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.	

Fowl Pox Vaccine, Live

Pigeon Pox Vaccine, Live

Fowl Pox Vaccine, Live is a preparation of a suitable strain(s) of pigeon pox virus or fowl pox virus. This monograph applies to vaccines intended for administration to chickens for active immunization against avian pox virus.

Production

Preparation of the vaccine

The vaccine virus is grown in embryonated hens' eggs from SPF flocks or in primary cell cultures using SPF eggs or suitable cell lines (2.7.7).

Substrate for virus propagation

Embryonated hens' eggs

If the vaccine virus is grown in embryonated hens' eggs, they are obtained from flocks free from specified pathogens (SPF) (2.7.7)

Cell cultures

The vaccine virus is grown in cell cultures derived from SPF eggs (2.7.13) or in suitable cell lines.

Seed lots

Extraneous Agents

The master seed lot complies with the tests for extraneous agents (2.7.10).

Choice of the vaccine virus

The vaccine virus shall be shown to be satisfactory with respect to safety (2.7.17) and efficacy (2.7.12) for the chickens for which it is intended. The following tests for safety, test for reversion to virulence and immunogenicity may be used during demonstration of safety and efficacy.

Identification

Carry out an immunostaining or neutralization test in cell culture derived from SPF eggs (2.7.7) to demonstrate the presence of the vaccine virus or inoculate the vaccine into eggs and notice the characteristic lesions.

Manufacturers Tests

Water (2.3.43): Not more than 3.0 percent.

Mycoplasma (2.7.9): Complies with the test for mycoplasma**.**

Safety. Carry out the test for each route and method of administration to be recommended for vaccination. Use SPF chickens or healthy susceptible chickens, not older than the minimum age to be recommended for vaccination. (2.7.7). Use vaccine virus at the least attenuated passage level that will be present in a batch of the vaccine. Inject 10 times of the normal dose of the vaccine to each of 10 SPF chickens or healthy susceptible chickens. Observe the chickens daily for at least 21 days. The test is not valid if more than 10 percent of the chickens show abnormal signs of disease or during observation period not more than 2 chickens die from causes not attributable to the vaccine. The vaccine virus complies with the test if no chicken shows abnormal signs of disease or dies from causes attributable to the vaccine virus.

Test for reversion to virulence. Carry out the test using chickens not older than the minimum age to be recommended for vaccination and from an SPF flock (2.7.7). Administer to each chicken (10chickens in each of 5 groups) of the 1st group by a suitable route a quantity of the vaccine virus that will allow recovery of virus for the passages described below. Prepare 4-7 days after administration a suspension from the induced skin lesions of each chicken and pool these samples. Administer 0.2 ml of the pooled samples by cutaneous scarification of the comb or other un-feathered part of the body, or by another suitable method to each chicken of the next group. Carry out this passage operation not fewer than 4 times; verify the presence of the virus at each passage. If the virus is not found at a passage level, repeat the passage by administration to a group of 10 chickens.

If the 5th group of chickens shows no evidence of an increase in virulence indicative of reversion during the observation period, further testing is not required. Otherwise, carry out an additional safety test and compare the clinical signs and any relevant parameters in a group of at least 10 chickens receiving the material used for the 1st passage and another similar group receiving the virus at the final passage level.

Immunogenicity. A test is carried out for each route and method of administration to be recommended for vaccination. Use SPF chickens or healthy susceptible chickens, not older than the minimum age to be recommended for vaccination. Use vaccine virus at most attenuated passage level that will be present in the batch of vaccine. The quantity of the vaccine virus administered to each chicken is not greater than the minimum virus titre to be stated on the label. Use for the test not fewer than 20 chickens of the same origin and from an SPF flock (2.7.7) or healthy susceptible chicken. Vaccinate by a route to be recommended not fewer than 10 chickens. Maintain not fewer than 10 chickens as controls. Challenge each chicken after 21 days by the intrafollicular administration or by scarification with a sufficient quantity of virulent fowl pox virus. Observe the chickens daily for 21 days after post challenge. Record the deaths and the number of surviving chickens that show clinical signs of disease. Examine each surviving chicken for macroscopic lesions: cutaneous lesions of the comb, wattle and other unfeathered areas of the skin and diphtherical lesions of the mucous membranes of the oropharyngeal area.

The test is not valid if:

The vaccine complies with the test if not less than 90% of the vaccinated chickens survive and show no signs of disease except transient local reactions of fowl pox during observation period. Not less than 90% unvaccinated control chickens show lesions of fowl pox.

If the potency test has been performed with satisfactory results on a representative batch of the vaccine, it may be omitted as a routine test during production of the other batches of the vaccine prepared from the same seed lot.

Batch tests

Identification. Vaccine complies with the requirement of the test mentioned under production.

Alternatively suitable validated immunochemical/ molecular biology methods can be used with the approval of competent authority.

Bacterial and fungal contamination (2.2.11). **.** Vaccines intended for administration by injection, scarification or wing web piercing comply with the test for sterility (2.2.11)

Frozen or freeze-dried vaccines produced in embryonated eggs and not intended for administration by injection, scarification or wing web piercing either comply with the test for sterility (2.2.11) or with the following test: carry out a quantitative test for bacterial and fungal contamination; carry out identification tests for micro-organisms detected in the vaccine; the vaccine does not contain pathogenic micro-organisms and contains not more than 1 non-pathogenic micro-organism per dose.

Any diluent supplied for reconstitution of the vaccine complies with the test for sterility (2.2.11).

Mycoplasmas (2.7.9) Complies with the test for mycoplasma.

Water (2.3.43) Not more than 3.0 per cent.

Extraneous agents (2.7.11) The vaccine is free from extraneous agents.

Safety. Administer 10 doses of the vaccine to each of ten SPF chickens (2.7.7, Table 3) or healthy susceptible chickens of recommended age by the route stated on the label. Observe the birds for 21 days. No chicken dies from causes attributable to the vaccine or shows signs of vaccine reactions other than mild, transient, local reactions for a temporary period. If during the observation period more than two chickens die from causes not attributable to the vaccine, repeat the test.

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

Virus titre. Not less than 10^2 $EID_{50}/TCID_{50}$ of the virus per dose, determining the titre by inoculation into the chorioallantoic membrane of SPF embryonated eggs, between 9-11 days old, or one or more route for virus titration depending upon the strain.

Potency. The vaccine complies with the requirements of one of the tests prescribed under Immunogenicity when administered according to the recommended schedule by a recommended route and method. Virus titer can replace in-vivo potency testing during batch test if a correlation of virus titer and potency is established.

If potency test has been performed with satisfactory results on a representative batch of the vaccine, using one vaccinating it may be omitted as a vaccine test during production on the other batches of vaccine prepared from the same seed lot.

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 –reconstituted with the diluent supplied for reconstitution where applicable"; (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) Minimum virus titre; (9) Dose of vaccine.