

Almac Voice

Melamine Contamination Testing.



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FDA guidance on Pharmaceutical Components at Risk for Melamine Contamination (CDER) was introduced in August 2009 following reports from China that food articles contaminated with melamine. This has resulted in thousands of kidney problem hospitalisations and at least three deaths.

Melamine is a nitrogen-based compound that is characterised by its high nitrogen content. It is also known by other chemical names, such as triaminotriazine, cyanuramide, and cyanuric acid amide. Melamine is an industrial chemical used in the manufacturing of resins for surface laminates and adhesives in the production of wood-based panels.

All manufacturers should take steps to ensure that susceptible components are not contaminated with melamine. At-risk components are those ingredients or raw materials that rely on a test for nitrogen content for their:

- Identity
- Purity
- Strength
- Nitrogen in amounts greater than 2.5 percent

The FDA guidance is intended to alert suppliers and pharmaceutical manufacturers of finished products to the potential risk of melamine contamination in pharmaceutical components.

It is critical that all manufacturers determine whether they are using a component at-risk of melamine contamination to manufacture or prepare a drug product. Contamination by melamine can result in:

- Loss of active ingredient strength and potency
- Disrupt the processing of the finished product
- Affect product or component stability
- Reduce therapeutic effectiveness
- Possible long-term exposure risks

The current good manufacturing practice (cGMP) regulations require that all components (i.e. ingredients or raw materials) be tested before they are released for use in the manufacture or preparation of drug products (21 CFR 211.84).

Almac's LC- MS/MS Test for Melamine

At Almac, we have developed and validated an in-house LC-MS/MS method to detect the presence of melamine in raw materials. This method is highly sensitive and achieves a limit of 1.25ppm for both Melamine and Cyanuric Acid, which is half of what is recommended by the FDA of 2.5ppm.

We perform the in-house limit test method to test for both Melamine and Cyanuric Acid using state of the art LC/MS/MS technology that can validate methods for any new materials prior to testing.

Examples of at-risk pharmaceutical components

The following listed components are considered to be at-risk for melamine contamination and have been recommended by the FDA to be monitored for the presence of melamine. This list is not considered to be exhaustive, and it is essential that manufacturers evaluate their drug components to determine whether they are vulnerable to melamine contamination.

- Adenine (USP)
- Albumin (IID)
- Amino acids derived from casein protein hydrolysates
- Ammonium salts
- Calcium Pantothenate (USP)
- Caseinate or sodium caseinate (IID)
- Chlorophyllin copper complex sodium (USP)
- Colloidal oatmeal (USP)
- Copovidone (USP/NF)
- Crospovidone (USP/NF)
- Dihydroxyaluminum aminoacetate (USP)

- Gelatin (IID)
- Glucagon (USP)
- Guar gum (USP/NF)
- Hyaluronidase (USP)
- Imidurea (USP/NF)
- Lactose (USP/NF, IID)
- Melphalan (USP)
- Povidone (USP/NF)
- Povidone-Iodine (USP)
- Protamine sulfate (USP)
- Protein hydrolysate (powder) for injection (USP)
- Taurine (USP)
- Thioguanine (USP)
- Urea (USP)
- Wheat bran (USP)
- Zein (USP/NF)

We would be delighted to hear from you and help with your testing requirements, please contact:

almacanalytical@almacgroup.com

References

Guidance for Industry: Pharmaceutical Components at Risk for Melamine Contamination.

U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Veterinary Medicine (CVM) August 2009.

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