

From: Sista, Ramani V
Sent: Monday, February 09, 2015 10:45 AM
To: 'Heather Pratt'
Subject: RE: NDA 125552 - IR-(b)(4) Inoculum Information Attached

Importance: High

Hi Heather,
Unfortunately, this is not the information the reviewer is looking for.

When B&F test of CPD solution was performed, (b)(4). You are supposed to (b)(4).

(b)(4). We want to see the results of (b)(4) (in other words (b)(4)).

Please provide this information latest by COB Friday, February 13.
Thanks,
Ramani

Ramani Sista, PhD, RAC, CQA
RPM

OCTGT/CBER/FDA

Phone: 240 402 8354

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From: Heather Pratt [mailto:heather@macopharmausa.com]
Sent: Monday, February 02, 2015 4:39 PM
To: Sista, Ramani V
Subject: NDA 125552 - IR-(b)(4) Inoculum Information Attached

Dear Ramani,

As requested, please find attached the Lyophilized Microorganism Specification and Performance Certificates for the microorganisms used in the sterility test validation and (b)(4) results. The recovery is stated on the certificate.

Thanks,
Heather

Best Regards,

Heather Pratt

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• Provide Solutions

Heather Pratt
Manager, Regulatory & Clinical
Affairs

heather@macopharmausa.com

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Duluth, GA 30096
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From: Sista, Ramani V [mailto:Ramani.Sista@fda.hhs.gov]
Sent: Thursday, January 29, 2015 2:16 PM
To: Heather Pratt
Subject: RE: NDA 125552 - IR-Sterility Testing Attached for Reference MSC1207DD English Translation Attached

Hi Heather,
Any updates on the (b) (4) inoculum results associated to the report you sent in the email below?
Thanks,
Ramani

Ramani Sista, PhD, RAC, COA
RPM

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Phone: 240 402 8354

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From: Heather Pratt [mailto:heather@macopharmausa.com]
Sent: Thursday, January 22, 2015 2:06 PM
To: Sista, Ramani V
Subject: NDA 125552 - IR-Sterility Testing Attached for Reference MSC1207DD English Translation Attached

Dear Ramani,

Please find attached the English translation of the Sterility Testing for (b) (4) batches of MSC1207DD at T0 and T18 months.

We hope to have the inoculum (b) (4) results from the supplier soon as well.

Thanks,
Heather

Best Regards,

Heather Pratt

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From: Heather Pratt
Sent: Monday, January 19, 2015 5:57 PM
To: 'Sista, Ramani V'
Subject: RE: NDA 125552 - IR-Sterility Testing Attached for Reference MSC1207DD

Dear Ramani,

Please find attached the Sterility Testing results for (b) (4) batches of MSC1207DD at T0 and T18 months. These are the conformance lots since there is no routine production as yet. Kindly note, the document is in French and Polish. I have put in a rush order to have the document translated and will forward as soon as it is received. I hope by Wednesday.

In regards to the inoculum (b) (4) results, we are waiting on some information from our supplier and will provide that response as soon as we receive it.

Thanks,
Heather

Best Regards,

Heather Pratt

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From: Sista, Ramani V [mailto:Ramani.Sista@fda.hhs.gov]
Sent: Thursday, January 15, 2015 10:04 AM
To: Heather Pratt
Subject: RE: NDA 125552 - IR
Importance: High

Hi Heather,
The reviewer is looking for information below regarding the attached:

Conformance lots are lots manufactured in support of the BLA application. If you have sterility results on any lots of collection bags for MSC1207DD and MSC1208DD, that would work.

The attached sterility test validation submitted for sterility test was translated from Polish and looks like missed some information. Could you please ask for the clarification?

1. Please confirm the inoculum/ colony forming units for each microorganism used in sterility test validation (protocol no. (b) (4) 01);
2. Please provide (b) (4) results for microorganisms used in the sterility test validation.

Thanks,
Ramani
Ramani Sista, PhD, RAC, COA
RPM
OCTGT/CBER/FDA
Phone: 240 402 8354

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From: Heather Pratt [mailto:heather@macopharmausa.com]
Sent: Wednesday, January 14, 2015 2:55 PM
To: Sista, Ramani V
Subject: RE: NDA 125552 - IR

Dear Ramani,

I received your email below requesting sterility test results, however, can you please clarify what you mean by "conformance lots"?

Thanks,
Heather

Best Regards,

Heather Pratt

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From: Sista, Ramani V [mailto:Ramani.Sista@fda.hhs.gov]
Sent: Wednesday, January 14, 2015 10:39 AM
To: Heather Pratt
Subject: NDA 125552 - IR
Importance: High

Hi Heather,
Please provide the information below by COB tomorrow.

Please provide sterility test results of conformance lots for cord blood sterile collection bags with anticoagulant Citrate Phosphate Dextrose (CPD).

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

Ramani Sista, PhD, RAC, CQA
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