



## Melamine Testing in Pharmaceutical Components

### Background

The Food and Drug Administration released a guidance document for industry titled, *Pharmaceutical Components at Risk for Melamine Contamination* in August 2009. The document, identifies various pharmaceutical components that are considered high risk for melamine contamination and recommends monitoring of these pharmaceutical components for the presence of melamine prior to release into production.

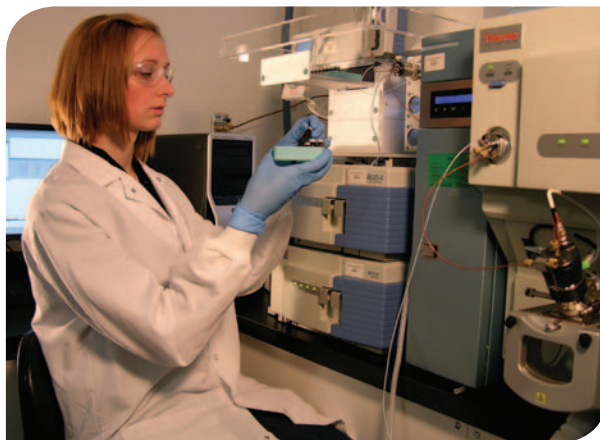
Melamine is used in the manufacturing of a variety of products ranging from various resin-based products (countertops, glues, housewares, etc.), cleaning products and industrial cleaners. Melamine has a low acute toxicity and is not readily metabolized.

Cyanuric acid is a structural analogue of melamine and is used in the manufacturing of herbicides, dyes, resins and antimicrobial agents. It is also used as a stabilizer and disinfectant in swimming pools and also utilized as a component of feed-grade biuret (a ruminant feed additive). Cyanuric acid has a low acute toxicity.

The combined presence of melamine and cyanuric acid leads to the formation of melamine cyanurate. This compound has low solubility, which can lead to the formation of crystals in the kidneys. Formation of these crystals has been documented in numerous animal studies where the ingestion of both melamine and cyanuric acid was controlled. The formation of these crystals has led to renal failure and kidney toxicity, and in some subjects, death.

### Why Choose Lancaster Laboratories?

- Using Thermo TSQ Vantage LC/MS/MS systems, we offer a standard two-week turnaround time for melamine testing.
- We will validate methods for any new materials prior to testing.
- We provide method validation for most materials listed in the FDA guidance document for



melamine testing and have expanded our capabilities to include numerous materials not listed in the document.

### Additional Information

Lancaster Laboratories has developed and validated a method to test the pharmaceutical components listed in the guidance document. The method utilizes LC/MS/MS technology, providing greater sensitivity and specificity over other analytical techniques. The method that we provide has been validated by performing accuracy studies on each pharmaceutical component listed in the guidance document. Any pharmaceutical component that is listed in the guidance document that has not been previously validated will be validated by Lancaster Labs prior to any sample analysis. The methodology will meet the guidance document established limit for melamine of 2.5 ppm for most matrices. The limit for certain matrices had to be elevated due to solubility and recovery issues within those matrices. The methodology will provide quantitative amounts of both melamine and cyanuric acid in various pharmaceutical components.

Any pharmaceutical component that is requested for Melamine Testing that is not included in the guidance document can be added to Lancaster Labs' method following the pricing structure listed in our melamine pricing document.



### Information Needed from the Client

- What is the pharmaceutical component being tested?
- Can 2 grams of sample be provided for testing and 50 grams of sample for the matrix spiking study?

### The Pharmaceutical Components Listed in the Guidance Document are:

- Adenine
- Albumin
- Amino acids derived from casein protein hydrolysates
- Ammonium salts
- Calcium pantothenate
- Caseinate or sodium caseinate
- Chlorophyllin copper complex sodium
- Colloidal oatmeal
- Copovidone
- Crospovidone
- Dihydroxyaluminum aminoacetate
- Gelatin
- Glucagon
- Guar gum
- Hyaluronidase
- Imidurea
- Lactose
- Melphalan
- Povidone
- Povidone-Iodine
- Protamine sulfate
- Protein hydrolysate (powder) for injection
- Taurine
- Thioguanine
- Urea
- Wheat bran
- Zein

Discover our solutions at: [LancasterLabsPharm.com](http://LancasterLabsPharm.com)

#### Global Services:

Biochemistry  
Cell Bank Manufacturing  
Facility & Process Validation  
Method Development & Validation  
Microbiology  
Molecular & Cell Biology

Mycoplasma Services  
Raw Materials Testing  
Release Testing  
Residuals & Impurities Testing  
Stability Testing & Storage  
Viral Clearance & Viral Safety

#### Facilities:

USA  
Lancaster, PA | 717-656-2300  
Portage, MI | 269-323-3366

Ireland  
Dungarvan Co. Waterford | 00 353 (0) 58 48300