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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Goat Pox Vaccine, Live

Goat Pox Vaccine, Live attenuated is a freeze dried preparation obtained by producing attenuated goat pox virus in a suitable cell culture and mixed with a suitable stabilizer and freeze dried. The freeze-dried vial is reconstituted with a suitable diluent and used immediately. This monograph applies to vaccines intended for the active immunisation of goats against goat pox virus infection.

Production

Preparation of the 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 the goats does not cause goat pox but immunizes them with specific neutralizing antibodies. 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 goat 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. Inject 10 doses of the vaccine contained in 1 ml of the reconstituted vaccine subcutaneously into each of 6 susceptible goats, 6 to 8 months old. Observe the goats for 14 days. None of the animals shows abnormalities other than local erythema of not more than 3 cm in diameter around the site of injection.

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 goats of the minimum age recommended for the vaccination that are free of goat pox antibodies. Administer to each goat with the vaccine virus having a titre of at least $10^5 TCID_{50}$ /ml by intradermal route 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 /pox scrapings to prepare 10% suspension for the next passage in 2 fresh goats. Carry out this passage operation not less than 3 more times to ascertain any presence of the virus. If the 5^{th} group of goats 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. Use 9 susceptible goats of 8 to 10 months old. Inject subcutaneously with one dose of the vaccine stated on the label into each goat. Use 3 goats as unvaccinated controls which should be kept along with the inoculated goats. Observe the animals for 14 days and record the rectal temperature daily of each goat during the observation period. None of the vaccinated goats shows any thermal reaction or local or generalized lesion. After 21 days, challenge the vaccinated and control animals with sufficient quantity of a virulent goat pox virus by intradermal injection. Observe the animals for 14 days and record the rectal temperature daily of each goat during the observation period. None of the vaccinated goats shows any thermal reaction or local or generalized lesion. The test is valid only if the control animals develop high fever or show local or generalized lesions

Batch tests

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

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

Water (2.3 .43). Not more than 3.0 per cent.

Virus titer. 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.

Sterility (2.2.11). Complies with the test for sterility. Any diluents supplied with the vaccine complies with test for sterility.

Safety. Inject by a recommended route and method with 10 times the minimum dose stated on the label into each of 2 goats 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 representative batch 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 titer 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 preparation should be shaken well before use or 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 and number of doses; (8) Minimum virus titre per dose of vaccine; (9) Dose of vaccine