



ASEAN STANDARD REQUIREMENTS FOR SWOLLEN HEAD SYNDROME VACCINE, LIVE

I. SEED AND PRODUCTION SUBSTRATE REQUIREMENTS

1. SEED VIRUS

Master and working seed viruses are produced in Specific-Pathogen-Free (SPF) embryonated eggs in seed lot system. The seed viruses must satisfy sterility, purity, safety and potency tests before they are used for vaccine production. The seed viruses are preserved and stored under suitable validated systems, such as the lyophilized seed viruses should be kept at 2 to 8°C. The liquid form of seed virus should be stored at -70 °C or lower.

2. PRODUCTION SUBSTRATE

Embryonated eggs used throughout the production of the vaccine must be derived from SPF flocks complying with tests that appear as Appendix 1.

II. QUALITY CONTROL REQUIREMENTS

1. STERILITY TEST

Final container samples shall be tested for the absence of bacteria, fungi, Salmonella and Mycoplasma by the methods that appear as Appendix 2. However, tests for Salmonella and Mycoplasma may be carried out on bulk samples.

2. PURITY TEST

Seed lot or bulk production samples should be tested for the absence of extraneous viruses by the egg inoculation test or the chicken inoculation test or the tissue culture inoculation test, and by the test for Avian Leucosis Virus subgroups A and B using the methods that appear as Appendix 3.

3. SAFETY TEST

Final container samples should be tested as follows:

At least 10 susceptible chickens of the minimum age for which the vaccine is intended, are each inoculated with ten doses of the vaccine by one of the recommended routes and observed for a minimum of 21 days. No abnormal or systemic reaction attributable to the product should occur in any of the chickens.



4. POTENCY TEST

Final container samples should be tested as follows:

At least 10 susceptible chickens of the minimum age for which the vaccine is intended, are each inoculated with one dose of the vaccine by the recommended route. Ten unvaccinated chickens are used as control. At least 21 days post-vaccination, the sera of vaccinated and control chickens are collected. Antibody titres are examined by Serum Neutralization Test (SN Test) with 100 TCID₅₀ of swollen head syndrome virus. The vaccine is considered satisfactory if Geometrical Mean Titer (GMT) of vaccinated chickens is at least 1:256 and GMT of control chickens should not be more than 1:4.

An alternative test may be used based on the establishment of a correlation with protection.

5. VIRUS CONTENT

The vaccine should have a virus titre of not less than 10^{2.5} EID₅₀ or TCID₅₀ per dose when tested at any time before the expiry date.

III. OTHER REQUIREMENTS

The vaccine should comply with the General Requirements for Veterinary Vaccines that appear as Appendix 4.





ASEAN STANDARD REQUIREMENTS FOR SWOLLEN HEAD SYNDROME VACCINE, INACTIVATED

I. SEED AND PRODUCTION SUBSTRATE REQUIREMENTS

1. SEED VIRUS

Master and working seed viruses are produced in Specific-Pathogen-Free (SPF) embryonated eggs in seed lot system. The seed viruses must satisfy sterility, purity, safety and potency tests before they are used for vaccine production. The seed viruses are preserved and stored under suitable validated systems, such as the lyophilized seed viruses should be kept at 2 to 8°C. The liquid form of seed virus should be stored at -70 °C or lower.

2. PRODUCTION SUBSTRATE

Embryonated eggs used throughout the production of the vaccine must be derived from SPF flocks complying with tests that appear as Appendix 1 or healthy flocks.

II. QUALITY CONTROL REQUIREMENTS

1. STERILITY TEST

Final container samples should be tested for absence of bacteria, fungi, Salmonella and Mycoplasma by the methods that appear as Appendix 2. However, tests for Salmonella and Mycoplasma may be carried out on bulk samples.

2. PURITY TEST

Bulk production samples should be tested for absence of extraneous viruses by the egg inoculation test or the chicken inoculation test or the tissue culture inoculation test, and by the test for Avian Leucosis Virus subgroups A and B using the methods which appear as Appendix 3. This test may be omitted if it can be demonstrated that the inactivating agent inactivates avian leucosis viruses.

3. INACTIVATION TEST

At least 10 embryonated chicken eggs susceptible to swollen head syndrome (SHS) virus are each inoculated with 0.2 ml of the inactivated product by the allantoic sac route. The eggs are incubated for a minimum of 7 days. One subculture is carried out. There should be no evidence of SHS virus. A validated test may be carried out in chicken embryo fibroblast cell cultures or other suitable cell culture system.



4. SAFETY TEST

Final container samples should be tested as follows:

At least 10 susceptible chickens of the minimum age for which the vaccine is intended, are each inoculated with at least two doses of vaccine by one of the recommended routes and observed for a minimum of 21 days. No abnormal local or systemic reaction attributable to the vaccine should occur in any of the chickens.

5. POTENCY TEST

Final container samples should be tested as follows.

At least 10 susceptible chickens of the minimum age for which the vaccine is intended, are each inoculated with one dose of the vaccine by the recommended route. Ten unvaccinated chickens are used as control. At least 21 days post-vaccination, the sera of vaccinated and control chickens are collected. Antibody titres are examined by Serum Neutralization Test (SN Test) with 100 TCID₅₀ of swollen head syndrome virus. The vaccine is considered satisfactory if Geometrical Mean Titer (GMT) of vaccinated chickens is at least 1:256 and GMT of control chickens should not be more than 1:4.

An alternative test may be used based on the establishment of a correlation with protection.

III. OTHER REQUIREMENTS

The vaccine should comply with the General Requirements for Veterinary Vaccines that appear as Appendix 4.

