

From: Khurana, Taruna
Sent: Tuesday, December 13, 2016 4:19 PM
To: nadine_margaretten@merck.com
Cc: Sweeney, Colleen (Colleen.Sweeney@fda.hhs.gov); Steele, Matthew (Matthew.Steele@fda.hhs.gov)
Subject: STN 125592 HDM IR Microbial 12132016

Hello Nadine,

We have the following request for information;

1. In section 3.2.P.5.1 (drug product), microbiological specification for (b) (4) and section 3.2.P.5.4 batch analyses we notice results (b) (4) CBER requests to add an alert limit to microbiological examination specification for drug product to better track/trend your manufacturing process for better quality oversight.
2. In section 3.2.P.5.2 qualification test for specified microorganisms of drug product states that (b) (4) were tested, however these results were not included in the report (Section 3.2.P.5.3). Please provide these results to include the inoculum counts for these specified microorganisms.

Feel free to contact me if you have any question.

Thank you

Taruna Khurana, PhD

Biologist (Regulatory)

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
Taruna.khurana@fda.hhs.gov



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