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.	

Reo Virus Vaccine, Inactivated

Reo virus vaccine, inactivated consists of an emulsion or suspension of a suitable strain/s of Reo virus which has been inactivated in such a manner that immunogenic activity is retained. The vaccine may contain one or more strains and a suitable adjuvant.

Production

Preparation of the vaccine

Substrate for virus propagation

The virus is propagated in fertilized eggs obtained from healthy flock or in suitable cell culture derived from SPF flocks (2.7.7) or susceptible cell line.

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) (2.7.7).

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).

Seed lots

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

Identification.

In susceptible chickens, the vaccine stimulates the production of specific antibodies against each of the virus serotypes in the vaccine detected by virus neutralization. Alternatively suitable validated immunochemical and molecular biology methods can be used with the approval of competent authority.

Choice of vaccine composition

A reference strain obtained from an authentic source shall be used for the vaccine production. The master seed which has been established as pure, safe and immunogenic shall be used for the vaccine production.

Safety

Inject each of ten SPF chickens (2.7.7, Table 3) or healthy susceptible chickens, of recommended age with double the minimum vaccinating dose and by one of the routes stated on the label. Observe the chickens for 14 days. No abnormal local or systemic reaction should be seen.

Immunogenicity

Inject each of twenty SPF chickens (2.7.7, Table 3) or healthy susceptible chickens 3 to 4 weeks old, with the minimum dose and by the route stated on the label. Use ten chickens of the same flock and age as controls. After 21 days, collect serum samples from each bird including the ten-control chickens and perform quantitative agar gel precipitation test or serum neutralization test on each serum sample. The mean antibody titre of sera in vaccinated group shall be 1:8 by Agar gel diffusion test and 10000 units per ml by serum neutralization test and there should be no specific antibodies in the sera of control chicken.

Manufacturer's tests

Identification. Vaccine complies with the requirements of test mentioned under Production.

Residual live virus. An amplification test for residual live Infectious Avian Reo Virus is carried out on each batch of antigen after inactivation and the test is carried out in fertilized SPF hen eggs or in suitable cell culture derived from SPF eggs (2.7.7). The quantity of inactivated virus used in the test is equivalent to 10 doses of the vaccine. No live virus is detected.

In Cell culture derived from SPF eggs (2.7.7): Inoculate 10 doses of vaccine into suitable cell culture derived from SPF eggs (2.7.7). Incubate at 36 ± 1^0 for 7 days. Make a passage on another set of cell culture derived from SPF eggs (2.7.7) and incubate at 36 ± 1^0 for 7 days. None of the cultures shows signs of infection i.e. cytopathic effect.

Embryonated eggs: Inject quantity of inactivated virus equivalent to 10 doses of vaccine into the SPF embryonated hen eggs, between 9-11 days old and incubate. Examine each embryo for lesions of Reo virus. The sample complies with the test if there is no evidence of lesions of Reo virus. The test is valid only if not more than 20 per cent of the embryos die at either stage of the test. If more than 20 per cent of the embryos die at either one of the stages of the test, repeat that stage. In any repeat test, not more than 20 per cent of the embryos die from non-specific causes. Antibiotics may be used to control extraneous bacterial infection.

Batch test

Identification. Vaccine complies with the requirements of test mentioned under Production.

Sterility/ Bacterial and fungal contamination (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 or test(s) mentioned under Immunogenicity when administered by a recommended route and method.

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 virus used in preparing the vaccine;