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

Description	**Details**
Document version	1.0
First Draft published on IPC website for public comments	21st March 2025
Last Date for Comments	5th May 2025
Monograph Revision proposed for Inclusion in	IP 2026
Tentative effective date of proposed amendment	January, 2026
Draft revision published on IPC website for public comments	NA
Further follow-up action as required.	

Sheep Pox Vaccine, Live

Sheep Pox Vaccine, Live is a freeze dried preparation obtained by producing attenuated sheep pox virus in a suitable cell culture and mixed with a suitable stabilizer and freeze dried. This monograph applies to vaccines intended for the active immunisation of sheep against sheep pox virus infection.

Production

A reference vaccine strain obtained from an authentic source should be used.

Preparation of Vaccine

The virus is propagated in suitable cell cultures

Substrate for virus propagation. *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.

Master Seed lot

Identification. Vaccine administration in sheep does not cause sheep pox but immunizes them with specific neutralizing antibodies. The immunogenicity test also serves the identification. Alternatively, a suitable method based on molecular or immunochemical techniques is also acceptable.

Extraneous agents (2.7.19). Neutralize the vaccine virus with a suitable mono specific antiserum against sheep pox and inoculate into cell suitable cultures. Carry out 2 passages with an interval of 4 to 6 days. The vaccine complies with the test if no cytopathic effect is observed.

Safety. Carry out test for each route and method of administration recommended for the vaccination. Inoculate not less than 6 sheep of 8 to 12 months old, free from neutralizing antibodies against sheep pox virus, with 10 times the field dose of the vaccine contained in 1 ml by the route stated on the label. Observe the animals for 21 days. The vaccine complies the test if none of the vaccinated animals show deep necrotic or generalized lesions either locally or away from the inoculation site.

Test for reversion to virulence. If the source organization has carried out the test for reversion to virulence of vaccine strain it may be omitted. Otherwise carry out the following test.

Carry out the test using two sheep of the minimum age recommended for the vaccination that are free of sheep pox antibodies. Administer to each sheep with the vaccine virus by intradermal route with $10^{4.5}$ $TCID_{50}$ titre per ml at 5 sites (0.1 ml per site) on the flank region that will allow recovery of virus for the passages and most likely to lead to reversion to virulence. Observe the animals for 5 to 14 days and collect the skin /pock scrapings to prepare 10% suspension for the next passage in two fresh sheep. Carry out this passage operation not less than 3 more times to ascertain any presence of the virus. If the 5^{th} group of sheep shows no evidence of an increase in virulence indicative of reversion during the observation period, further testing is not required, and the vaccine virus complies for non-reversion to virulence.

Immunogenicity. Administer each of three sheep, between 8 and 12 months old, free from sheep pox virus neutralizing antibodies, with the dose of the vaccine and by the route stated on the label. Use two sheep as un-vaccinated controls. Shave the animals closely on the flank shoulder area. Challenge each animal after 21 days post-vaccination by inoculating intradermally with 0.1 ml of a

suspension six, tenfold dilution of sheep pox challenge virus. Make five separate inoculations in a vertical line for each serial dilution from the anterior to the posterior of the animals. The titre of the challenge virus is calculated using' standard statistical method for the vaccinated and control sheep by the number of pock lesions observed in each dilution. The titre of the challenge virus is calculated for the vaccinated and control animals. The vaccine passes the test if there is a difference of log titre of more than $10^{2.5}$.

Batch tests

Identification. Complies with the identification test as mentioned under master seed lot. Alternatively suitable validated immunochemical/ molecular biology methods can be used with the approval of competent authority.

Water (2.3.43). Not more than 3.0 per cent.

Mycoplasmas (2.7.8). Complies with the test for Mycoplasma.

Virus titre. Not less than 10^3 $TCID_{50}$ of the virus per dose, determining the titre of the vaccine in a suitable cell culture using suitable medium.

Bacterial and fungal contamination (2.2.11). Complies with the test for sterility**.** Any diluents supplied with the vaccine complies with test for sterility 2.2.11.

Safety. Inject by a recommended route and method with 10 times the minimum dose stated on the label into each of two sheep of the minimum age recommended for vaccination. Observe the animals for 21 days. None of the animals shows abnormal local or systemic reactions or dies of any causes attributable to the vaccine.

NOTE- General Requirements shall be referred regarding omission of the batch safety test.

Potency. The vaccine complies with the requirements of the test prescribed under Immunogenicity when administered by a recommended route and method. It is not necessary to carry out the potency test for each batch of the vaccine if it has been carried out on a batch prepared using a vaccinating dose containing not more than the minimum virus titre stated on the label.

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

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 freeze dried vaccine shall be reconstituted with the diluent supplied” (4) the animal species for which the vaccine is intended; (5) storage temperatures; (6) Batch Number, Manufacturing date and expiry date; (7) Precautions in pregnant [animals] (If applicable) (8) Total volume and number of doses; (9) Minimum virus titre per dose of vaccine