



DBSQ/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: The file STN 125786

From:

Reviewer	Role	Date Finalized	Stamp	Supervisor	Stamp
Kouassi Ayikoe, Ph.D.	Reviewer	4/09/2024		Kenneth S. Phillips, Ph.D.	

Through: Maryna Eichelberger, Ph.D., Division Director, CBER/OCBQ/DBSQ

Product: BEQVEZ™, fidanacogene elaparvec.

Applicant: Pfizer, Inc.

Subject: Review of analytical methods used for fidanacogene elaparvec; (BEQVEZ™) (b) (4) drug product (DP) lot release.

Recommendation: Approval

Executive Summary:

On April 28, 2023, Pfizer submitted an original Biologics License Application (BLA STN 125786) for BEQVEZ for treatment of hemophilia B in patients ≥18 years of age. The following analytical methods used for lot release were reviewed:

1. Appearance
 - a. Clarity and Color (b) (4) DP
 - b. Visible Particulates (DP)
2. (b) (4)
3. (b) (4)
4. Extractable Volume (DP)
5. (b) (4)
6. Poloxamer 188 (DP)
7. (b) (4)

Conclusion: The analytical methods and their validations and/or qualifications reviewed for the BEQVEZ (b) (4) drug product were found to be adequate for their intended use.

Documents Reviewed

Information was reviewed in sections of the original submission that describe control of (b) (4) DP (3.2.S.4 and 3.2.P.5, respectively), including descriptions of (b) (4) DP specifications, analytical procedures for lot release testing of (b) (4) DP and validation of these procedures. Additional information in amendments specified in the review narrative was also reviewed.

Background

This review covers the analytical method validations or qualifications for lot release testing of BEQVEZ (b) (4), DP, and excipients.

Review Narrative

1. Appearance

a) Clarity and Color of (b) (4) DP

The specifications for clarity and color: Acceptance criterion for clarity for (b) (4) DP based on (b) (4) Acceptance criterion for color for (b) (4) DP (b) (4)

Method

The analytical procedure for clarity determines the (b) (4) of fidanacogene elaparvovec (b) (4)

[Redacted text block]

(b) (4)

(b) (4)

Conclusion:

Since all the study parameters passed the acceptance criteria per SOP-73930, the method is suitable for determination of (b) (4) DP appearance.

b. Visible Particulates (DP)

A (b) (4) method is used to determine the presence or absence of extraneous, mobile, or undissolved particles by visual assessment of the DP. The specification for release and stability is set at “Essentially free from visible particulates”.

Method

(b) (4)

Method Verification

(b) (4) the results demonstrated that the acceptance criterion of “Free from visible particulates” was met.

Conclusion:

The Appearance (Visible Particulates) (b) (4) method is suitable for lot release testing of DP samples.

(b) (4)

(b) (4)

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4. Extractable Volume (DP)

The specification for extractable volume for DP is 'Not less than' the labeled volume

(b) (4)

Method

The extractable volume procedure is performed in accordance with the current

(b) (4)

describes the

procedure for performing extractable volume testing of solutions in the Quality Control (QC) department at Pfizer Sanford.

Method verification

(b) (4)

Conclusion

The method for determining extractable volume of DP is suitable for its intended use.

(b) (4)

(b) (4) [Redacted]

[Redacted]

6. Poloxamer 188 (DP)

Specification of Poloxamer 188 (P188) content in fidanacogene elaparvovec DP is

(b) (4) [Redacted]

Method.

(b) (4) [Redacted]

Method Validation

(b) (4) [Redacted]

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(b) (4)

[Redacted]

[Redacted]

Conclusion:

The (b) (4) test method (b) (4) for determination of P188 concentration in fidanacogene elaparvovec DP is suitable for its intended use.

(b) (4)

[Redacted]

[Redacted]

[Redacted]

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