

From: Maruna, Thomas
Sent: Wednesday, September 30, 2015 9:42 AM
To: 'ade.denloye@baxalta.com'
Subject: 9-30-2015 Information Requested - Baxalta BLA 125596.0 - Please Respond by October 14, 2015

Importance: High

Baxalta US Inc.
Attention: Ms. Ade Denloye
September 30, 2015
Sent by email

Dear Ms. Denloye:

We are reviewing your September 14, 2015 biologics license application (BLA) to treat primary immune deficiency disorders associated with defects in humoral immunity for the following:

STN	Name of Biological Products
125596/0	Immune Globulin Subcutaneous (Human), 20% Liquid

We determined that the following information is necessary to continue our review:

Sterility and Endotoxin Test

1. For the control of IGSC, 20%, please provide the qualification report for the sterility test showing the test was qualified in accordance with (b) (4) to confirm the product matrix for the final container drug product is suitable for the intended test method. Please include the indicator microorganisms tested, their media, conformance lot numbers, and incubation conditions used in the qualification.
2. Please provide the (b) (4) bacterial endotoxin test qualification report showing the IGSC, 20%, final container drug product matrix is suitable for the intended test method (in accordance with (b) (4)), to include maximal valid dilution, tested dilutions, positive product control percent recoveries, lot numbers, selected testing dilution and endotoxin test results.

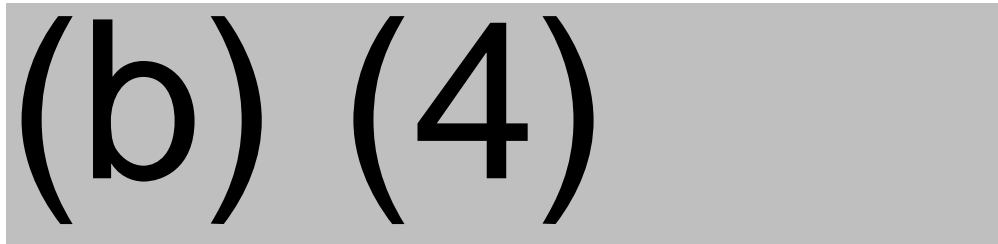
Validation of Analytical Procedures

3. We have reviewed your analytical procedures and validation of analytical procedures for the drug product and request you to provide the following documents:

- a. Document number PV-LA-14.012 entitled “Validation of Triton X-100 for IGSC 20%”
 - b. Document number PV-LA-13.032 entitled “Purity determination in IGSC 20% products by (b) (4)”
 - c. Document number PV-LA-09.007 which is cited in page 3 of the “Validation Analytical Procedures LE-65-A04001S (b) (4)”
 - d. Document number PV-LA-08.032 which is cited in page 2 of the “Validation Analytical Procedures LE-65-A22001S Glycine”
 - e. Document numbers PV-LA-06.033 and PVLA 06-022 which are cited in page 2 of the “Validation Analytical Procedures LE-65-A26002S (b) (4)”
4. Document LE-65-A03008S/01 Validation Analytical Procedures (b) (4) :

In Table 5 on pages 6 and 7, in the columns for Repeatability and Intermediate Precision, please correct what appears to be a typographical error in the data for TnBP, Triton X-100, and Tween80. Part of the table is shown below to illustrate the error.

Table 5: Repeatability and intermediate precision (%RSD)



Lot Release Protocol

5. Please submit a blank lot release protocol template to the BLA for review.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your responses as an amendment to this file by October 14, 2015 referencing the date of this request.

The action due date for these files is September 13, 2016.

If you have any questions, please contact me.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP)^{CM}

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