Melamine

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

MEGGLE Products:

- Lactose Monohydrate: CapsuLac® 60, FlowLac® 90, FlowLac® 90 MS, FlowLac® 100, FlowLac® 90 MS, FlowLac® 100 SD, GranuLac® 70, GranuLac® 70 MS, GranuLac® 80, GranuLac® 140, GranuLac® 140 S, GranuLac® 200, GranuLac® 200 MS, GranuLac® 200 S, GranuLac® 230, InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 150, InhaLac® 160, InhaLac® 180, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, StarLac®, Tablettose® 70, Tablettose® 80, Tablettose® 100, Tablettose® 100 MS
- Co-processed Excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, RetaLac®, , StarLac®

The MEGGLE Products are or contain 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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