



**ASEAN STANDARD REQUIREMENT FOR
AVIAN SALMONELLA GALLINARUM OR PULLORUM VACCINE, LIVE**

I. SEED AND PRODUCTION SUBSTRATE REQUIREMENT

1. SEED BACTERIA

The master and working seeds of *Salmonella gallinarum* or *pullorum* should be produced in suitable media in a seed lot system. The seeds shall satisfy sterility, purity, safety and potency tests before they are used for vaccine production. The seeds are preserved and stored under suitable validated systems, such as the lyophilized seed should be kept at 2 to 8°C. The liquid form of seed should be stored at -18 °C or lower.

2. PRODUCTION SUBSTRATE

The medium should contain appropriate nutrients to allow optimal growth of the bacteria.

II. QUALITY CONTROL REQUIREMENTS.

1. STERILITY TEST

Final container samples should be tested for absence of extraneous bacteria and fungi by the methods that appear as Appendix 2.

2. PURITY TEST

Bulk and final product samples should be tested as follows:

a. Gram stained smears of live cultures are examined for morphological characteristics. Only *S. gallinarum* or *pullorum* shall be present.

b. The appropriate strain of *S. gallinarum* or *pullorum* is confirmed by suitable serological or immunochemical methods. Only vaccine strains of *S. gallinarum* or *pullorum* shall be present.

3. SAFETY TEST

Final container samples should be tested in the species intended as follows:

At least 10 susceptible fowls of the minimum age for which the vaccine is intended, are each vaccinated with ten doses of the vaccine by the recommended route and observed for at least 7 days. No abnormal local and systemic reaction attributable to the product should occur in any of the chickens.

4. POTENCY TEST

Bulk or final container samples should be tested in the species intended as follows:

At least 15 susceptible fowls of the minimum age for which the vaccine is intended, are each vaccinated with 1 dose of vaccine by the recommended route. After 21-28 days post vaccination, the vaccinated fowls together with 15 unvaccinated fowls are deprived of food for approximately 18 hours. The fowls are then challenged by oral administration of 1 ml of a broth suspension containing 5×10^7 organisms of a virulent strain of *S. gallinarum* or *pullorum* mixed with 300 mg of a powder consisting of chalk (40%), light kaolin (43%) and magnesium trisilicate (17%). All fowls are observed for 14-21 days. The vaccine passes the test if at the end of this period the number of surviving vaccinated fowls that show no macroscopic lesions of fowl typhoid or pullorum at post-mortem exceeds the number of controls with no lesions, by eight or more.

5. VIABLE COUNT

One dose of vaccine should contain between 5×10^6 and 5×10^7 organisms.

III. OTHER REQUIREMENTS

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