

From: Alicea, Candido
Sent: Wednesday, November 21, 2018 1:56 PM
To: 'Joan.Robertson@grifols.com'
Subject: Information Request #10: STN 125683/0, Grifols Therapeutics LLC Immune Globulin Subcutaneous (Human)

Our Reference: BL 125683 DBSQC CMC IR

Dear Ms. Robertson:

We are reviewing your July 9, 2018 biologics license application STN 125683/0 for Immune Globulin Subcutaneous (IGSC) (Human), 20%. We have the following requests for information regarding the method and the validation report of the analytical procedure (b) (4)

1. Analytical method (DOC#: CS-000-BC-034)

In the appendix C of the SOP, it is stated that samples must be capable of (b) (4)

How would this procedure apply to the drug product of Immune Globulin Subcutaneous (Human), 20%?

2. Method validation report (DOC#: QOAS-2014-116)

a. It is well known that (b) (4)

b. Please provide experimental data for the evaluation of accuracy, linearity, range and robustness for the (b) (4)

c. Please provide (b) (4)

d. We do not agree with the method you used for (b) (4)

e. Please provide (b) (4) in Figure 6-4 (b) (4) and Figure 6-5 (b) (4) with appropriate experimental data.

f. Please provide the robustness study for the (b) (4) condition for the method.

Please response by Dec. 15, 2018.

Warm regards,
Candido

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