Nitrosamine Impurities: Keeping Medicines Safe

What are nitrosamines?

- **Nitrosamines** are chemicals that are naturally found in water and foods. Since 2018, elevated levels of these impurities have been discovered in some commonly prescribed medications.

The pharmaceutical industry and regulators around the globe are working to limit the presence of nitrosamines to ensure a safe medicine supply.

Some nitrosamines can increase the risk of developing cancer; a drug product intended for chronic use poses greater risk than a drug product intended for only short-term use.

How are safe levels determined?

- Regulatory agencies around the world, including the U.S. FDA, work with manufacturers to establish safe levels of nitrosamines in medicines. Many regulators have adopted a Carcinogenic Potency Categorization Approach (CPCA) to help determine limits.
- These limits are determined by a calculation of the carcinogenic potency of a nitrosamine substance and the frequency and duration of exposure.

Some medicines that have been recalled due to nitrosamines include:

- Angiotensin II receptor blockers (ARBs)
- Ranitidine
- Metformin
- Rifampin
- Rifapentine
- Quinapril

How is USP helping?

USP has standards and other resources that manufacturers and regulators can use to address nitrosamine impurities in medicine, including:

- Documentary standards (General Chapter <1469> *Nitrosamine Impurities*).
- USP's **official Reference Standards** and **Pharmaceutical Analytical Impurities**: Physical samples that can help ensure accurate quantitative and qualitative impurity analysis.
- **Nitrosamines Exchange**: A knowledge-based online community for information sharing and collaboration.
- The Exchange includes the **Analytical Hub**, a public repository of downloadable analytical procedures to test for nitrosamine impurities.
- **Education, trainings, and workshops.**

Scan for more information:

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