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

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Further follow-up action as required.	

Infectious Coryza Vaccine, Inactivated

Infectious Coryza Vaccine is a suspension of inactivated culture of suitable strains of one or more serotype/s or preferably locally prevalent strain/s of *Avibacterium (Haemophilus) paragallinarum* in a suitable medium.

Production

Preparation of the vaccine

The seed material is inoculated in a suitable medium. If the vaccine contains more than one strain of bacterium, the different strains are grown and harvested separately. The bacterial harvests are inactivated with a suitable agent. The vaccine may contain suitable adjuvant.

Choice of vaccine strain and composition

The vaccine is shown to be satisfactory with respect to overall vaccine composition, safety (2.7.17) & immunogenicity for its intended use.

Test on Seed lot

The master seed lot complies with the test of purity and identity for the organisms and a representative batch of vaccine prepared from the master seed lot complies with full range of control tests i.e. identification, safety and potency. The following tests for safety and immunogenicity may be used during the demonstration of safety and efficacy

Safety

Inject double dose of vaccine subcutaneously into each of 10 healthy susceptible chickens at the minimum age group at which vaccine is intended. Observe these birds for 14 days; no bird shows untoward reactions other than slight transient local swelling.

Immunogenicity

Inject subcutaneously each of 10 SPF chickens (2.7.7. Table 3) or healthy susceptible chickens of the minimum age group at which vaccine is used for each strain incorporated in vaccine, with minimum dose stated on the label. Repeat the vaccination after 2 to 4 weeks. Use 10 healthy chickens of same age group and of same stock as controls. Two to three weeks later, challenge vaccinated and control chickens by instillation with 0.2 ml of 18 hour broth culture of homologous strain of *A. paragallinarium* diluted suitably so as to contain 1 x 10^6 colony forming units by infra-orbital sinus instillation. Observe the chickens for 7 days for eye swelling, nasal discharge. There should be not less than 70 per cent protection of vaccinated birds. The test is not valid unless 70 per cent of control chickens exhibit typical symptoms of eye swelling and nasal discharge typical of infectious coryza.

Manufacturer's tests

Potency

It is not necessary to carry out the relevant Potency test or tests for each batch of the vaccine if it has been carried out using a batch of vaccine with a minimum potency. 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 -immunogenicity.

Residual live bacteria/ toxins

The test shall consist at least two passages in production medium or if solid medium has been used for production, in suitable liquid medium. Incubate inoculated medium at 35^0 to 37^0 and 4.5 to 5.5% CO2 for 72 hrs. The product complies with the test, if no evidence of presence of live *Avibacterium paragallinarum* is observed.

Batch tests

Identification. Vaccine protects susceptible chickens against infection with *Avibacterium paragallinarum*.

Results obtained in Potency test can serve as Identification test. Alternatively suitable validated immunochemical and molecular biology methods can be used with the approval of competent authority.

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

Safety. Inject double dose of vaccine subcutaneously into each of 10 healthy susceptible chickens at the minimum age group at which vaccine is intended. Observe these birds for 14 days; no bird shows untoward reactions other than slight transient local swelling.

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 if a correlation is established between potency test and alternative test with approval of competent authority.

-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