

INFORMATION

Quality Management



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Melamine

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

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac[®] 70, GranuLac[®] 140, GranuLac[®] 200
- Anhydrous Lactose: DuraLac[®] H

The MEGGLE USA Products are lactose.

They are not covered by the definition for an “at-risk component” as referenced in footnote 3 of the FDA Guidance for Industry. On the other side Lactose is listed as an example of an “at-risk pharmaceutical component” as “sourced starting material can be derived from milk”.

Any addition of melamine would lead to OOS-results. In this respect there is no motivation to consider such an adulteration.

Nevertheless, a monitoring program for melamine and cyanuric acid is implemented.

Testing is performed by an independent laboratory using the following method:

Liquid Chromatography/Tandem Mass Spectrometry (LC-MS-MS).

Detection limit melamine: 0.05 mg/kg. Detection limit cyanuric acid: 0.5 mg/kg.

Melamine and cyanuric acid are not detectable in the products.

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