



Food and Drug Administration
CBER/OCBQ/DBSQ

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Subject: DBSQ Chemistry Test Results for human plasma derived Fibrin sealant, VeraSeal Drug product

Sponsor: Instituto Grifols, S.A.

STN: 125640/0

Lots #:

1BND6L3MP1

A4YCB00021

B4YBB00021

Chemistry tests for Fibrinogen and Thrombin components:

- 1) Appearance of frozen product,
- 2) Appearance of solution,
- 3) pH

To: File STN 125640/0

Through: Lokesh Bhattacharyya, Lab Chief LACBRP, DBSQ/OCBQ

Maryna Eichelberger, Division Director, DBSQ/OCBQ

Summary of Testing:

Test results by DBSQ and Instituto Grifols, S.A. indicate compliance with proposed drug product specifications.

Fibrinogen component

1) Appearance of Frozen product

Specification for Appearance of Frozen Product is "Pass if colorless or pale yellow, opaque solid". Evaluations of appearance were performed concurrently with tests for appearance after thawing and determination of pH. CBER analyst was R. Agarwal. CBER observations were consistent with this requirement along with those submitted by the sponsor.

2) Appearance of solution after thawing

Specifications for Appearance of Solution after thawing were described as: “Pass if colorless or pale yellow solution”. CBER analyst was R. Agarwal. CBER observations were consistent with this requirement. Certificates of analysis submitted by the sponsor indicated that these criteria were met in their testing.

3) pH

pH was performed as described in DBSQC test method Doc. ID 000482, “pH Determination”. pH was evaluated on a single vial of each lot. As specified in the submission, samples were tested after thawing. CBER analyst was R. Agarwal.

Table 1 – pH

<u>Lot#</u>	<u>CBER</u>		<u>Instituto Grifols</u>
	<u>pH</u>	<u>Test Date</u>	<u>pH</u>
1BND6L3MP1 10 mL	7.6	08/14/17	7.6
A4YCB00021 6 mL	7.0	08/14/17	7.5
B4YBB00021 4 mL	6.8	08/14/17	7.4

The allowable range for pH in the license application submitted for this product is 6.5 – 8.0. Results obtained by CBER meet this specification along with those submitted by the sponsor.

Thrombin component**4) Appearance of Frozen product**

Specification for Appearance of Frozen Product is “Pass if colorless or pale yellow, opaque solid”. Evaluations of appearance were performed concurrently with tests for appearance after thawing and determination of pH. CBER analyst was R. Agarwal. CBER observations were consistent with this requirement along with those submitted by the sponsor.

5) Appearance of solution after thawing

Specifications for Appearance of Solution after thawing were described as: “Pass if colorless or pale yellow solution”. CBER analyst was R. Agarwal. CBER observations were consistent with this requirement. Certificates of analysis submitted by the sponsor indicated that these criteria were met in their testing.

6) pH

pH was performed as described in DBSQC test method Doc. ID 000482, “pH Determination”. pH was evaluated on a single vial of each lot. As specified in the submission, samples were tested after thawing. CBER analyst was R. Agarwal.

Table 2 – pH

<u>Lot#</u>	<u>CBER</u>		<u>Instituto Grifols</u>
	<u>pH</u>	<u>Test Date</u>	<u>pH</u>
1BND6L3MP1 10 mL	6.7	08/14/17	6.8
A4YCB00021 6 mL	6.2	08/14/17	6.8
B4YBB00021 4 mL	6.2	08/14/17	6.7

The allowable range for pH in the license application submitted for this product is 6.0 – 8.0. Results obtained by CBER meet this specification along with those submitted by the sponsor.