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.	

Duck Pasteurella Vaccine, Inactivated

Definition

Duck Pasteurella Vaccine, Inactivated consists of an emulsion or suspension of a virulent strain of *Pasteurella multocida* which has been inactivated in such a manner that the pathogenicity is eliminated and the immunogenic activity is retained.

Production

Preparation of the vaccine

Production of the vaccine is based on a seed-lot system as per the Veterinary Vaccines: General Requirements. The seed material is cultured in a suitable medium to ensure optimal growth under the chosen incubation conditions. After cultivation, the bacterial suspensions are collected and inactivated by a suitable method. The vaccine may contain an adjuvant.

Choice of vaccine strain and composition

The vaccine virus shall be shown to be satisfactory with respect to safety (2.7.17) and efficacy (2.7.12) for the ducks for which the vaccine is intended.

Safety

Administer double dose of vaccine by the recommended route into each of 10 susceptible ducks of minimum recommended age. Observe the ducks for 14 days. No untoward reaction except slight transient local swelling at the site of administration.

Immunogenicity

Either test A or test B may be carried out.

A. Inject subcutaneously with the minimum dose of the vaccine stated on the label five healthy susceptible ducks, between 4 and 6 weeks old. Use another two ducks of the same stock and age as unvaccinated controls. Three weeks later, challenge each of the vaccinated and control ducks, subcutaneously with 10^2 mouse LD_{50}, in 0.2 ml. Observe the ducks for 7 days. Not less than four of the vaccinated ducks remain in normal health and both the controls die of pasteurellosis.

B. Inject subcutaneously each of six mice, each weighing between 25 and 30 g, with 0.2 ml of the vaccine under examination. Use another six mice of the same stock and weight range as unvaccinated controls. Three weeks later, challenge each of the vaccinated and control mice subcutaneously with 0.2 ml of a suitably diluted 18-hour broth culture of the homologous virulent strain of *P. multocida* containing 50 mouse LD_{50}. Observe the animals for 7 days. All the vaccinated mice survive. The test is not valid unless all the control mice die of pasteurellosis during the observation period.

Manufacturer's tests

Batch 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.

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 Potency.

Residual live bacteria/ toxins

The test shall consist of at least 2 passages in production medium or in solid medium, if solid medium has been used for production or in a suitable liquid medium. Incubate the inoculated medium for 72 h at 30-35°C. The product complies with the test if no evidence of *Pasteurella multocida* is observed.

Batch tests

Identification. The vaccine contains the inactivated *Pasteurella multocida* antigen

Sterility/Bacterial and fungal contamination (2.2.11). The vaccine complies with the test for sterility

Safety
Either test A or test B may be carried out.

A. Inject 5-ml vaccine subcutaneously into each of four healthy rabbits, weighing between 1.0 and 1.5 kg. Observe the animals for 7 days. No untoward reaction except slight and transient local swelling occurs.

B. Inject 0.5 ml vaccine subcutaneously or intraperitoneally into each of six mice, weighing between 25 and 30 g. Observe the animals for 7 days. No untoward reaction except slight and transient local swelling occurs in both species of animals.

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 NRA, 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) the serotype and strains of bacteria used to prepare vaccine (9) Adjuvant used.