

**DBSQ/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** the file STN 125786

**From:**

Reviewer	Role	Date finalized	Stamp	Supervisor	Stamp
	Lead Reviewer				
Wei Tu, MD	Reviewer	3/13/2024			
	Reviewer				

**Through:** Muhammad Shahabuddin, Ph.D., Lab Chief, LBVI, DBSQ/OCBQ/CBER

Maryna Eichelberger, Ph.D., Director, DBSQ/OCBQ/CBER

**Applicant:** Pfizer

**Subject:** Review of Analytical Methods used for Fidanacogene Elaparovec (b) (4)

**Recommendation:** Approval

**Executive Summary:**

The following analytical methods used for Fidanacogene Elaparovec, and the associated analytical method validations were reviewed:

1. (b) (4) (Wei Tu)
2. (b) (4) (Wei Tu)
3. (b) (4), (Wei Tu)

**Conclusion:** The analytical methods and their validations reviewed for the Fidanacogene Elaparovec (b) (4) were found to be adequate for their intended use.

**Documents Reviewed**

Information in sections of the original submission that describe control of (b) (4) (3.2.S.4), including descriptions of (b) (4) specifications, analytical procedures and validation of these analytical procedures were reviewed. Additional information in Amendment 35 was also reviewed.

**Background:**

On April 28, 2023, Pfizer submitted a Biologics License Application (STN125786) for Fidanacogene Elaparvovec (BEQVEZ), a treatment of hemophilia B in patients aged eighteen and older. Fidanacogene Elaparvovec is a non-replicating recombinant adeno-associated viral vector (AAV) carrying the human coagulation factor IX (FIX) Padua (R338L) variant gene. The (b) (4)

[Redacted]

(b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

