



MEMORANDUM

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To: Biologics License Application Submission Tracking Number 125640/0

Through: Lokesh Bhattacharyya, Ph.D., CBER/OCBQ/DBSQC
William M. McCormick, Ph.D., Director, DBSQC/OCBQ/CBER

Subject: Test Results for (b) (4) in Fibrinogen Component for Drug Product of Fibrin Sealant (Human) from Grifols

STN: 125640/0
Lots IBND6L3MP1, 10 mL Presentation
A4YCB00021, 6 mL Presentation
B4YBB00021, 4 mL Presentation

Summary of Test Results

Test results obtained by DBSQC and the sponsor, Grifols, for (b) (4) determination in fibrinogen component by (b) (4) method are in compliance with the proposed drug product (DP) specification.

Procedure

A (b) (4) method, as described in “(b) (4) in Fibrinogen by (b) (4)” (IG_MA000158E_ING), is used for the determination of (b) (4) in fibrinogen component of the DP. (b) (4)



(b) (4)

Results and Conclusion

The (b) (4) values of the current control (Lot # 070613) were 1.04% and 1.05% respectively for May 17 and June 28, 2017 tests, which meet the established limits of (b) (4) from the sponsor.

<u>Lot#</u>	<u>CBER Results</u>		<u>Grifols Results</u>
	(b) (4)	<u>Test Date</u>	(b) (4)
IBND6L3MP1	0.6	05/10/17	0.5
A4YCB00021	0.5	06/28/17	0.2
B4YBB00021	0.7	06/28/17	0.3

The results from the sponsor are obtained from amendments 14 and 27 respectively.

The proposed DP specification is (b) (4). Test results for the above lots obtained by CBER and Grifols meet the specification.