controls. Administer to each of 10 chickens 1 dose of vaccine by a recommended route. Where the schedule stated on the label requires a booster injection to be given, a booster vaccination may also be given in this test provided it has been demonstrated that this will still provide a suitably sensitive test system. At a given interval after the last injection, collect blood from each vaccinated and control chicken and prepare serum samples. Measure the titre of antibodies against *S. enterica* Typhimurium in each serum sample using a suitable validated serological method. Calculate the titre for the group of vaccinates.

The test is not valid if specific *S. enterica* Typhimurium antibodies are found in 1 or more sera from control chickens at a given interval after the time of administration of the vaccine in the vaccinated group.

The vaccine complies with the test if the antibody titres of the group of vaccinates at a given interval after each vaccination, where applicable, are not significantly lower than the value obtained with a batch that has given satisfactory results in the test described under Potency (section 3-3).

3 BATCH TESTS

3-1 Identification

The vaccine contains the antigen or antigens stated under Definition.

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

The vaccine complies with the requirements of the test mentioned under Immunogenicity (section 2-2-2) when administered by a recommended route and method.
