# 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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# Peste Des Petits Ruminants Vaccine, Live

Peste Des Petits Ruminants (PPR) Vaccine, Live is a preparation of a suitable strain of PPR virus that is attenuated for use in sheep and goats

## Production

**Preparation of the vaccine**. The vaccine strain is grown in suitable cell cultures. The viral suspension is harvested, mixed with a suitable stabilizing liquid and freeze-dried.

**Substrate for virus propagation.** 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

**Choice of vaccine strain.** A reference strain obtained from an authentic source shall be used for the vaccine production. Only a virus strain shown to be satisfactory with respect to identification, safety, test for extraneous pathogens, test for mycoplasma and potency may be used in the preparation of the vaccine.

**Identification.** When injected into target animals, the vaccine stimulates the production of specific PPR virus neutralization antibodies. Alternatively, a suitable method based on molecular or immunochemical techniques is also acceptable.

**Extraneous agents (2.7.19).** The master seed lot complies with the test for extraneous agent. Neutralize the vaccine virus with a suitable mono specific antiserum against PPR virus 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.

**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.

Two male/female goats of approximately 4 months of age are inoculated with 2 ml of attenuated virus having a titre not less than 105 $TCID_{50}$/ml. Heparinized blood is collected on day 5 and day 7 days post-inoculation, pooled aseptically and inject 10 ml each subcutaneously into two fresh animals. Repeat the passages in similar manner for at least 3 more times. The animals are monitored for rise of temperature, secretion of virus and development of antibody against PPR. The goats at the beginning of the test initiation should be seronegative for PPR antibodies (less than 1:4 SNT) and collect blood samples before start of the test and at day 14 to 21 days from the surviving animals at each passage for the evaluation of antibodies. The vaccine virus complies with the test if no indication of increased virulence of the organism recovered from the final passage compared with the material used for the 1st passage is observed and the animals shall be sero-positive.

**Safety.** Inject 2 susceptible goats of one year old free from antibodies to PPR by subcutaneous route with 100 times the dose of vaccine stated on the label. Observe the animals for 21 days. The vaccine is considered as safe if there no sign of illness.

**Immunogenicity.** Use not less than 6 healthy goats and 6 healthy sheep of 1 year old free from antibodies to PPR virus. Collect sera from animals before the time of vaccination and 3 weeks after vaccination and just before challenge. Vaccinate 2 goats and 2 sheep subcutaneously with 1/10 dose each and 2 goat and 2 sheep with 1 dose of vaccine. Keep the remaining animals as the in contact controls. Monitor each animal for clinical signs, in particular respiratory symptoms and record temperature daily for three weeks.

Three weeks after vaccination collect sera samples from all vaccinated as well as control animals and challenge the vaccinated and in contact controls group with a suspension of virus containing either $10^3$ $LD_{50}$ pathogenic PPR or 2.5 ml of a 10 per cent splenic suspension by subcutaneous route. The animals are observed for clinical signs and the body temperatures are recorded daily for two weeks. The vaccine passes the test if all vaccinated animals resist challenge infection and all the in contact controls develop signs of PPR. The serum neutralization test must be positive for PPR antibody in vaccinated animals only, in samples taken three weeks after vaccination.

## Batch tests

**Identification.** The vaccine complies with the requirements of the test mentioned under master seed lot.

**Virus titre.** Not less than $10^{2.5}$ $TCID_{50}$ per dose.

**Mycoplasma** (2.7.8). Complies with the test for mycoplasma**.**

**Bacterial and fungal contamination (2.2.11).** Complies with the test for sterility.

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

**Safety.** The vaccine complies with the requirements of the test prescribed under master seed lot.

*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. 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. Virus titre can replace in-vivo potency testing during batch 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 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) Total volume or number of doses; (8) Strain of virus used in preparing the vaccine