



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[®] 100 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[®] 145, InhaLac[®] 150, InhaLac[®] 160, InhaLac[®] 180, InhaLac[®] 230, 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, 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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