

Nitrosamine Impurities Reference Standards

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Why in News?

The Indian Pharmacopoeia Commission (IPC) launched seven Indian Pharmacopoeia Nitrosamine Impurities Reference Standards.

- The launch took place during IPC's first-ever interactive meeting with the Central Drugs Laboratory (CDL) and Central Cosmetics Laboratory (CCL) in Kolkata.
- Marks the first time IPC has introduced reference standards specifically for ***nitrosamine impurities***, boosting self-reliance in critical testing materials for drug safety.
- Event Theme** - Held under the theme **"IP 2026: Perspectives, Suggestions & Way Forward"** to align national drug testing protocols, laboratory capabilities, and regulatory standards.
- Therapeutic Importance** - Vital for detecting and controlling chemical impurities in widely used formulations for chronic diseases like hypertension, diabetes, gastric disorders, and tuberculosis.
- Analytical Impact** - Enhances India's capacity for accurate detection, quantification, method validation, and quality assurance, facilitating alignment with global pharmacopoeial standards.

THE SEVEN NITROSAMINE REFERENCE STANDARDS

1	NDMA – N-Nitrosodimethylamine	$\begin{array}{c} \text{H}_3\text{C} \\ \text{H}_3\text{C} \end{array} \text{N}-\text{N}=\text{O}$
2	NDEA – N-Nitrosodiethylamine	$\begin{array}{c} \text{H}_3\text{CH}_2\text{CH}_2 \\ \text{H}_3\text{CH}_2\text{CH}_2 \end{array} \text{N}-\text{N}=\text{O}$
3	NEIPA – N-Nitrosoethylisopropylamine	$\begin{array}{c} \text{H}_3\text{CH}_2 \\ (\text{CH}_3)_2\text{CH} \end{array} \text{N}-\text{N}=\text{O}$
4	NDBA – N-Nitrosodibutylamine	$\begin{array}{c} \text{H}_3\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_2 \\ \text{H}_3\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_2 \end{array} \text{N}-\text{N}=\text{O}$
5	NMPA – N-Nitrosomethylphenylamine	$\text{C}_6\text{H}_5-\text{NH}-\text{CH}_3-\text{N}=\text{O}$
6	NDIPA – N-Nitrosodiisopropylamine	$\begin{array}{c} (\text{CH}_3)_2\text{CH} \\ (\text{CH}_3)_2\text{CH} \end{array} \text{N}-\text{N}=\text{O}$
7	NMBA – N-Nitroso-N-methyl-4-aminobutyric acid	$\text{HOOC}-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{N}(\text{CH}_3)-\text{N}=\text{O}$



Nitrosamines are a class of compounds of concern due to their potential carcinogenicity. These seven reference standards are critical for testing and ensuring pharmaceutical safety.



Testing Today,
Safer Tomorrow.

- **Nitrosamine Impurities** - Chemical compounds identified as **genotoxic and carcinogenic** (cancer-causing).
- They can unintentionally form during active pharmaceutical ingredient (API) synthesis, storage, packaging, or via contamination from raw materials.

Reference

[PIB | First-Ever Interactive Meeting with CDL Kolkata](#)

