Elisa,

The review team has the below three question for you regarding the measurement of endotoxins using the LAL procedures. They have requested a response as soon as possible and no later than Friday, August 13, 2021.

1. Your procedure for measuring endotoxin in Drug Product (DP) includes a step. While you provide data demonstrating the does not impact the activity of endotoxin that is , you have not provided data to evaluate the potential endotoxin-like activity of the . Please provide data to address potential endotoxin-like activity of .

2. You state that the step is performed to is the usual approach to . Please provide data from a ).

3. From the data generated in the preceding request, we ask that you identify a for testing DP within the , . Please use this information to establish the endotoxin limit and establish a specification for DP endotoxin activity levels for samples that are . Please comment and provide a date by which results from the test using samples can be included for DP lot release, together with the endotoxin results for samples .
Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS

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