



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To The file: STN 125833/0

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Applicant Grifols Therapeutics LLC

Product Fibrinogen (Human) (BT524)

Subject Review of the (1) Test Method, "Determination of the protein content and activity of fibrinogen via (b) (4) (SOP-Q-00438)", and (2) Method Validation Report/Method Verification Report (VAL-Q-00232_REP-01 5.0), "Determination of total protein, fibrinogen activity and specific fibrinogen activity in Fibrinogen Concentrate (BT524) product stages according to SOP-Q-00438."

Recommendation: Approval

Summary of review:

SOP-Q-00438 provides the procedures for determining the protein content, fibrinogen activity, specific fibrinogen activity and fibrinogen activity per vial of fibrinogen Drug Product (DP) (b) (4). The test method was adequately described, and validation data demonstrate the suitability of the analytical test method for measuring fibrinogen activity of the DP.

Documents Reviewed:

Information in sections of the original submission that describe control of DP, including descriptions of DP specifications, analytical procedures for determining the fibrinogen activity in DP and related validation of the analytical procedure as listed below were reviewed.

- 125833/0.0 (0001-Original Application) – Recd. December 24, 2024.
 - 3.2.P.5 >
 - Control of Drug Product
 - 3.2.P.5.1 Specification(s)
 - 3.2.P.5.2 Analytical Procedures
 - Fibrinogen Activity
 - SOP-Q-00438: Determination of the protein content and activity of fibrinogen via (b) (4)
 - 3.2.P.5.2.8 Total Protein
 - 3.2.P.5.2.9 Total amount of active fibrinogen per vial
 - 3.2.P.5.2.10 Specific fibrinogen activity
 - 3.2.P.5.3 > Validation of Analytical Procedures
 - 3.2.P.5.3.1 – Fibrinogen Activity
 - Method Validation Report – VAL-Q-00232_REP-01 v3.0 and v5.0: Determination of total protein, fibrinogen activity and specific fibrinogen activity in fibrinogen concentrate (BT524) product stages according to SOP -Q-00438.
 - 3.2.P.5.3.8 Total Protein
 - 3.2.P.5.3.9 Total amount of active fibrinogen per vial
 - 3.2.P.5.3.10 Specific fibrinogen activity


Background:

The test for fibrinogen activity is performed at Grifols/Biotest site (Quality Control Department). Validation studies were performed at the Quality Control Department and Analytical Development and Validation laboratory (ADV) which are located at the (b) (4) in Dreieich, Germany. The DP specification is: 20g/L (b) (4). The (b) (4) specification for the fibrinogen activity is (b) (4).

Method:

The method for determining fibrinogen activity in the product (b) (4) of fibrinogen concentrate BT524 and DP for release /stability testing is based on protein content determination by (b) (4). The protein determination is based on the (b) (4), method (b) (4). The protein content is determined (b) (4) protein).

(b) (4)



Conclusion: The parameters tested for the validation of the assay for fibrinogen activity described in the Method Validation Report, VAL-Q-00232_REP-01 5.0 indicate that the test method (SOP-Q-00438), has been validated for testing and release (b) (4) the final Drug Product.

The use of the test method, SOP-Q-00438 is suitable for the intended use and is recommended for approval.