

From: [Patel, Manisha](#)
To: [Giordano, Erica](#)
Cc: [Riggins, Cindy](#); [Ahmed, Narin](#); [Wonnacott, Keith](#); [Azevedo Santos, Joana](#)
Subject: RE: BL 125646 DBSQC Information Request
Date: Wednesday, May 10, 2017 12:02:33 PM
Attachments: [image001.png](#)
Sensitivity: Confidential

Dear Erica,

I confirm receipt of this request.

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Wednesday, May 10, 2017 12:01 PM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 DBSQC Information Request
Sensitivity: Confidential

Good afternoon,

Please see the information request below and provide a response by noon on May 24, 2017.

CTL019 Final Product: Endotoxin test

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According to section 3.2.P.5.1 Specifications, endotoxin release specification is (b) (4). However, a specification of (b) (4) was used in qualification of the endotoxin test and calculation of Maximum Valid Dilution (MVD) (section 4 of validation report AM70321). Please clarify the discrepancy and provide an updated qualification report with corrected MVD.

Please confirm receipt of this request.

Thank you,

Erica Giordano

Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8298
Erica.Giordano@fda.hhs.gov



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