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.	

Theileriosis Vaccine, Live

Theileriosis Vaccine, Live is a lymphoblast cell culture containing *Theileria annulata* macroschizonts attenuated by passage in such a manner that it remains avirulent while it retains its immunogenicity. The concentrate of the vaccine is diluted with a suitable diluent after thawing and used immediately preferably within 1 hour of reconstitution. This monograph applies to vaccines intended for the active immunisation of cattle against Theileria infection.

Production

A reference lymphoblast cell culture containing *Theileria annulata* macroschizonts obtained from an authentic source should be used for the production. The vaccine is recommended to be stored at -196° in liquid nitrogen containers and must be transported in the same temperature till it is used in the target animals. If any alternate methods of storage are employed, number of schizonts/lymphoblast culture cells in the vaccine must be in the range suggested for the vaccine production per dose till the vaccine is used in the target animals.

Master seed lot

The master seed lot complies with the tests of identity for the organism and a batch of vaccine prepared from the master seed lot should comply with full range of control tests, i.e. identification, safety and immunogenicity. Once immunogenicity is established on the representative batch, this test can be omitted as a routine test for the batch release and the count per dose is considered for a batch release provided the traceability of the lymphoblast cell culture containing *Theileria annulata* macroschizonts used is from the same master seed. 99% of the lymphoblast should contain macroschizonts

Identification. Vaccine administration in the target species cattle does not cause theileriosis but immunizes them against the infection. Alternately, identification on the final antigen lot by immunochemical/ molecular approaches is acceptable and can be used in the routine batch release tests also.

Extraneous agents (2.7.19). The master seed lot complies with the tests for extraneous agents.

Sterility (2.2.11). Complies with the test for sterility.

Cell count. Contains not less than 2 million live lymphoblast cells in each dose.

Safety. Carry out test for each route and method of administration recommended for the vaccination. Inoculate not less than 6 cattle in the age group of 4 to 9 months with double dose of the vaccine. Observe the animals for 45 days. None of the animals shows systemic reactions other than mild pyrexia and mild swelling of superficial lymph nodes. No schizonts/piroplasms should be seen in the blood smears/lymph node smear.

Immunogenicity. Inject each of three susceptible cattle not less than 9 to 12 months old with the minimum dose by the route stated on the label. Use two cattle of the same age as controls. After 30 to 35 days, challenge each of the vaccinated as well as the control animals with a preparation of gut homogenate of ticks containing suitable quantity of sporozoites to infect adult cattle. Observe the animals for 30 days; none of the vaccinated, animals shows any abnormal signs. The test is not valid unless both the control animals show typical signs of theileriosis.

If these tests have been performed with satisfactory results on a representative batch of the vaccine from the seed lot, they may be omitted by the manufacturer as a routine control on other batches of the vaccine prepared from the same seed lot.

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

Manufacturer's tests

The tests stated under Master seed lot such as identification and immunogenicity need not be carried out provided the above tests are demonstrated at the development stage with the vaccine.

Batch tests
Cell count. Contains not less than 2 million live lymphoblast cells in each dose.

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

Safety. Vaccine complies with the safety test under master seed lot.

Note- General Requirements shall be referred regarding omission of the batch safety 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 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) Dose of vaccine