

From: Heather Pratt <heather@macopharmausa.com>
Sent: Tuesday, August 30, 2016 10:44 AM
To: Sista, Ramani V
Subject: Response to Macopharma NDA 125552 - IR 1

Dear Ramani,

Kindly find below the response to your 29 August 2016 email request to provide the following information regarding the Sterility Test.

FDA IR 1:

1. Please provide lot numbers of (b) (4) in (b) (4) and used in Bacteriostasis and Fungistasis qualification report (Number (b) (4) 358A1-1).

MacoProductions Response to IR 1:

The batch numbers of (b) (4) that were used during the qualification are:

- 1) (b) (4)
- 2) (b) (4)
- 3) (b) (4)

If you can please let me know you received the email response that would be most appreciated.

Thanks,
Heather

Best Regards,

Heather Pratt, RAC

Listen • Understand
• Provide Solutions

Heather Pratt, RAC
Manager, Regulatory & Clinical
Affairs
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From: Sista, Ramani V [mailto:Ramani.Sista@fda.hhs.gov]
Sent: Monday, August 29, 2016 8:58 AM
To: Heather Pratt <heather@macopharmausa.com>
Subject: Macopharma NDA 125552 - IR 1
Importance: High

Hi Heather,

Please provide the following information regarding the Sterility Test by COB Thursday, September 1st.

1. Please provide lot numbers of (b) (4) in (b) (4) and used in Bacteriostasis and Fungistasis qualification report (Number (b) (4) 358A1-1).

Please acknowledge receipt and let me know if you have questions.
Thanks,
Ramani

Ramani Sista, PhD, RAC, COA
RPM
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