

From: Hooban, Christopher
Sent: Wednesday, June 17, 2015 9:27 AM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Information Request, (b) (4) for (b) (4) Assay - BL 125587/0; Original BLA; Octapharma; ADD 14-APR-2016

Our Reference: BL 125587/0

Octapharma Pharmazeutika Produktionsges.m.b.H.

Dear Mr. Ammons:

We are reviewing your April 15, 2015 biologics license application (BLA) for Immune Globulin Intravenous, Human 10%. We determined that the following information is necessary to continue our review:

(b) (4) method (130SOP071/03) and validation reports (000VAL071 FC 84x 85x IP 7xx/01 and 000VAL071 FC 84x 85x IP 7xx/01 Supplement 1)

1. Please add the following details in the SOP and resubmit for review:

- a. Your validation report shows that the samples should be analyzed within (b) (4) of preparation. Please update section 5.1 of your SOP to indicate that the samples should be analyzed within (b) (4) of preparation.
- b. Please add the (b) (4) preparation procedure, storage condition and duration of use in section 5.
- c. Describe (b) (4) in section 5.5.
- d. Describe the (b) (4) parameters such as (b) (4) in section 6.1.

2. Please provide the following details in the validation report:

- a. Please provide the acceptance criteria for recovery studies of (b) (4) percentages using (b) (4) in section 6.3.
- b. Please provide the (b) (4) acceptance criterion for (b) (4) percentage using (b) (4) in section 6.3.
- c. Provide repeatability and intermediate precision results of (b) (4) percentage for the negative control (590CTR02) using (b) (4) in section 6.4.
- d. You have not reported the experiment data and acceptance criteria for Accuracy, Precision, Linearity, Range and Robustness study for the percentage of monomer plus dimer using (b) (4) in the validation report. Please provide the data 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 response to this information request as an amendment to this file by July 1, 2015 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

The action due date for this file is April 14, 2016.

If you have any questions, please contact me at (240) 402-8376 or christopher.hooban@fda.hhs.gov.

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