



DBSQ/OCBQ ANALYTICAL METHOD REVIEW MEMO

To The file: STN 125786/0

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Applicant Pfizer Inc.

Subject Review of Bioburden, Mycoplasma, Endotoxin, and Sterility Analytical Methods used for fidanacogene elaparovec

Recommendation: Approval

Executive Summary:

The bioburden, mycoplasma, endotoxin, and sterility analytical methods used for testing and release of fidanacogene elaparovec and the associated analytic method qualifications, were reviewed. The assays were adequately described and shown to be suitable for their intended purpose.

Conclusion: The analytical methods and their qualifications reviewed for fidanacogene elaparovec (b) (4) drug product were found to be adequate for their intended use.

Documents Reviewed

Information in sections of the original submission that describe control of (b) (4) Drug Product (DP) (3.2.S.4 and 3.2.P.5, respectively), including descriptions of (b) (4) DP specifications, analytical procedures of (b) (4) DP and qualifications of these analytical procedures were reviewed. In addition, responses to CBER's Information Requests (IRs) received on June 13, 2023 (Amendment #4), June 28, 2023 (Amendment # 7), July 13, 2023 (Amendment # 9) and September 6, 2023 (Amendment # 15) were also reviewed as mentioned below.

3 pages determined to be not releasable: (b)(4)

3. Endotoxin Method (b) (4) DP

Introduction

Endotoxin testing for fidanacogene elaparvec (b) (4)

(b) (4) DP testing is performed at Pfizer in Sanford, NC and at Pfizer in Algete, Spain. Specifications of (b) (4) vector genome (vg) for (b) (4) (b) (4) for DP must be met for release of fidanacogene elaparvec.

(b) (4)

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(b) (4)

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(b) (4)-BET Qualification for DP

Pfizer Sanford qualified their (b) (4)-BET method for DP to determine if the method is suitable under the actual conditions of use. The test was performed using (b) (4) lots

of DP (b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

The BET concentration results for (b) (4) DP (b) (4) [Redacted] were all within the release specification (b) (4) [Redacted] DP and were found acceptable.

Conclusion

The method suitability tests were performed and compliant with (b) (4) [Redacted] and the test results indicate there is no product interference from (b) (4) DP test samples, thus indicating the (b) (4) [Redacted] BET test method is appropriate under the actual conditions of use.

4. Sterility Method (DP)

Introduction

Sterility testing is performed on the DP at Pfizer in Stanford, NC (b) (4) [Redacted] Acceptance criteria of 'No Growth Detected' must be met for the lot release of fidanacogene elaparvovec.

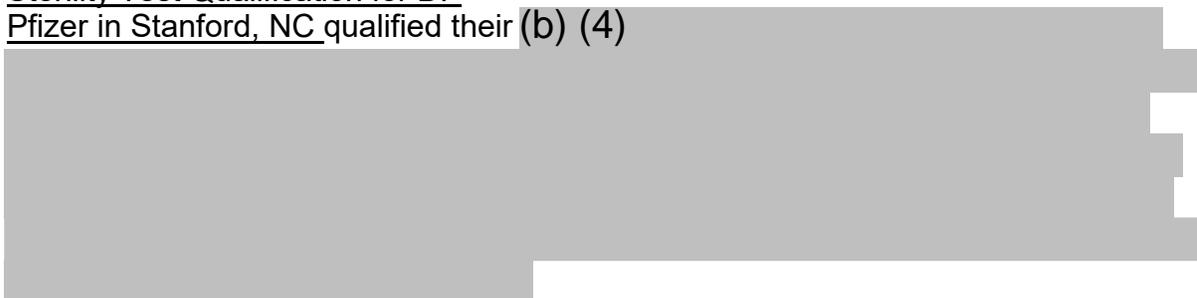
Method

(b) (4)

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Sterility Test Qualification for DP

Pfizer in Stanford, NC qualified their (b) (4)

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(b) (4)

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(b) (4) qualified their (b) (4) method using (b) (4) lot of DP (i.e., (b) (4) . The test was performed using same procedure as Pfizer in Stanford, NC described above (b) (4)

(b) (4)

Conclusion

The method suitability tests were performed and compliant with (b) (4) and the test results indicate there is no product inhibition of microorganism growth, thus indicating the (b) (4) sterility test method is appropriate under the actual conditions of use.