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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Infectious Chicken Anaemia Vaccine, Inactivated

Definition

Infectious Chicken Anaemia Vaccine (CAV), Inactivated is a preparation of a suitable strain of chicken anaemia virus, inactivated in such a manner that the immunogenic activity is retained. This monograph applies to vaccines intended for administration to chickens for immunization.

Production

Preparation of the vaccine

The vaccine virus is grown in embryonated hens' eggs and/or in cell culture or in suitable cell lines. The virus harvest is inactivated. The vaccine may be adjuvanted.

Substrate for virus propagation

The vaccine is grown in embryonated hen's egg obtained from SPF flocks or in suitable cell culture derived from SPF eggs (2.7.7) or susceptible cell line. Harvested virus is inactivated using suitable inactivating agent.

Embryonated hens' eggs.

If the vaccine virus is grown in embryonated hens' eggs, they are obtained from a healthy flock free from specified pathogens (SPF) (2.7.18).

Cell cultures

If the vaccine virus is grown in cell cultures, they comply with the requirements for cell cultures for production of veterinary vaccines (2.7.13). If continuous cell line is used for the vaccine manufacturing, the cell line should be from seed lot system

Seed lots

The master seed lot complies with the tests for extraneous agents as described in the General monograph for Veterinary Vaccines (2.7.10).

Choice of vaccine composition. The vaccine is shown to be satisfactory with respect to safety (2.7.17) and efficacy (2.7.12) for the birds for which it is intended.
The following tests for safety and immunogenicity may be used during the demonstration of safety and efficacy.

Safety. Inject each of ten SPF chickens (2.7.7, Table 3) or healthy susceptible chickens of recommended age with twice the minimum vaccinating dose and by one of the routes stated on the label. Observe the chickens for 21 days. No abnormal local or systemic reaction should be seen

Immunogenicity.

Carry out a potency test for the route of administration stated on the label. Vaccinate, 10, 21 to 28 day old SPF chickens (2.7.7, Table 3) or healthy susceptible chickens with one dose of vaccine. Keep 10 unvaccinated birds of the same age group as controls. Observe the birds for 28 days. Collect serum samples from each bird including the ten-control chickens. Detect the virus specific antibodies by serological methods i.e. Enzyme Linked Immunoassay or Serum Neutralization test. The mean serum neutralization antibody titre of sera in vaccinated group shall be 5000 units per ml and there are no CAV specific antibodies in the sera of control chickens.

Manufacturer's tests

Identification

In susceptible chicks, the vaccine stimulates the production of specific antibodies against vaccine virus detected by suitable serological tests. The vaccine contains the antigen or antigens stated under Definition. Suitable immunochemical methods can be used Alternatively, identification on the final bulk by molecular techniques is acceptable and can be used for the routine batch release tests.

Residual live virus.

An amplification test for residual live chicken Infectious anaemia virus is carried out on each batch of antigen immediately after inactivation. The test is carried out in embryonated eggs derived from SPF flock (2.7.7) or suitable cell culture derived from SPF eggs (2.7.7) or using susceptible cell lines. The quantity of inactivated virus used in the test is equivalent to not less than 10 doses of the vaccine. The inactivated virus harvest complies with the test if no live virus is detected.

Batch Test

Identification

In susceptible chicks, the vaccine stimulates the production of specific antibodies against vaccine virus detected by suitable serological tests.

The vaccine contains the antigen or antigens stated under Definition. Suitable immunochemical methods can be used. Alternatively, identification on the final bulk by molecular techniques is acceptable and can be used for the routine batch release tests

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

Safety. The vaccine complies with the tests for safety mentioned under production.
Note: General Requirements shall be referred regarding omission of the batch safety test

Potency.

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

Suitable *in-vitro* tests such as antigen content estimation can replace *in-vivo* potency test for batch release if a correlation is established between potency test and alternate 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 and number of doses; (8) Strain of virus used in preparing the vaccine (9) Route of administration.

The label states whether the strain in the vaccine is embryo-adapted or cell-culture-adapted.