

From: Wood, Lorraine

Sent: Wednesday, April 26, 2017 12:00 PM

To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>

Subject: Information Request for BLA 125644: Analytical Procedures

Importance: High

Dear Dr. Lamb,

We are reviewing your submission for BLA 125644 Human Albumin Solution (HAS) 5% and 25% and we request the following information to continue our review:

- 1) *Please provide current SOPs for all 3.2.P.5.2 Analytical Procedures.*
- 2) *Please respond to the following questions on 3.2.P.5.2 Analytical Procedure-1.3.1 Determination of Total Protein by (b) (4) :*
 - a) *The information provided does not clearly state what type of (b) (4) method was used. Please provide detailed information for this method as described in FDA's "Analytical Procedures and Methods Validation for Drugs and Biologics" Guidance for Industry. This guidance is available on the FDA website.*
 - b) *It is indicated that a reference standard is not used for the analytical procedure. Please provide justifications for not using a reference standard to generate standard curves for determining protein concentrations. We recommend the use of alternative concentration determination methods to compare with the results determined by your (b) (4) method. Representative (b) (4) and standard curves should be submitted.*
- 3) *Please respond to the following questions on 3.2.P.5.3 Validation of Analytical Procedures-1.2.3.1 Total Protein by (b) (4) :*
 - a) *Please clarify whether you have performed System Suitability for the method.*
 - b) *The information provided for Specificity assessment is not clear. Please provide detailed information along with representative (b) (4) for the assessment of the method.*
 - c) *Please provide the detailed characterization of the secondary standard you used for the accuracy assessment.*
 - d) *Please explain why you chose (b) (4) as your target concentration throughout the analysis.*

Please respond to this request by May 10, 2017.

Thanks
Lorraine

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