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.	

Salmonella Abortus Equi Vaccine, Inactivated

Salmonella abortus equi Vaccine, Inactivated is a suspension of killed mixture of equal parts of pure cultures of smooth laboratory strains of *Salmonella abortus equi* inactivated using a suitable inactivated agent. This monograph applies to vaccines intended for preventing *Salmonella abortus equi* induced equine abortion.

Production

Preparation of the vaccine. The whole culture or its filtrate or a mixture is inactivated using a suitable inactivated agent in such a manner that pathogenicity is eliminated and immunogenic activity is retained. The inactivated cultures may be treated with a suitable adjuvant.

Choice of vaccine strain and composition. The vaccine is shown to be satisfactory with respect to overall vaccine composition, safety, efficacy and stability for its intended use.

Safety. Inject 0.5 ml of the vaccine intraperitoneally to each of six mice, each weighing not less than 18 g. Observe the mice for 96 hours, none of the mice dies of salmonellosis.

Immunogenicity. Inject each of twelve mice, each weighing not less than 18 g, subcutaneously with 0.5 ml of the preparation under examination. Use another twelve mice of the same weight range and from the same stock as controls. Three weeks later, challenge the mice from both groups by injecting intraperitoneally each animal with 0.5 ml of a suspension of an 18-hour old culture containing 10 LD_{50} virulent organisms of *S. abortus equi*. Observe the mice for 7 days. The vaccine passes the test if not less than nine mice of the vaccinated group survive. The test is not valid unless not less than nine of the control mice succumb to the challenge

Manufacturer's Tests

Potency test

The vaccine complies with the test as mentioned under immunogenicity.

Residual live bacteria/ toxins.

A suitable validated method is used for the detection of residual live bacteria/ toxins by the approval of competent authority.

Batch Tests

Identification. It protects susceptible animals against infection with *Salmonella abortus equi.*

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

Potency. The vaccine complies with the requirements of the test or test(s) mentioned under Immunogenicity when administered by a recommended route and method.

Safety. The vaccine complies with the requirements of the safety test mentioned under Production

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) Precautions in pregnant [animals] (If applicable); (8) Total volume and number of doses; (9) Strain of bacterium used for vaccine production.