

From: Sista, Ramani V
Sent: Friday, October 10, 2014 8:48 AM
To: 'Heather Pratt'
Subject: Macopharma Response - Requesting Additional Clarification

Importance: High

Hi Heather,
Thank you for the response. We have some follow up questions. Please see below and provide the requested information by COB, October 24, 2014.

1. Please provide the exact location of the cold spots identified during the empty chamber study. Please clarify if these locations are the same locations that thermocouples and biological indicators were placed during the PQ.
2. Regarding the (b) (4)
 - a. Having (b) (4) and storing the units (b) (4) could encourage microbial growth. Please address this concern.
 - b. Please clarify how you know if the (b) (4) actually becomes sterilized. Do you test the (b) (4) with inoculation?
 - c. Please explain how you confirm the (b) (4) stays sterile, even during storage and shipping.
 - d. Typically the purpose of the (b) (4). Please clarify the purpose of your (b) (4).
 - e. Please clarify if the bags of the actual unit are porous or semi-permeable and could let in contamination if stored (b) (4).
3. Please provide additional details for the in-process (b) (4) test, and (b) (4) test for the containers and transfusion ports. The test method details should include information such as the (b) (4).

Thanks,
Ramani

Ramani Sista, PhD, RAC, CQA
RPM
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From: Heather Pratt [mailto:heather@macopharmausa.com]
Sent: Thursday, October 09, 2014 4:53 PM
To: Sista, Ramani V
Subject: Macopharma Response-NDA 125552-22 Sep 14 Email

Dear Ramani,

Please find attached a copy of the response to your 22 Sep 14 email request to provide additional

information regarding the sterilization and Container Closure Integrity Testing for the MacoProductions' NDA 125552 filing. The paper and electronic copies were sent out today via UPS for delivery tomorrow.

Thanks,
Heather

Best Regards,

Heather Pratt

Listen • Understand
• Provide Solutions

Heather Pratt
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