



Indian Pharmacopoeia Commission (IPC) Organises First-Ever Interactive Meeting with CDL Kolkata to Promote Quality of Medicines

**“IP 2026: Perspectives, Suggestions & Way Forward”
Focuses on Strengthening Pharmacopoeial Standards and
Drug Quality**

**IPC Launches Seven Indian Pharmacopoeia Nitrosamine
Impurities Reference Standards for the First Time**

**Seven Nitrosamine Reference Standards to Strengthen
Accurate Detection, Quality Assurance and Regulatory
Compliance of Pharmaceuticals**

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The Indian Pharmacopoeia Commission (IPC), under the Ministry of Health & Family Welfare, Government of India, organised an Interactive Meeting at the Central Drugs Laboratory (CDL) and Central Cosmetics Laboratory (CCL), Kolkata. The meeting, being organised for the first time in Kolkata, West Bengal, brought together experts and stakeholders to discuss the way forward for pharmacopoeial standards and drug quality in the country.

The meeting focused on “IP 2026: Perspectives, Suggestions & Way Forward” and the significance of Indian Pharmacopoeia Reference Standards and Impurity Standards in assuring the quality, safety and efficacy of pharmaceuticals.



A major highlight of the event was the launch of seven Indian Pharmacopoeia Nitrosamine Impurities Reference Standards, marking the first-ever introduction of these critical reference standards by IPC. The standards launched are N-Nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), N-Nitrosoethylisopropylamine (NEIPA), N-Nitrosodibutylamine (NDBA), N-Nitrosomethylphenylamine (NMPA), N-Nitrosodiisopropylamine (NDIPA), and N-Nitroso-N-methyl-4-aminobutyric acid (NMBA).

Nitrosamines are highly potent genotoxic and carcinogenic compounds that may arise unintentionally during manufacturing, storage, packaging or through contamination from various materials used in pharmaceutical production. Controlling of these impurities are crucial in some of the drug formulations used for hypertension, gastric disorder, diabetes, and tuberculosis, etc.

The launch of these seven impurities reference standards represents a significant step towards strengthening India's capability for the accurate detection and quantification of nitrosamine impurities in pharmaceuticals. The initiative will support pharmaceutical testing, method validation, quality assurance and regulatory compliance, while further promoting harmonisation with international quality standards and self-reliance in critical reference materials.



Dr. V. Kalaiselvan, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, during the inaugural address, highlighted the collaborative approach with CDL lab is crucial in ensuring the quality of medicines. Other dignitaries Dr. Suparna Chatterjee, Professor and Head of Pharmacology, IPGMER Kolkata, Dr. Rakesh Kumar Rishi, Director- Central Drugs Laboratory also graced the occasion.

The meeting served as an important platform for experts from regulatory authorities, laboratories and IPC to exchange perspectives, share suggestions and contribute towards further strengthening the Indian Pharmacopoeia and the national drug quality ecosystem.

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