

Draft Revision for Comments and Inclusion in The Indian Pharmacopoeia

DRAFT REVISIONS FOR COMMENTS

These draft amendment contains revised text of monographs 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](mailto:lab.ipc@gov.in/biologics-ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

Description	Details
Document version	1.0
First Draft published on IPC website for public comments	22 nd July 2024
Last Date for Comments	5 th September 2024
Monograph Revision proposed for Inclusion in	IP 2026
Tentative effective date of proposed amendment	January, 2026
Draft revision published on IPC website for public comments	NA
Further follow-up action as required.	

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and *Haemophilus influenzae* Type b Conjugate Vaccine, (Pg. 4334)

FINAL LOT

Tests

Absence of residual pertussis toxin and irreversibility of pertussis toxoid

Insert following at the end

“A validated test based on the clustering effect of the toxin for Chinese Hamster Ovary (CHO) cells may be used instead of the test in mice.”

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Hepatitis B (rDNA) Vaccine (Pg. 4337)

FINAL LOT

Tests

Absence of residual pertussis toxin and irreversibility of pertussis toxoid

Insert following at the end

A validated test based on the clustering effect of the toxin for Chinese Hamster Ovary (CHO) cells may be used instead of the test in mice.”

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component), Inactivated Poliomyelitis Vaccine and *Haemophilus influenzae* Type b Conjugate Vaccine (Pg. 4339)

FINAL LOT

Tests

Absence of residual pertussis toxin and irreversibility of pertussis toxoid

Insert following at the end

A validated test based on the clustering effect of the toxin for Chinese Hamster Ovary (CHO) cells may be used instead of the test in mice.”

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component), Hepatitis B (rDNA), Poliomyelitis (Inactivated) and *Haemophilus influenzae* Type b Conjugate Vaccine (Pg. 4342)

FINAL LOT

Tests

Absence of residual pertussis toxin and irreversibility of pertussis toxoid

Insert following at the end

A validated test based on the clustering effect of the toxin for Chinese Hamster Ovary (CHO) cells may be used instead of the test in mice.”

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis Vaccine(Pg. 4346)

FINAL LOT

Tests

Absence of residual pertussis toxin and irreversibility of pertussis toxoid

Insert following at the end

A validated test based on the clustering effect of the toxin for Chinese Hamster Ovary (CHO) cells may be used instead of the test in mice.”

Adsorbed Pertussis (Acellular Component), (Pg. 4353)

FINAL LOT

Tests

Absence of residual pertussis toxin and irreversibility of pertussis toxoid

Insert following at the end

“A validated test based on the clustering effect of the toxin for Chinese Hamster Ovary (CHO) cells may be used instead of the test in mice.”

Adsorbed Pertussis (Acellular Co-purified), (Pg. 4356)

FINAL LOT

Tests

Absence of residual pertussis toxin

Insert following at the end

“A validated test based on the clustering effect of the toxin for Chinese Hamster Ovary (CHO) cells may be used instead of the test in mice.”

Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed)(Pg. 4444)

FINAL LOT

Tests

Delete the following

General safety (innocuity). The...human use.

Tetanus Vaccine (Adsorbed), (Pg. 4472)

Final lot

Potency of tetanus component

Biological assay of Tetanus Vaccine

(B) Test on mice

Change

From: Test animals. Use healthy mice from the same stock weighing between 14 and 20 g.....The mice should all be of the same sex or the males and females should be distributed equally among the groups.

to: Test animals. Use healthy mice from the same stock, about 5 weeks old or 14 to 20g and from a strain shown to be suitable. Use mice of the same sex or with males and females equally distributed between the groups. Distribute the mice in not fewer than 6 equal groups; use groups containing a number of animals sufficient to obtain results that fulfil the requirements for a valid assay prescribed below. If the challenge toxin to be used has not been shown to be stable or has not been adequately standardised, include 3 further groups of not fewer than 5 mice to serve as unvaccinated controls.