



International Alliance for  
Biological Standardization

**Animal Testing Replacement for Vaccines.  
A One Health View: Global Outlook and Future Strategy**  
December 2-4, 2025  
Bangkok, Thailand

***Indian Pharmacopoeia perspectives on alternatives to animal methods in testing of vaccines for human and animal use***

Dr. M Kalaivani, Principal Scientific Officer, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Govt. of India

The global shift toward replacing animal-based vaccine testing is accelerating, driven by scientific advancements, ethical imperatives, and the integrated principles of One Health. Indian Pharmacopoeia Commission (IPC), an Autonomous Institution under the Ministry of Health and Family Welfare, Govt. of India, has taken proactive steps to implement 3Rs principles (Replacement, Reduction, Refinement) through Indian Pharmacopoeia (IP). During implementation of alternatives to animal methods, IPC adopts one or more strategies like Comparability and applicability of suitable non-animal method or test in place of current *in vivo* method or test. Recent edition of IP 2022 and upcoming edition IP 2026 have progressively aligned with global pharmacopoeia's and WHO "Guidelines on the replacement or removal of animal tests for the quality control of biological products". IP implements and promotes alternate method approaches to reduce use of animal in tests such as *in vivo* potency, safety, and pyrogen tests with non-animal methods such as *in-vitro* assays, Bacterial endotoxin tests, and other validated tests. Key forward-looking priorities for the IP are to include expanded monograph updation, structured pathways for alternative method validation, and collaborative data generation with industry. These efforts position the IP to play a pivotal role in accelerating India's transition toward sustainable, science-driven, and internationally harmonized non-animal testing and approaches for vaccines.

