DRAFT REVISIONS FOR COMMENTS

This draft revision contains revised monograph 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 themonograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in before the last date for comments.

Document History and Schedule for the Adoption Process

Description	Details
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Further follow-up action as required.	

Classical Swine Fever Vaccine, Live, Pg. 5506
Potency

Change From:

As an alternate to determine the 100 PD_{50} content in each vaccine dose by challenge method, Fluorescent Antibody Virus Neutralization (FAVN) method can be used in which vaccinated animals are not to be challenged and instead 28 days post vaccinated sera to be used. Sera collected from both the vaccinated groups (1/40 and 1/160 dilutions of a single dose) and control are tested by FAVN in PK-15 cells to measure virus neutralizing antibodies. Each vaccinated pig is considered to be protected if FAVN titre is greater than or equal to 10 and accordingly PD_{50} may be determined as per the calculations in challenge method. FAVN should be performed with PK-15 adapted virus**.** A vaccine passes the potency if it contains 100 PD_{50} per dose.

To:

As an alternate to determine the 100 PD_{50} content in each vaccine dose by challenge method, Fluorescent Antibody Virus Neutralization (FAVN) method can be used in which vaccinated animals are not to be challenged and instead 28 days post vaccinated sera to be used. Sera collected from both the vaccinated groups (1/40 and 1/160 dilutions of a single dose) and control are tested by FAVN in PK-15 cells to measure virus neutralizing antibodies. Each vaccinated pig is considered to be protected if FAVN titre is greater than or equal to 1:10 and accordingly PD_{50} may be determined as per the calculations in challenge method. FAVN should be performed with PK-15 adapted virus**.** A vaccine passes the potency if it contains 100 PD_{50} per dose.

Test for Reversion to Virulence
Change from:

Carry out the test, using piglets 6-10 weeks ……10 animals, the vaccine virus also complies with the test.

To:

The test for increase in virulence consists of the administration of the virus from the master seed lot or one or two passages above to piglets that do not have antibodies against pestiviruses. This protocol is repeated five times. Administer to each of two healthy piglets free of antibodies to pestiviruses, 6–10

weeks old, by intravenous route, a quantity of the vaccine virus equivalent to not less than the maximum virus titre likely to be contained in 1 dose of the vaccine. Collect an appropriate quantity of blood from each piglet daily between day 2 and day 7 after administration of the vaccine virus, and pool the samples taken on the same day. Administer 2 ml of the pooled blood sample to each of two other piglets of the same age and origin. If no virus is found, repeat the administration once again with the same material in two more piglets. Repeat this procedure for the next 2 passages. If no virus is found at this point, end the process here. The vaccine virus complies with the test if no indication of increasing virulence (monitored by clinical observations) is found. Indication of any virulence and typical signs and symptoms of CSF virus at the end of the 5th passage reveals that virus is not suitable for use as a vaccine strain.

Avian Infectious Laryngotracheitis Vaccine, Live
Batch tests
Safety
Change From:

Use not less than ten chickens from an SPF flock ……..clinical signs of disease or dies from causes attributable to the vaccine.

To:

A) For chicken embryo-adapted vaccine only

Twenty-five 3 to 4 weeks old laryngotracheitis susceptible chickens shall be injected intratracheally with 0.2 ml of vaccine rehydrated at the rate of 30 ml for 1,000 doses. Chickens shall be observed each day for 14 days. Deaths shall be counted as failures. Two- stage sequential testing may be conducted if the first test (which then becomes stage one) has five, six, or seven failures. The results shall be evaluated according to the following table:

Stage	Number of chickens	Failures for satisfactory serials	Failures for unsatisfactory serials
1.	25	4 or less	8 or more
2.	50	10 or less	11 or more

If unfavorable reactions occur which are not attributable to the vaccine, the test shall be declared a No Test and repeated or in lieu thereof, the serial declared unsatisfactory.

B) Tissue culture vaccine only

Carry out the test for each route and method of administration to be recommended for vaccination, using in each case chickens not older than the minimum age to be recommended for vaccination and from an SPF flock (2.7.7) or healthy susceptible chickens (2.7.18). Use vaccine virus at the least attenuated

passage level that will be present in a batch of the vaccine. For each test performed in chickens younger than 3 weeks of age, use not fewer than 10 chickens. For each test performed in chickens older than 3 weeks of age, use not fewer than 8 chickens. Administer to each chicken a quantity of the vaccine virus equivalent to not less than 10 times the maximum virus titre likely to be contained in 1 dose of the vaccine. Observe the chickens at least daily for at least 14 days.

The test is not valid if more than 10 per cent of the chickens younger than 3 weeks of age show abnormal signs of disease or die from causes not attributable to the vaccine. For chickens older than 3 weeks of age, the test is not valid if non-specific mortality occurs.

The vaccine virus complies with the test if no chicken shows abnormal signs of disease or dies from causes attributable to the vaccine virus.

Avian Infectious Bronchitis Vaccine, Inactivated, Pg. 5482

Manufacturer's Test
Potency
Last line
Change from: Serum neutralization titre should not be less than 10^2 neutralization units.

To: Serum neutralizing titre should not be less than 1:100.