DRAFT REVISED MONOGRAPH FOR COMMENTS

This draft revised monograph contain text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to further revisions prior to publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in/ biologics-ipc@gov.in **before the last date for comments.**

Document History and Schedule for the Adoption Process

Description	**Details**
Document version	1.0
First Draft published on IPC website for public comments	1st November 2024
Last Date for Comments	15th December 2024
Monograph Revision proposed for Inclusion in	IP 2026
Tentative effective date of proposed amendment	January, 2026
Draft revision published on IPC website for public comments	NA
Further follow-up action as required.	

Salmonella Vaccine, Inactivated

Salmonella Vaccine, Inactivated is a preparation of one or more suitable strains of one or more serovars *of Salmonella* organism and inactivated in such a manner that it maintains adequate immunogenic properties. This monograph applies to vaccines intended for the active immunization of chickens against infections of Salmonella organism in chickens and reducing Salmonella colonization and fecal excretions in chickens.

Production

Preparation of the Vaccine

The seed material is inoculated in a suitable medium. If the vaccine contains more than one strains of bacterium, the different strains are grown and harvested separately. During production, parameters such as growth rate, purity and identity is verified on harvests using suitable culture. The bacterial harvests are inactivated with suitable agent. The vaccine may contain suitable adjuvant.

Identification

Vaccine prepared from master seed, stimulates production of strain specific antibodies against *Salmonella* organisms in susceptible birds. Results of potency / immunogenicity can serve as identification test.

Choice of vaccine strain and composition.

The vaccine is shown to be satisfactory with respect to overall vaccine composition, safety (2.7.17), efficacy (2.7.12) and stability for its intended use. The vaccine strain should be obtained from an authentic source. The following tests for safety and immunogenicity may be used during the demonstration of safety and efficacy

Safety

Administer double dose of vaccine subcutaneously into each of ten SPF chickens (2.7.7, Table 3) or healthy susceptible chickens of minimum age recommended for vaccination. Observe the birds at least for 21 days. The test is not valid if more than 20 per cent of the chickens show abnormal signs or die from causes not attributable to the vaccine. The vaccine complies with the test if no chicken shows notable clinical signs of disease or dies from causes attributable to the vaccine.

Immunogenicity

Carry out separate ~~potency~~ immunogenicity test for each strain of *Salmonella* organism incorporated in the vaccine preparation. Use not less than 10 SPF chickens (2.7.7, Table 3) or healthy susceptible chickens of the minimum age recommended for vaccination. Administer 1 dose of vaccine by a recommended route. Maintain 10 chickens as unvaccinated controls from the same source and flock used for vaccination for each strain used in vaccine. Repeat the vaccination with the same dose and route after 21 days to vaccinated birds. Challenge both the groups, 2 weeks after last administration of vaccine, by oral administration to each chicken a sufficient quantity of a homologous strain of *Salmonella* organisms that is able to colonize chickens. Observe the birds daily for 14 days. Collect fecal samples on 14th day for detection of presence of *Salmonella* organisms by direct plating. The vaccine complies with the test, if the number of *Salmonella* organisms in fresh fecal samples after challenge is significantly lower in vaccinated birds than in unvaccinated controls.

Manufacturer's Tests

Potency test

The vaccine complies with the requirements of the test or test(s) mentioned under Immunogenicity when administered by a recommended route and method. Where the relevant test or tests is/are 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(s) described under Potency.

Residual live bacteria/ toxins. The test shall consist at least two passages in production medium or any suitable liquid medium. Incubate inoculated medium at 30 to 35˚c for 72 hrs. The product complies with the test if no evidence of presence of live *Salmonella* is observed.

Batch test

Identification

Vaccine complies with the requirement of the test mentioned under Production.

Sterility (2.2.11). The vaccine, complies with the test for sterility.

Safety. Vaccine complies with the test mentioned under safety.

Note: General Requirements shall be referred regarding omission of the batch safety test.

Potency. The vaccine complies with the requirements of the test or test(s) mentioned under Immunogenicity when administered by a recommended route and method. Alternative in-vitro method can be used as potency test for batch release with approval of competent authority if a correlation is established between potency test and alternative test.

Labelling The label must state that (1) the vaccine is for veterinary use only; (2) the recommended routes of administration; (3) the instructions for use, such as – "the preparation should be shaken well before use"; (4) the animal species for which the vaccine is intended; (5) storage temperatures; (6) Batch Number, Manufacturing date and expiry date; (7) Total volume or number of doses; (8) Strain of bacterium used in preparing the vaccine.